



CANCER PREVENTION &
RESEARCH INSTITUTE OF TEXAS

Policies and Procedures Guide
CPRIT Applications and Funding Awards

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CPRIT Application and Funding Awards
Policies and Procedures Guide
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Introduction

In 2007, Texas voters overwhelmingly approved an amendment to the Texas Constitution establishing the Cancer Prevention and Research Institute of Texas (“CPRIT” or “the Institute”) and providing the state with the authority to issue \$3 billion in general obligation bonds over 10 years. Bond proceeds are to be distributed as funding awards for the express purpose of expediting innovation in cancer research and lowering the incidence of cancer in Texas. The Institute’s governing body, the Oversight Committee, is vested with the responsibility to award CPRIT funds for a wide variety of projects relevant to cancer research and prevention. CPRIT encourages applications that apply or develop state-of-the-art technologies, tools, and/or resources for cancer research and prevention programs, including proposals with potential commercialization opportunities.

CPRIT is charged by the Texas Legislature to:

- Create and expedite innovation in the area of cancer research, thereby enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this State; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

CPRIT will maintain the highest integrity and dedication to the mission of finding a cure for cancer. The Institute will become a world-class leader in research and prevention through collaboration with a variety of entities, including public and private institutions of higher education, academic health institutions, universities, governmental organizations, nongovernmental organizations, public and private companies, and others involved in the fight against cancer. The Institute supports innovation in the selection of research

projects emphasizing immediate or long-term medical breakthroughs; commercialization opportunities for research, and prevention services and health education for citizens with culturally appropriate information about ways in which their risks of developing and dying from cancer can be reduced.

Applicability of the CPRIT Policies and Procedures Guide

CPRIT provides this *Policies and Procedures Guide* for individuals and organizations interested in the CPRIT cancer research and prevention funding award program. The *Policies and Procedures Guide* contains the framework for CPRIT to award, implement, and monitor cancer research and prevention program awards. It is effective for all funding awards made in response to requests for applications (RFAs) issued by CPRIT on or after August 21, 2009.

The guidance applies to all CPRIT applications and awards unless there are statutory, regulatory, or award-specific requirements to the contrary. Each CPRIT-funded award will be made pursuant to a contract between the recipient and the Institute. Applicable provisions of the *Policies and Procedures Guide* will be incorporated by reference in the CPRIT final contract award. While the *Guide* is intended to address major issues in the application and funding award process, the guidelines are not all-inclusive. The final award contract may include additional terms and conditions.

The information in this document may be revised to address changes in state or federal statutes, regulations, or policies adopted subsequent to its effective date. Questions regarding the *Policies and Procedures Guide* may be directed to PPG@cprit.state.tx.us. CPRIT maintains a list serve for individuals who wish to be notified when substantive revisions or updates are made to the guidelines. A subscription to the list serve may be requested through the “List Serve Subscription” link on the CPRIT web page.

Statement of Revision:

This is the second revision to the *Policies and Procedures Guide* originally issued on September 15, 2009. Two attachments have been added -- the Model Conflict of Interest Statement for SRPP Committee Members and the Model Non-Disclosure Agreement for SRPP Committee Members. Changes have been made throughout the document to reference the roles played by the Chief Commercialization Officer and the Commercialization Review Council in the review process. Changes to Section One: subsection A is revised to remove

information regarding on-going funding opportunities; subsection D.1. is revised to reference the attachment; subsection E.3. is revised to reflect that a fee may be assessed to company applicants to cover additional costs associated with commercialization review; subsection E.4. is revised to reference the attachment; subsections F.1. and F.2. are revised to clarify that CPRIT may use a two-stage peer review process; subsection F.6. is revised provide guidance regarding the cost review that will be conducted during the grant review process; subsection I is revised to provide guidance regarding conflict of interest investigations by the Executive Director. Changes to Section Two: subsection D.1. is revised to require certification that a person working on a CPRIT project may not be debarred, suspended, or otherwise ineligible; subsection G. is revised to clarify CPRIT's policy regarding acknowledgement of funding; subsection I.3. is revised to clarify reporting requirements; subsection J.1. is revised to provide CPRIT's policies regarding unilateral termination. Changes to Section Three: subsection D is revised to provide further clarification regarding patient support services costs that are not allowable; subsection J.2. is revised to clarify CPRIT's policies on budget transfers. Change to Section Four: the deadline in subsection A is revised.

Terms Used:

- “Applicant” is used to refer to the individual or organization applying for an award of CPRIT funds.
- “CPRIT,” “Institute,” and “agency” are used interchangeably to refer to the Cancer Prevention and Research Institute of Texas.
- “Project” and “program” are used interchangeably to refer generally to CPRIT-funded activities.
- “Recipient” is generally used to refer to an applicant who has been recommended to receive CPRIT funds and who executes an award contract with CPRIT.

Acronyms Used:

ASO –	Authorized Signing Official
CCO -	Chief Commercialization Officer
CPO –	Chief Prevention Officer
CPRIT –	Cancer Prevention and Research Institute of Texas

CRC –	Commercialization Review Council
CSO –	Chief Scientific Officer
IACUC -	Institutional Animal Care and Use Committee
IRB -	Institutional Review Board
NFR -	Notice of Funding Recommendation
PIA –	Texas Public Information Act
PI/PD –	Principal Investigator/Program Director
PRC –	Prevention Review Council
RFA –	Request for Application
SRC –	Scientific Review Council
SRPP –	Scientific Research and Prevention Program
UGMS –	Uniform Grant Management Standards

1 CPRIT RESEARCH AND PREVENTION AWARDS PROCESS

A. Available Cancer Research and Prevention Funding Awards

In carrying out its mission, CPRIT endeavors to identify and support innovative cancer research and prevention programs that represent the best science and programmatic vision. CPRIT funding opportunities for cancer research and prevention programs are announced through official solicitations on the CPRIT website (www.cprit.state.tx.us). Announcements summaries regarding CPRIT RFAs are also published in the *Texas Register*. Each RFA provides the objectives and requirements that apply to the specific CPRIT-funded award and the review criteria that will be used to evaluate the merit of applications submitted in response to the RFA.

B. Sources for Requirements for CPRIT Applications and Awards

All CPRIT awards have unique terms, such as duration, funding levels, recipient designations, eligibility requirements and project requirements. These terms are delineated in the individual RFA and will be reflected in the award contract between CPRIT and the successful applicant. An applicant is expected to be familiar with the requirements and prohibitions, if any, relevant to the particular RFA for which he/she is applying.

In addition, generally applicable public laws and regulations, including state and federal laws and regulations, agency rules, and state policies pertain to awards issued by CPRIT. These include Tex. Health and Safety Code, Chapter 102; Title 25, Texas Administrative Code, Chapters 702 and 703; and the Uniform Grant Management Standards (UGMS), developed by the Governor's Budget and Planning Office as directed under the Uniform Grant Management Act of 1981, Tex., Government Code, Chapter 783. These requirements provide the framework for the terms and conditions of CPRIT awards.

C. Roles and Responsibilities

1. CPRIT

CPRIT is responsible to the Texas Legislature and to Texans to cost-effectively carrying out its mission to expedite innovation in cancer

research and prevention programs. In fulfilling this objective, certain CPRIT employees and other individuals are relevant to the application and award process. The roles and responsibilities of these individuals are as follows:

- Scientific Research and Prevention Program (SRPP) committee members. SRPP members are experts in the field of cancer research and prevention who are appointed by the Executive Director and approved by the 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.
- Chief Prevention Officer (CPO). The CPO is the CPRIT employee who oversees the scientific and programmatic aspects of CPRIT's cancer prevention program activities. Among the duties of the CPO is the responsibility to act as the CPRIT liaison with the Prevention Review Council (PRC) for all aspects of the review and evaluation of the prevention program applications.
- Prevention Review Council (PRC). The PRC is the 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.
- PRC Chair. The PRC Chair is responsible primarily for coordinating and conducting the review of cancer prevention program applications. In conjunction with the CPO, the PRC Chair is responsible for pre-review activities including the receipt and assignment of applications for review to the appropriate SRPP committees.
- Chief Scientific Officer (CSO). The CSO is the CPRIT employee who oversees the scientific and programmatic aspects of the cancer research program including review and evaluation of the research program applications. Among the CSO's duties is the responsibility to act as the CPRIT liaison with the Scientific Review Council (SRC) on all aspects of the review and evaluation of the research program applications.

- Scientific Review Council (SRC). The SRC is the 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.
- SRC Chair. The SRC Chair is responsible primarily for coordinating and conducting the review of cancer research applications. In conjunction with the CSO, the SRC Chair is responsible for pre-review activities including the receipt and assignment of applications for review to the appropriate SRPP committees.
- Chief Commercialization Officer (CCO). The CCO is the CPRIT employee who oversees the programmatic aspects of CPRIT's commercialization activities. Among the CCO's duties is the responsibility to act as the CPRIT liaison with the Commercialization Review Council (CRC) for all aspects of the review and evaluation of the commercial prospects of cancer research and prevention program applications.
- Commercialization Review Council (CRC). The CRC will review commercialization plans of applications that have demonstrated scientific merit (as determined by the SRPP committee reviewing the application) and may make recommendations to the Executive Director regarding the award of CPRIT funds for cancer research and prevention programs.
- CPRIT Executive Director. The Executive Director is the CPRIT employee who oversees the strategy and operations of the Institute; which includes creating the list of applications recommended for funding substantially based on the list proposed by the SRC and/or PRC and submitting the list to the CPRIT Oversight Committee for final approval.
- CPRIT Oversight Committee. The CPRIT Oversight Committee is the entity charged with the governance of the Institute. An important obligation of the Oversight Committee is the consideration of the Executive Director's funding recommendations. Unless two-thirds of the committee members vote to reject the Executive Director's funding

recommendations, the funding recommendations are approved. The Oversight Committee also negotiates the award contract between CPRIT and the recipient. The Oversight Committee may delegate contract negotiation authority to the Executive Director and General Counsel.

2. Applicant/Recipient

CPRIT awards are generally made to organizations. The organization is legally accountable for the accuracy of the application, the performance of the award, and the expenditure of funds. Award recipients must adhere to all applicable state and federal laws, regulations, and policies. The roles and responsibilities of designated individuals at applicant/recipient organizations, who serve as agents of the organization, are as follows:

- Authorized Signing Official (ASO). The ASO is the designated representative of the applicant/recipient organization with authority to act on the organization's behalf in matters related to the application for and administration of a CPRIT funding award. By signing the application, the ASO certifies that the applicant organization complies with all applicable federal and state laws and regulations and that all eligibility requirements have been satisfied. Unless an applicant is required to submit proof of eligibility, the ASO's signature on the application will serve as certification that the applicant is eligible to apply for and receive a CPRIT funding award.

The ASO's signature also indicates the organization's agreement that it will assume the obligations imposed by applicable state and federal law and other terms and conditions of the award, including any assurances, if an award of CPRIT funds is made. These responsibilities include accountability both for the appropriate use of funds awarded and the performance of the CPRIT-supported program or activities as specified in the approved application.

- Principal Investigator/Program Director (PI/PD). The PI/PD is the individual, designated by the applicant/recipient, responsible for the scientific, technical, or programmatic aspects of the project, as well as for day-to-day management. The PI/PD is the member of the recipient team responsible for ensuring compliance with the financial and administrative

aspects of the award. The PI/PD generally is an employee of the recipient organization and works closely with the organization to create and maintain necessary documentation and ensure compliance with state, federal, and grant-specific requirements.

D. Duty to Avoid Conflicts of Interest

1. CPRIT

CPRIT personnel, SRPP committee members, and Ad Hoc and Oversight Committee members are subject to specific, mandatory conflict of interest provisions. Generally, to the extent that a financial, professional or personal conflict of interest exists for an individual that is in a position to affect the award of a CPRIT award contract, the individual must promptly notify the CPRIT Executive Director and recuse himself/herself from participation, discussion of the award application, or any action taken. The Conflict of Interest Agreement for SRPP Committee Members is included as Attachment 2 to this document.

2. Applicant/Recipient

Organizations receiving CPRIT funds must have established safeguards to prevent employees, consultants, members of governing bodies, and others who may be involved in CPRIT-supported activities from using their positions for purposes that are, or give the appearance of being, motivated by self-dealing. The recipient is responsible for enforcing its established standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, informing CPRIT if the infraction is related to a research or prevention program award.

E. Application

1. Submission of On-line Application

Applications for CPRIT funding awards are managed through an online application system. Applications must be submitted via the CPRIT Application Receipt System (www.CPRITGrants.org). All applicants must

register a user name to start and submit an application. Only applications submitted at this portal will be considered eligible for evaluation.

2. Eligibility

This section provides general eligibility requirements applicable to all recipients of CPRIT-funded awards. Eligibility may vary based on the type of program; however, the RFA will contain specific eligibility requirements. In addition, authorizing legislation and governing programmatic regulations specify eligibility requirements to receive CPRIT funds for individual research and prevention programs.

- CPRIT-funded research and delivery of prevention programs and services must be conducted in Texas. An applicant for CPRIT funds must be a Texas-based entity, including a public or private institution of higher education, academic health institution, university, government organization, nongovernmental organization, other public or private company, or an individual residing in Texas. To the extent possible, any new or expanded preclinical testing, clinical trials, commercialization, or manufacturing of any real or intellectual property resulting from the award must be conducted in the state, including the establishment of facilities to meet this purpose.
- The PI/PD should reside in Texas during the term of the CPRIT-funded project, and the work specified in the award must be conducted within the state.
- CPRIT encourages collaborations, and collaborators are not required to reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but organizations not located in Texas are not generally eligible to receive CPRIT funds (some exceptions may be made for the purchase of goods and services not available in this state.)

By signing the application, the ASO certifies that the applicant organization complies with all applicable federal and state laws and regulations and that all eligibility requirements have been satisfied.

3. Submission of a Commercialization Plan for Certain Applications

Applications for certain funding opportunities will include a question regarding whether the applicant anticipates that the research that is the subject of the application will lead to the development of a product that requires a regulatory filing.

A private or publicly-held company applicant who responds affirmatively to the question of commercialization must submit a commercialization plan describing the problem the product addresses, how the product will address the problem, a technology summary, barriers to entry, competition, market opportunity, the business/revenue model, use of funds, and the product status and timeline. The company may be assessed a fee to cover the additional costs associated with the commercialization review.

A non-company applicant responding affirmatively to the question must complete the “Commercial Translational Research Abstract” form that is available on-line.

4. Use of Application Information

CPRIT will protect information contained in an application from unauthorized disclosure, consistent with the need for objective review of the application and the requirements of state law. Personal information collected about individuals through the application and award process will be kept in a secure environment.

Within legal requirements and to the best of its ability, CPRIT will not release trade secrets and commercial, financial, and otherwise intrinsically valuable items of information that are obtained from an application submitted to CPRIT. CPRIT is subject to the requirements of the Texas Public Information Act (PIA), Texas Government Code Chapter 552, *et. seq.* The PIA requires that information or records that are collected, assembled,

or maintained by a state agency be generally available to the public upon request.

CPRIT's enabling legislation provides that the following information is public information subject to disclosure under the PIA:

- The name and address of the applicant.
- The amount of funding sought by the applicant.
- The type of cancer to be addressed by the applicant's proposal.
- Any other information designated by CPRIT with the consent of the applicant.

Other information relevant to the application process may be considered public information subject to disclosure requirements. However, the PIA contains numerous exceptions to required disclosure, including exceptions for information considered to be trade secret or commercial or financial information that would give an advantage to competitors. Should CPRIT receive a request for information related to the application process, the Institute will exert its best efforts to protect trade secrets and commercial, financial, or otherwise intrinsically valuable information from public disclosure; however, applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application.

If the application contains information that the applicant organization considers to be trade secret, information that is commercial or financial, or information that is privileged or confidential, the pages containing that information should be identified in the application. This requirement is for administrative purposes only. Designating information as trade secret or confidential permits CPRIT staff to easily identify information otherwise relevant the PIA request that may qualify for an exception to public disclosure. Failure of the applicant to so identify information as trade secret or confidential in the application does not constitute a waiver of applicable exceptions to public disclosure. Similarly, the applicant's designation of trade secret or confidential information is not legally binding. The final determination of whether information sought by a PIA must be disclosed rests with the Office of the Attorney General.

Prior to receiving access to confidential and proprietary information submitted by a grant applicant, all individuals, including SRPP committee members, CPRIT employees, Oversight Committee members, and grants management system employees shall certify that confidential and proprietary information will be disclosed or used in any way other than for the purposes of evaluating and awarding grants. The Non-Disclosure Agreement for SRPP committee members is included as Attachment 3 to this document.

F. Process for Objective Review of Applications (see Attachment 1)

CPRIT will endeavor to ensure that the most creative, innovative cancer research and prevention projects representing the best science and programmatic initiatives are funded, while providing assurance to the public that the evaluation process is impartial and fair. This will be accomplished through an objective review of applications for CPRIT funding supervised by the CSO, the CPO and the CCO in coordination with the SRC, the PRC, the CRC, and CPRIT staff. The CPRIT review process involves the following phases:

1. Confirmation of Administrative Compliance

Applications will be administratively rejected without further review if they are missing any component required by the individual RFA, exceed the specified page, word, or budget limits set by the RFA, or do not otherwise meet the eligibility requirements.

If an applicant is found to be ineligible or the application does not meet the published objective criteria, CPRIT will notify the organization's ASO by letter that no further review will be conducted by the Institute.

2. Initial Review

Based upon the number of applications received and the resources available for the SRPP committees, CPRIT reserves the option to conduct an initial peer review evaluation of the grant applications by one or more SRPP committees. An application determined to be incomplete or otherwise noncompetitive during the initial evaluation will not be

considered for further review. All applications not triaged at this stage will be assigned to the appropriate SRPP committee for the second round of peer review.

3. Peer Review by SRPP Committees

Applications that are not triaged or administratively rejected during the initial peer review process will be submitted for a second, more intense peer review conducted by at least two unbiased SRPP committee members with an expertise in the programmatic area for which the application was submitted. Peer review of the scientific and programmatic content of all eligible applications will be conducted to evaluate the scientific, technical, programmatic, and commercialization (if applicable) merit of the application.

The reviewing SRPP members will assess and score individual cancer research and prevention applications based on primary scored criteria and secondary unscored criteria published for each RFA. Generally, primary criteria will evaluate the merit of the proposed work as outlined in the RFA. A score reflecting an overall assessment will be assigned by the SRPP committee for each application.

Based upon the results of the peer review process, each SRPP committee will submit a recommendation for funding awards based upon all applications reviewed by the committee. The individual SRPP committee funding award recommendations will be forwarded to the SRC, PRC and/or CRC for consideration.

4. SRC/PRC Review

Funding recommendations made by individual SRPP committees and will be evaluated by the SRC, the PRC and/or the CRC, as appropriate. In addition to the information and analysis provided by the SRPP committees, state law has established criteria that the SRC, PRC and/or CRC will consider when developing the prioritized list of funding recommendations. Priority will be given to proposals that:

- Could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer;

- Strengthen and enhance fundamental science in cancer research;
- Ensure a comprehensive coordinated approach to cancer research and prevention;
- 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 from a private or nonprofit entity and institution or institutions of higher education;
- Use CPRIT funds to obtain additional cancer research and prevention funding from other sources;
- 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 this state;
- Enhance research superiority at institutions of higher education in this state by creating new research superiority, attracting existing research superiority from institutions not located in this state and other research entities, or enhancing existing research superiority by attracting from outside this state additional researchers and resources; and
- Expedite innovation and commercialization, attract, create, or expand private sector entities that will drive a substantial increase in high-quality jobs, and increase higher education applied science or technology research capabilities.

5. Commercialization Review by CRC

All applications that self-identify during the on-line application process as including a commercialization component (by submitting a proposed

commercialization plan or a Commercial Translational Research Abstract form) and are deemed to have sufficient scientific merit will be reviewed by a CRC. The CRC will evaluate the proposed plan and provide input that may be considered as part of the overall funding recommendation decision.

6. Review of Budget Information

In addition to the scientific and programmatic review, budget information provided with the application will be reviewed as part of the overall funding recommendation decision.

Individual RFAs will provide specific requirements for the proposed budget to be submitted with the application. A review of the costs included in the proposed budget may be performed; the extent of the review will generally depend upon the complexity of the project. The cost review may involve obtaining cost breakdowns, validating cost data, evaluating specific elements of cost, and examining data to determine the necessity for, and the reasonableness and permissibility of, the costs included in the application budget.

7. List of Applications Recommended for Funding Submitted to Executive Director

The SRC, the PRC and/or the CRC will submit a prioritized list of funding recommendations to the CPRIT Executive Director.

8. Executive Director's Recommendation Submitted to Oversight Committee

The CPRIT Executive Director will submit to the Oversight Committee a prioritized list of applications to be awarded CPRIT funds for cancer research and cancer prevention programs. The Executive Director's recommendations will be substantially based upon the lists received from the SRC, PRC and/or the CRC. Unless the Oversight Committee votes by at least a 2/3 majority to reject the Executive Director's recommendations, the awards will be funded, subject to an executed contract between the agency and the recipient organization.

G. Notice of Funding Recommendation

The ASO will be notified by letter and an attached Notice of Funding Recommendation when an application has been approved. At a minimum, the Notice of Funding Recommendation (NFR) will include pertinent information about the award, such as the name of the CPRIT award, the name of the PI/PD, the approved project period and budget period, and the amount of matching costs to be demonstrated by the applicant.

The NFR is not an award contract. All CPRIT funds will be awarded pursuant to a contract between the recipient of a NFR and CPRIT. An applicant that receives a NFR but fails to meet certain conditions precedent (i.e., demonstrating available matching funds) or cannot agree to contractual terms will not receive a CPRIT award. Until an award contract is executed between CPRIT and the successful applicant, the applicant is responsible for any costs incurred by the applicant for the project.

H. Disposition of Applications Not Recommended for Funding

The ASO will be notified by letter that the application was not recommended for funding, and a brief explanation regarding the evaluation of the application and further recommendations, if any. The decision not to recommend the application for funding is discretionary and not subject to appeal, except for as provided herein.

I. Appeal Limited

The decision to recommend an application for funding is based upon the scientific merit, sufficiency of the application, the results of the peer review by the individual SRPP committee, input from CPRIT employees regarding the application budget, and, if applicable, the results of the review conducted by the CRC, the SRC, and/or the PRC. Differences of scientific opinion between or among PIs and reviewers are not grounds for appeal.

Grounds for appeal are strictly limited to circumstances in which an applicant can show that a demonstrable financial, professional, or personal conflict of interest (as defined by the statute or CPRIT's governing rules) held by a member of the SRPP committee that reviewed the application, or a member of the CRC, SRC, or

PRC, if the application was considered by the CRC, SRC, or PRC, was unreported and had a negative impact on the review process.

The applicant may file with the Executive Director a request for reconsideration of the review process no later than 30 days from the date of the notification letter sent to the applicant's ASO informing the organization that the application was not recommended for funding. The request for reconsideration shall include all information related to the alleged conflict of interest.

If the Executive Director finds that no conflict of interest affecting the review of the application exists, then the applicant will be notified that the request for reconsideration is rejected. For purposes of the Executive Director's evaluation, if the reviewer fully complied with the requirements in CPRIT's rules and applicable law, then no conflict of interest exists.

A final determination regarding the existence of a conflict of interest will be made by the Executive Director. The Executive Director's determination will include actions to be taken, if any, to address the conflict of interest, including reconsideration of the application and referral of the application to a different SRPP committee for review. The Executive Director's decision will be considered final unless three or more Oversight Committee members request that the issue be added to the agenda of the Oversight Committee's next open meeting for a final determination by the Oversight Committee.

2 TERMS AND CONDITIONS OF CPRIT AWARD

A. All CPRIT Funding Awards by Contract

Texas law requires that all CPRIT funds be awarded pursuant to a contract between the applicant and CPRIT. An NFR does not constitute a legal entitlement to CPRIT funds nor entitle an applicant to CPRIT award proceeds until a final contract is executed. After the applicant receives a NFR, the applicant organization and the CPRIT contract negotiation team (named by the Oversight Committee) will negotiate the terms of the final award contract.

The recipient indicates acceptance of an award and the associated terms and conditions by executing the contract and accepting funds from CPRIT. If a contract cannot be executed by the successful applicant, or if the successful applicant cannot perform in accordance with the legal obligations and contract provisions, the applicant should notify CPRIT immediately. If resolution cannot be reached, CPRIT will void the NFR.

Once an award contract is executed by the recipient, the contents of the contract are binding upon the recipient and CPRIT unless and until modified by a contract revision signed by the recipient and CPRIT Executive Director or the contract is terminated.

If the NFR or the contract is awarded on the basis of false or misrepresented information submitted by the applicant, the NFR and/or contract is void and all CPRIT funds must be returned.

B. General Terms Applicable to all CPRIT Award Contracts

CPRIT funding awards are subject to certain contract terms and conditions as specified by Texas law and/or CPRIT administrative rules. These terms and conditions include:

- For award funds that have been approved by the Oversight Committee to be used to build a capital improvement, the contract must specify that the state retains a lien or other interest in the capital improvement in proportion to the percentage of CPRIT funds used to pay for the capital improvement and that the award recipient agrees to repay to the state the CPRIT funds used to pay for the capital improvement, with interest, and share with the state a proportionate amount of any profit realized from the sale if the capital improvement is sold.

- Terms relating to intellectual property rights.
- Terms related to publication of material created with CPRIT funds or related to the research that is the subject of such funds, including acknowledgement of CPRIT funding and copyright ownership issues.
- Repayment terms, including interest rates, to be enforced if the recipient has not used CPRIT funds for the purposes for which the award was intended.
- A statement that CPRIT does not assume responsibility for the conduct of the research project or prevention program, and that the conduct of the project and activities of all investigators/program directors, subcontractors, or other agents are under the scope and direction of the recipient. The recipient shall not be considered an agent or employee of CPRIT or the State of Texas for any purpose under the award contract.
- A statement that the cancer research project or prevention program is conducted with full consideration for the ethical and medical implications of the research and that the project will comply with all federal and state laws regarding the conduct of the research or delivery of the prevention program.
- An agreement that the recipient shall indemnify or insure and hold CPRIT harmless against any and all losses, damages, expenses, or liabilities, including attorney's fees arising from research, commercialization, or prevention programs conducted by the recipient pursuant to a CPRIT award, to the extent permitted by law.
- A statement that the recipient will employ best efforts to purchase goods and services from Texas suppliers and from historically underutilized businesses as defined by Chapter 2161, Government Code, and any other state law.
- An agreement by the recipient to submit to regular inspection reviews of the CPRIT-funded project.
- An agreement by the recipient to present progress reports to the Executive Director on a specified schedule that includes information on an

award-by-award basis quantifying the amount of additional funding, if any, secured as a result of CPRIT funding.

- An agreement that a substantial percentage of any new or expanded preclinical testing, clinical trials, commercialization, or manufacturing of any real or intellectual product resulting from the award will be established and conducted in Texas, to the extent possible.
- An agreement that the recipient will abide by the Uniform Grant Management Standards adopted by the Governor's Office of Budget and Planning, if applicable.

For additional guidance, certain required contract terms and conditions listed above are described more fully in this section. These terms and conditions are not intended to be all-inclusive. All awards or a specified subset of awards may be subject to additional requirements and conditions, as set forth in the specific RFA. However, notice of award-specific terms and conditions in the RFA is not a prerequisite for including the term or condition in the final award contract.

C. Flow-Down Requirements

The terms and conditions in the CPRIT contract apply directly to the recipient of CPRIT funds. The recipient is accountable for the performance of the project, program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient as specified in the executed contract between CPRIT and the recipient. In general, the requirements that apply to the recipient also apply to sub-recipients, contractors, and sub-contractors that receive CPRIT funds, unless an exception is specified and expressly authorized.

D. Organizational Assurances

CPRIT does not assume responsibility for the conduct of a cancer research or prevention program or for the activities of an award recipient, since the conduct and activities are under the scope and direction of the recipient institution and subject to its policies. Recipients must provide assurances that all personnel and equipment are certified, licensed, or permitted by the appropriate regulating agency, where applicable.

By signing the award contract, the ASO certifies that the recipient organization will comply with all applicable state and federal requirements. These requirements include, but are not limited to, the following:

1. Standards of Conduct for Recipient Employees

The recipient is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project. The recipient is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, informing CPRIT if the infraction is related to a research award.

- **Objectivity In Research/Conflict of Interest**

At all times, recipients and investigators must promote objectivity in research and ensure that the design, conduct, and reporting of research funded by CPRIT awards will not be biased by any conflicting financial interests. The recipient must certify that written safeguards are in place to prevent employees, consultants, members of governing bodies, and others who may be involved in CPRIT-supported activities from using their positions for purposes that are, or give the appearance of being, motivated by self-dealing. The recipient must notify CPRIT of any conflicting financial interests and assure that the interest has been managed, reduced, or eliminated.

- **Research or Program Misconduct**

The recipient must certify that persons working on a CPRIT supported project are not debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in research projects by any federal or state department or agency.

The recipient will inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged or apparent research misconduct. If a misconduct investigation has been initiated, the recipient must take any necessary steps, in addition to its normal and ongoing responsibilities under the award, to protect

the scientific integrity of the project, protect human subjects and animals, provide reports to CPRIT, and ensure the proper expenditure of funds and continuation of the project during the investigation.

If the recipient finds research misconduct by anyone working on a CPRIT supported project, the recipient must assess the effect of that finding on the ability to continue the project, as originally approved, and must promptly request CPRIT prior approval of any intended change of PI or other key personnel. If research misconduct has affected the data validity or reliability, CPRIT may require the recipient and its employee and/or collaborator authors to submit a correction or retraction of the data to a journal, publish the corrected data, or both.

- **Criminal Misconduct**

The recipient must promptly report issues involving potential civil or criminal fraud, such as false claims or misappropriation of federal funds to CPRIT.

2. Human Subjects/Animal Use

Whenever human or animal subjects are part of a CPRIT-funded project, a copy of the recipient organization's Institutional Review Board (IRB) and/or Institutional Animal Care and Use Committee (IACUC) approval must be provided to CPRIT before funding can be released. For multi-year projects, annual confirmation of IRB or IACUC approval is required. This information is not required at the time of application submission.

Research involving human subjects will be guided by one of the following statements of ethical principles:

- The World Medical Association's Declaration of Helsinki (as adopted in 1996 or 2000);
- The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; or

- Other appropriate international ethical standards recognized by U.S. federal departments and agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects, known as the Common Rule.

Research involving animals must comply with the U.S. Public Health Service Policy on Humane Care and Use of Laboratory Animals or the International Guiding Principles for Biomedical Research Involving Animals.

3. Research Involving Human Biological/Anatomical Material

Research involving the use of human biological and/or anatomical materials should comply with the recommendations of the National Institutes of Health, Office of Human Subject Research Medical Administrative Series (MAS) #MO1-2 entitled “Procurement and Use of Human Biological Materials for Research,” and any other federal or state regulations.

4. Biosafety

For research involving the use of biohazardous materials, radioisotopes, and or controlled substances, the recipient of CPRIT funding must certify compliance with all relevant state and federal regulations.

5. Confidentiality of Patient Records

CPRIT award recipients must have a system in place to protect against inappropriate disclosure of patient records and all other documents deemed confidential by law, which are maintained in connection with the activities funded by the CPRIT award. A copy of the recipient’s confidentiality guidelines must be provided to CPRIT.

Programs working directly with patients are required to specifically address Health Insurance Portability and Accountability Act of 1996 regulations concerning confidentiality of personal and medical information. Any disclosure of confidential information (including information that may be required by reports and inspections) must be in accordance with applicable law.

E. Matching Requirement – Research Awards Only

Texas law requires that prior to the execution of a final research award contract between CPRIT and the recipient; the recipient must have an amount of funds equal to one-half of the award dedicated to the research that is the subject of the grant request.

To fulfill this requirement, a research award recipient must certify that at the time of the award it has funds, not yet expended equal one-half of the grant award, and that those funds will be spent on the same area of cancer research that is the subject of the award.

1. Certification – Timing and Certifying Entity

The certification is required at the time of the CPRIT award (and then annually for multi-year awards). An applicant is not required to provide documentation of the ability to meet the matching requirement when the application for CPRIT funding is submitted. However, all applicants should be aware of the law and be prepared to demonstrate compliance as a necessary condition of receiving a CPRIT award contract.

The recipient of a multi-year award may demonstrate available funds on a year-by-year basis. For example, if the research grant is awarded for a five-year project where the recipient will receive \$2 million each year (\$10 million total), the recipient's match requirement would be \$1 million for each year of the project (\$5 million total), to be demonstrated at the time of each annual progress report.

Organizations, not individuals, are the likely recipients of CPRIT funding awards. Certification of matching funds may be done on the organizational level, rather than an award-by-award or PI/PD level.

2. Appropriate Funding Sources

The recipient may rely upon federal, state, or non-governmental funds to fulfill the matching requirement. For purposes of meeting this requirement, a "Notice of Grant Award" is sufficient to demonstrate that funds have been awarded and encumbered but not yet received by the recipient.

In addition, the recipient can satisfy some portion of its match requirement (up to 10% of the total CPRIT award amount) by demonstrating that the recipient's own funds -- not CPRIT award proceeds -- will be spent on costs not directly associated with a specific project but are nonetheless true costs (e.g. security, utilities, business office administration.) These indirect costs may not be recovered with CPRIT funds and the recipient must have a documented federal indirect cost rate or a rate that has been certified by an independent accounting firm.

3. Dedicated to the Research that is the Subject of the Grant Request

CPRIT administrative rules provide five categories of cancer research that encompass most cancer projects. The subject matter of the CPRIT-funded project and the recipient's available funds must be grouped in the same category. Funds available to be spent on cancer research are measured at a category and institutional level, not by PI/PD.

For purposes of this section, the five cancer research categories 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)

F. Indemnification of CPRIT

Unless specifically prohibited by law, recipients must hold CPRIT harmless and indemnify CPRIT from and against all claims, demands, and causes of actions that may be asserted by any third party in connection with the performance of contracted services.

G. Acknowledgement of CPRIT Funding

Recipients must notify the CPRIT Communications Director prior to any press releases, advertising, publicity, or other promotional activities that arise during the course of or as a consequence of CPRIT funding. In the event that CPRIT wishes to participate in a joint press release, the recipient will coordinate with the CPRIT communications officer. Recipients may publish research results in academic or other peer-reviewed journals without approval from CPRIT but are required to submit an electronic version of their manuscript to PubMed Central in accordance with Section H, Public Access to CPRIT-Funded Research, of this Guide.

CPRIT must be acknowledged on all print and visual materials that are funded in whole or in part by CPRIT awards. Such materials include, but are not limited to, brochures, pamphlets, booklets, training fliers, project websites, videos and DVDs, manuals and reports, as well as on the labels and cases for audiovisual or videotape/DVD presentations. Funding acknowledgment must also appear within all project-related video or slide presentations. When CPRIT funds are used to disseminate works done by another entity, a label must be affixed acknowledging the Institute's part in the activity. Written permission must be obtained from the copyright owner prior to printing works by others. CPRIT reserves the right to review the material prior to printing.

H. Public Access to CPRIT-Funded Research

To help advance science and improve public health, it is CPRIT's policy that the public has access to CPRIT-funded research, as well as needs assessment information and cancer control data collected pursuant to prevention program awards. Recipients are required to submit an electronic version of their final peer-reviewed journal manuscripts that arise from CPRIT funds to the digital archive National Library of Medicine's *PubMed Central* upon acceptance for publication. These papers must be accessible to the public on *PubMed* no later than 12 months after publication. This policy will not supplant applicable copyright law.

I. Intellectual Property

Texas State law requires that all CPRIT funding awards be subject to an intellectual property agreement that allows the state to collect royalties, income,

and other benefits realized as a result of the projects undertaken with CPRIT funds. The determination of the state's intellectual property rights will take into account the opportunity of the state to benefit from the patents, royalties, licenses, and other benefits that result from basic research, therapy developments, and clinical trials, as well as the need to ensure that essential medical research is not unreasonably hindered by the intellectual property agreement or unnecessarily disincentivized. The intellectual property agreement may include the following terms and conditions:

1. Invention Reporting Requirements

To the extent applicable, recipient organizations are required to have written agreements with researchers requiring prompt disclosure of inventions made in the performance of CPRIT-funded research. (The award recipient bears responsibility for costs associated with patents and patent applications claiming their CPRIT-funded inventions.)

2. Notification Regarding Invention Discovery

The recipient organization must notify CPRIT of the invention within a set period of time. The notification must identify the CPRIT award under which the invention was made and the inventor(s), and be sufficiently complete in technical detail to convey a clear understanding of the nature, purpose, operation, and physical, chemical, biological or electrical characteristics of the invention. The notification will be considered confidential, trade secret information that will be protected from disclosure. The notification must also identify whether a manuscript describing the invention has been submitted for publication, and, if so, the publication and submission date.

3. Annual Reporting Requirement

At least annually, a CPRIT research award recipient must submit a report to CPRIT regarding: (1) activities to protect and commercialize new intellectual property made in performance of CPRIT-funded research; (2) established and new financial interests held by the recipient under intellectual property agreements made in performance of CPRIT-funded research; (3) revenues received from intellectual property made in performance of CPRIT-funded research; and (4) a statement of efforts

made to utilize CPRIT- funded inventions. The report may be prepared at the organizational level.

4. CPRIT-Funded Inventions Readily Accessible on Reasonable Terms

The recipient must agree to make its CPRIT-funded patented inventions readily accessible on reasonable terms, directly or through a licensee or licensees, to other CPRIT award recipients for non-commercial purposes, upon request from a recipient organization.

In addition, other terms and conditions regarding exclusive and non-exclusive licenses, commercial development milestones and benchmarks, remedies for failure to develop technology, march-in rights, and revenue sharing will be specifically included in the IP agreement and/or award contract. CPRIT reserves the right to negotiate separate intellectual property agreements applicable to for-profit and non-profit entities.

J. Termination of Award Contract

CPRIT may terminate an award contract if the recipient fails to comply with any applicable federal or state law, agency rule, regulation, policy, or the specific contract terms and conditions. The award contract may also be canceled by mutual consent or for convenience by the recipient. In addition, CPRIT may terminate an award if funds allocated should become reduced, depleted, or unavailable during the award period, and CPRIT is unable to obtain additional funds for such purposes.

1. Unilateral Termination

CPRIT must give at least thirty (30) days written notice to the recipient prior to the intended date of termination. Such notice shall include reasons for the termination and provide the other party an opportunity to rebut the reasons in writing. Early termination shall not nullify obligations already incurred for performance or failure to perform prior to the date of termination.

2. Termination for Lack of Funds

In the event that CPRIT must terminate an award contract because funds have become reduced, depleted, or unavailable during the award period, CPRIT shall immediately provide written notification to the recipient of

such fact and such award is terminated upon receipt of that notification. CPRIT shall not be charged a fee for terminating a contract. The recipient shall not incur new obligations after the date the written notification is received, unless expressly permitted by CPRIT in writing and shall cancel as many outstanding obligations as possible. CPRIT shall allow full credit to the recipient for noncancellable obligations, which are properly incurred prior to the termination date. CPRIT shall not be liable for any services performed or cost incurred after the effective date of termination.

3 FISCAL POLICIES AND COST CONSIDERATIONS

A. Award Funds Distributed on a Reimbursement Basis

CPRIT funds will be distributed on a reimbursement basis. Generally, costs must be incurred before CPRIT will make payment. Variances from this policy will be for exceptional circumstances that must be specifically addressed in the award contract executed by CPRIT and the applicant or an appropriately authorized amendment. This section does not create an entitlement by any CPRIT award recipient to advance payment.

B. Financial Administration

The recipient is responsible for managing the day-to-day operations of the CPRIT award supported activities and is accountable to CPRIT for the performance of the project, program, or activity; the appropriate expenditure of award funds by all parties; and all other obligations of the recipient. Recipients may use their established controls and policies, as long as they are consistent with award requirements. The financial management systems of recipients must meet the following standards:

1. Financial Reporting

Accurate, current, and complete disclosure of the financial results of financially assisted activities must be made in accordance with the financial reporting requirements of the award contract.

2. Accounting Records

Recipients must maintain records which adequately identify the source and application of funds provided for financially-assisted activities. These records must contain information pertaining to awards and authorizations, obligations, unobligated balances, assets, liabilities, outlays or expenditures, and income.

3. Internal Control

Effective control and accountability must be maintained for all award funds, real and personal property, and other assets. Recipients must adequately safeguard all such property and must ensure that it is used solely for authorized purposes.

4. Budget Control

Actual expenditures or outlays must be compared with budgeted amounts for each CPRIT award.

5. Allowable Cost

Applicable cost principles, CPRIT rules, and the terms of award contract will be followed in determining the reasonableness, allowability, and allocability of costs.

6. Source Documentation

Accounting records must be supported by such source documentation as canceled checks, paid bills, payrolls, time and attendance records, contract and subcontract award documents, etc.

CPRIT may review the adequacy of the financial management system of any applicant as part of the pre-award activities or at any time subsequent to award to ensure that the system is adequate to permit the tracing of funds to a level of expenditures sufficient to establish that such funds have not been used in violation of the award contract terms and prohibitions of applicable statutes.

C. Allowable Costs and Activities

CPRIT funds may be used to pay only allowable costs. To be considered allowable, a cost must be:

1. Reasonable

A cost is reasonable if the nature of the goods or services acquired and the amount involved reflect the action that a prudent person would have taken under the circumstances prevailing at the time the decision was made to incur the cost. Factors that are relevant to the consideration of reasonableness include sound business practices, arms length bargaining, market prices for comparable goods or services, and significant deviations from the established practices which may unjustifiably increase the cost. To the extent applicable, the cost should be determined in accordance with generally accepted accounting principles.

2. Necessary for the Proper and Efficient Performance and Administration of the Funded Project

CPRIT funds shall only be used for expenditures required to carry out the approved project and activities. Authorized expenses may include, but are not limited to: honoraria, salaries and benefits, travel, conference fees and expenses, consumable supplies, other operating expenses, contract research and development, capital equipment, and construction or renovation of state or private facilities.

3. Allocable to the Funded Project

See discussion of Direct Costs in Section Three, Subsection E.

4. Not Otherwise Prohibited from Recovery by State Law, CPRIT Administrative Rules, or Grant Guidelines

Otherwise authorized expenses must conform to the limitations or exclusions set forth in state law, CPRIT administrative rules, and terms and conditions of the award contract. For example, state law limits the amount of money that may be spent on facility construction, remodeling, or renovation. Similarly, conditions included in specific CPRIT awards prohibit recovery of costs like travel expenses or limit the amount of CPRIT funds that may be used to pay researcher salaries on certain projects.

5. Not Included as a Cost of Any Other Award, Except as Specifically Authorized

6. Adequately Documented

Documentation may include, but is not limited to, travel records, time sheets, invoices, contracts, mileage records, billing records, or other documentation that verifies the expenditure amount and appropriateness to the CPRIT award.

D. Unallowable Expenditures

The following expenditures are examples of items that will not be reimbursed by CPRIT:

- **Bad Debt:** Any losses arising from uncollectible accounts and other claims and related costs.
- **Contingencies:** Contributions to a contingency reserve or any similar provision for unforeseen events.
- **Contributions and Donations:** Made to any individual or organization.
- **Entertainment:** Costs of amusements, social activities, and incidental costs relating thereto, including tickets to shows or sports events, meals, alcoholic beverages, lodging, rentals, transportation and gratuities.
- **Food/Refreshments:** Costs relating to food and beverage items.
- **Fines and Penalties:** Costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.
- **An honorary gift or a gratuitous payment instead of being compensated for services rendered.**
- **Interest and other Financial Costs:** Interest on borrowing and cost of financing.
- **Legislative Expenses:** Salaries and other expenses of the state legislature or similar local governmental bodies whether incurred for purposes of legislation or executive direction.
- **Liability Insurance Coverage**
- **Benefit Replacement Pay or legislative mandated pay increases for eligible General Revenue funded state employees in state agencies or universities.**
- **Professional Association Fees/Dues for agencies and individuals.**
- **Promotional Items:** Costs relating to items such as T-shirts, coffee mugs,

buttons, pencils, and candy that advertise the project/organization.

- Patient Support Services: Costs relating to services such as personal care items and financial assistance for low-income clients.

This list is provided for explanatory purposes only. It is not intended to be an exclusive list of items and costs not allowed to be funded by a CPRIT award.

E. Direct Costs

Costs that are clearly associated with the research project and not otherwise prohibited by law or specific award conditions will be considered direct costs subject to recovery with award proceeds.

In general, in order to be considered a direct cost, the purchased good or service must benefit and be allocable to a particular sponsored project. The fact that the project expenditure simultaneously benefits other work of the institution will not prevent it from being considered a direct cost, so long as the expense can be assigned to the project through the use of reasonable methods.

Examples of expenditures associated with a research project that will be considered direct costs:

- Salaries and fringe benefits of personnel including faculty, technicians, post doctoral fellows, graduate research assistants and other personnel directly engaged in performing the sponsored project's scope of work subject to certain limitations included in the award contract or RFA. Tuition and fees for personnel directly engaged in the project's scope of work are also considered direct costs.
- Costs such as travel, scientific/equipment maintenance and repairs, utilities, communications costs, and other directly related costs necessary for performing the specific scope of work unless prohibited by the award contract.
- Supplies and materials (including cost of animals) necessary for performing the project's scope of work including educational material when approved in the budget.

- Research costs including institutional review board costs, facility fees, research office, etc., that are reasonable, directly associated with the project's scope of work, and approved in the budget.
- Rental/leasing costs for projects conducted in rental space not owned by the award recipient may be approved in extraordinary circumstances.
- Subcontracts necessary for performing the sponsored project's specific scope of work and approved in the budget.
- Consultant services contracted to accomplish specific award objectives and approved in the budget.
- Equipment, including capital equipment (as established by the State of Texas capitalization threshold), that can be allocated to the project and that is specifically approved in the budget.
- Service/maintenance agreements on equipment and facilities (including animal facility maintenance) directly associated with the project and approved in the budget.

F. Limitation on Recovery of Indirect Costs

Texas state law limits the amount of award proceeds that may be spent on indirect costs associated with research projects to no more than five (5) percent of the total award. Indirect costs are the expenses of doing business that are not readily identified with a particular award, contract, project, function, or activity, but may be necessary for the general operation of the organization or the performance of the organization's activities.

Costs that are clearly associated with the research funded by the CPRIT award will be considered direct costs and are not subject to the five percent limitation on indirect cost recovery. As set forth in the Section Three, Subsection E, direct costs are identified specifically with a particular award and directly assigned to project activities relatively easily and with a high degree of accuracy.

While state law does not specifically address a limit on indirect cost recovery for CPRIT-funded cancer prevention programs, it is CPRIT's long-standing policy to

not allow recovery of indirect costs for prevention programs unless under exceptional circumstances.

G. Certification of Franchise Tax Payment

The recipient must certify that payment of franchise taxes is current or, if the recipient is exempt from payment of franchise taxes that it is not subject to the State of Texas franchise tax. A false statement regarding franchise tax status shall be treated as a material breach of the contract between the recipient and CPRIT and may be grounds for termination at the option of CPRIT. If franchise tax payments become delinquent during the term of the CPRIT award, payments under the award will be held until the recipient's delinquent franchise tax is paid in full.

H. Withholding Payments

CPRIT will not withhold payments for proper charges incurred by a recipient of CPRIT funds unless the recipient has failed to comply with award contract terms and conditions or the recipient is indebted to the State of Texas.

Funds withheld for failure to comply with award contract terms and conditions, but without suspension of the award, shall be released to the recipient upon subsequent compliance.

CPRIT shall not make payment to recipients for amounts that are withheld by the recipient from payment to contractors to ensure satisfactory completion of work. Payments shall be made by CPRIT when the recipient actually disburses the withheld funds to the contractors or to ensure satisfactory completion of work.

I. Misuse of Funds

Recipients are under an on-going obligation to immediately report to CPRIT any cases of real or apparent fraud, waste, or abuse under a CPRIT award upon knowledge thereof. Examples of fraud, waste, and abuse that must be reported include, but are not limited to, embezzlement, misuse/misappropriation of award funds or property, the personal use of award funds, using funds for non-project-related purposes, theft of CPRIT-owned property or property acquired or leased with CPRIT funds, charging CPRIT for services of “ghost” individuals, submitting false financial reports, submitting falsified financial data in bids submitted to the

award recipient (for eventual payment with CPRIT funds) and false statements by organizations or individuals.

J. Cost and Budget Transfers

1. Cost Transfers – Limited to Correcting Bookkeeping Errors

Cost transfers by a recipient organization between funds awarded to the organization, whether as a means to compensate for cost overruns or for other reasons, are generally not permitted. Under certain circumstances, cost transfers may be necessary to correct bookkeeping or clerical errors. Permissible cost transfers should be made promptly after the error occurs, but no later than 90 days following the occurrence unless specific permission is requested and granted. The transfer must be supported by documentation that explains how the error occurred and a certification of accuracy of the new charge by a responsible official of the recipient. The recipient is not required to submit the documentation to CPRIT, but this information is subject to audit.

2. Budget Transfers

CPRIT expects the rates and types of the recipient's expenditures to be consistent with the approved project. Recipients are responsible for monitoring expenditures to ensure that they do not exceed the amount authorized by the award contract. Costs exceeding the contract award amount are not subject to be recovered with CPRIT funds.

Recipients may make transfers between or among line items within budget categories without prior written approval provided that:

- The total dollar amount of all changes of any single line item within budget categories (individually and in the aggregate) is less than 10% of the total budget;
- The transfer will not increase or decrease the total budget;
- The transfer will not materially change the nature, performance level, or scope of the project; and

- The recipient submits a revised budget.

All other budget changes or transfers require CPRIT's express approval. Transfer of funds between categories in a project's approved budget may be allowed if requests are in writing, fit within the scope of the contract and the total project budget, are beneficial to the achievement of project objectives, and appear to be an efficient, effective use of CPRIT funds.

K. Purchase, Construction, or Renovation of Laboratory Facilities

Subject to legal requirements and to the specific, written approval of CPRIT, award funds may be used for the purchase, construction, or renovation of laboratory facilities by or on behalf of a state agency or CPRIT award recipient.

1. Limitations

Certain RFAs may explicitly prohibit the use of CPRIT funds by the recipient to purchase, construct, remodel, or renovate facilities.

2. Express Authorization Required

Even if the RFA contains no such prohibition, Texas law limits the total amount of CPRIT bond proceeds that may be spent for facility purchase, construction, remodel, or renovation purposes during any year. To ensure that the statutory limit is not exceeded, any use of CPRIT funds for the purchase, construction, remodel, or renovation of facilities or other capital improvement shall be expressly approved by CPRIT pursuant to terms and conditions included in the award contract executed between CPRIT and the recipient.

3. Mandatory Terms

To the extent that funds awarded to be expended for capital improvements, including facility purchase, construction, remodel, or renovation, the award is subject to the following conditions:

- Money spent on facility purchase, construction, remodel, or renovation projects must benefit cancer prevention and research.

- The state retains a lien or other interest in the capital improvement in proportion to the percentage of the award amount used to pay for the capital improvement.
- If the capital improvement is sold, the CPRIT award recipient must repay to the state the CPRIT funds money used for the capital improvement, with interest at the rate set by the contract, and share with the state a proportionate amount of any profit realized from the sale.
- Any other terms and conditions specified by the award contract.

L. Purchase of Equipment

The recipient may use CPRIT funds to purchase equipment to be used for the purpose of the project, subject to the following conditions. For equipment costing more than \$5,000, CPRIT must authorize the acquisition. Title to equipment costing more than \$5,000 may vest with the recipient organization with CPRIT approval upon completion of the CPRIT-funded project. For equipment costing \$5,000 or less, title to equipment vests in the organization upon acquisition. Equipment purchased with CPRIT funds must stay within the State of Texas for the duration of the funding period.

M. Program Income

CPRIT award recipients are encouraged to earn program income to defray program costs and to develop and acquire long-term funding alternatives that will enable the program to be sustained without financial support from CPRIT. For purposes of this section, "program income" means gross income received by the grant recipient directly generated by a grant supported activity, or earned only as a result of the grant agreement during the funding period minus the costs incident to the generation of program income.

For purposes of this document, this section does not apply to program income such as fees or royalties earned from intellectual property created by the grant-funded activity. Instead, intellectual property issues are specifically addressed in Section Two, Subsection I.

All revenues received from the CPRIT-funded program shall be identified, reported and utilized as provided by the contract between CPRIT and the

recipient. Unless otherwise specified in the contract, project income shall be retained by the recipient and shall be used by the recipient for any purposes which further the objectives of the CPRIT-funded program and/or implementation of the Texas Cancer Plan. Program income shall be deducted from total program costs to determine the net costs on which CPRIT reimbursement will be based.

N. Audit Requirement

CPRIT, the state auditor and/or the Office of the Comptroller shall have the right to request and receive from the recipient and PI/PD copies of any and all documents and other information related to the award at any time during or for three years after the term of the award expires. This right includes, but is not limited to, the right to review all financial books and records of the recipient and PI/PD related to the CPRIT award and to perform an audit or other accounting procedures of all expenses related directly or indirectly to the subject of the award. The request for an audit will be made in writing.

The state auditor and the Office of the Comptroller may conduct a review, audit or investigation of any entity receiving funds from the state directly under the award contract or indirectly through a subcontract under the award contract. Acceptance of funds directly under the award contract or indirectly through a subcontract under the award contract indicates acceptance of the authority of the state auditor and the Office of the Comptroller to conduct an audit or investigation in connection with those funds.

All award recipients are expected to create and maintain complete and auditable fiscal records. The recipient shall make all information related to the contract available for inspection during regular working hours upon the request for such review, investigation, or audit. These records must be kept for three (3) years after the final reimbursement for the award has been paid and until any (if applicable) litigation, claims, or audit findings are resolved. Annual financial statements, tax returns, and agency budgets may be required from all recipients upon request.

All audits will be conducted in accordance with the requirements of the Uniform Grants Management Standards. A single or program specific audit must be completed if the project's organization has expended \$500,000 or more in total

state awards (e.g., expended \$100,000 from CPRIT and \$400,000 from the Department of State Health Services or at least \$500,000 in CPRIT funds).

Upon completion of an audit, the grantee will provide CPRIT one copy of the reporting package if the schedule of findings and questioned costs discloses an audit finding(s) related to Institute funds or provide a written notification to CPRIT if there were no findings related to CPRIT funding.

CPRIT staff will review the reporting package or written notification to determine if the report can be used in lieu of conducting a fiscal monitoring visit for the project. Recipients may use CPRIT award funds for the relative cost (or proportionate share) of the required audit only if the cost of the audit has been included in the recipient's budget approved by CPRIT.

O. Historically Underutilized Businesses (HUBs)

An effort should be made to purchase materials, supplies or services from an Historically Underutilized Business (HUB). The Texas Procurement and Support Services website will assist in finding HUB vendors (<http://www.window.state.tx.us/procurement.>) Projects are required to complete a HUB report with each quarterly performance report.

P. Preference for Texas Suppliers

CPRIT's enabling legislation established a goal that more than 50 percent of the goods and services used in CPRIT-supported research and programs is purchased from Texas suppliers. To achieve this goal, recipients of CPRIT funds are expected to purchase from Texas suppliers, to the extent reasonably possible, the goods and services it uses in CPRIT-supported research and prevention programs. Recipients failing to meet this standard must provide a clear and compelling explanation in writing in the progress report.

4 Reporting Requirements

Unless otherwise provided in an agreement between CPRIT and the award recipient, all progress, financial, and final reports are not considered confidential. CPRIT may share the award information and reports with the public and the legislature. Therefore, recipients are advised to not include any information in the reports the public disclosure of which may result in the waiver of the opportunity to obtain a patent.

A. Financial Report

Annual financial reports are due by each anniversary of the CPRIT-funded research project or prevention program for the duration of the project or program. A final financial report is due within 90 days following the budget period after the completion or early termination of the CPRIT award.

B. Progress Report

Throughout the term of the award, scientific and programmatic progress will be monitored by CPRIT staff assigned to the project or program. Generally, recipients are required to submit scientific or programmatic progress reports that detail research or program progress, challenges and their remedy, research or program outcomes, and inventions occurring during the reporting period. The reporting schedule and/or additional information to be reported are specified in the award contract.

A research or prevention program final report must be provided within 90 days after the completion or early termination of the funding award.

C. Serious Adverse Event Report

In the case of an adverse event occurring during a CPRIT-funded clinical trial or other program that is both serious and unexpected, the PI/PD must notify CPRIT of such event at the same time that the IRB and recipient are notified.

D. Failure to Comply Report

Recipients must report promptly to CPRIT the failure to comply with the terms and conditions of an award. Depending upon the severity and duration of the non-compliance, CPRIT actions may include, but are not limited to, temporary withholding of payment, placing special conditions on awards, precluding PI/PD or recipient organization, as appropriate, from obtaining future CPRIT awards for

a specified period, debarment from receipt of further CPRIT funds, recovery of previously awarded funds, civil action, including referring the matter to the Office of the Attorney General for investigation and enforcement, and other available legal remedies.

E. Other Reporting Requirements

CPRIT intends to maximize the flexibility of the recipient in the management of the CPRIT-funded research project or prevention program while maintaining the highest standard of accountability and preserving the integrity of the peer review and funding process.

Unless specifically stated in the award contract, all changes in the status of the CPRIT-funded project are considered amendments to the award contract and must be submitted for written approval by CPRIT. Some of the changes requiring prior approval include:

1. Change in Research/Program Plan

Material changes in the research design and/or specific aims require prior written approval. Minor adjustments in approach do not require written approval, but should be communicated to the CPRIT manager assigned to the project/program.

2. Change in Recipient Organization

If a PI/PD changes recipient organizations during the course of the CPRIT-funded project or program, prior written approval must be given by CPRIT for either the transfer of the award or the replacement of the PI/PD. CPRIT awards may not be transferred to organizations outside the State of Texas.

3. Change of Personnel

CPRIT must be notified of all changes in PI/PDs. Changes in key personnel that dedicate at least 10% of their time to a CPRIT-funded project or program must also be communicated in writing to CPRIT.

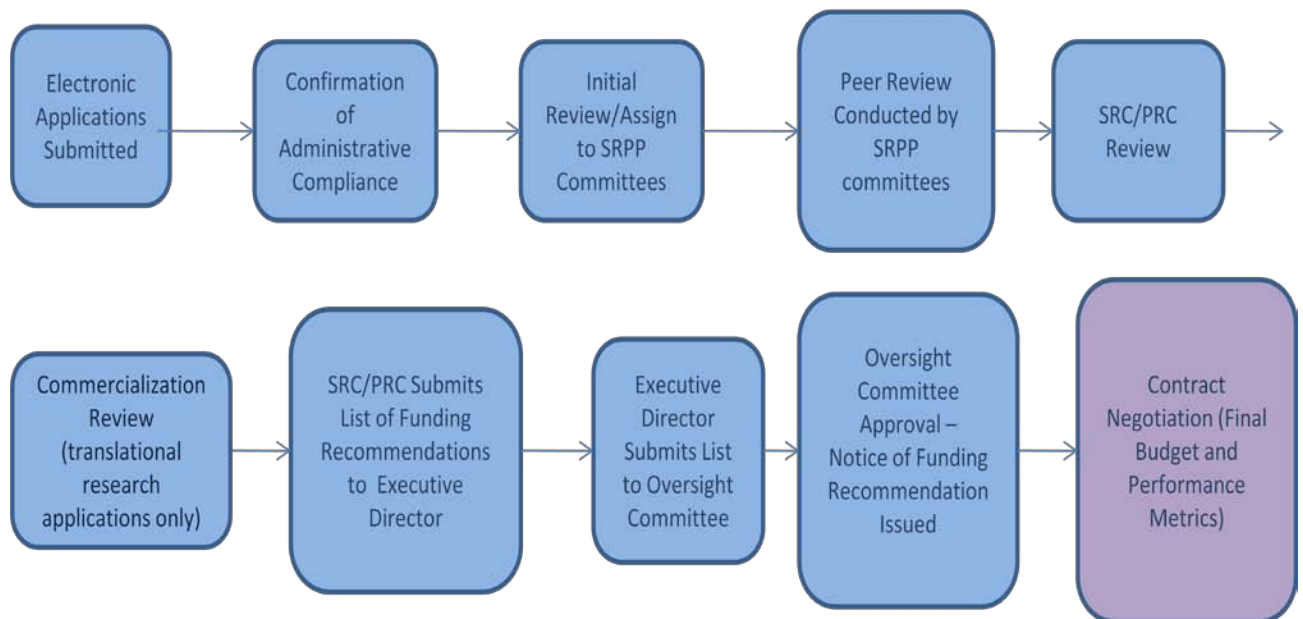
F. Overdue Reports

Failure to provide timely and complete reports will constitute an event of default of the award contract, which may result in the early termination of the CPRIT award, reimbursement to CPRIT of award funds, and cessation of future funding.

Attachments

CPRIT Grant Application Review Process

CPRIT Grant Application Review Process



CONFLICT OF INTEREST POLICY FOR CPRIT SCIENTIFIC RESEARCH AND PREVENTION PROGRAM (SRPP) COMMITTEE MEMBERS

To be successful, the Cancer Prevention and Research Institute of Texas (CPRIT) must make awards according to an open, fair and unbiased process. Consistent with this aim, the evaluation of funding award applications by the Scientific Research and Prevention Program (SRPP) committee members must be free both from real and apparent conflicts of interest. CPRIT is committed to strong and effective conflict of interest policies. The conflict of interest policy for members of the SRPP committee members is closely modeled on the policies of NIH.

A conflict of interest exists when a SRPP committee member has a real or apparent interest in the outcome of an application such that the member is in a position to gain financially, professionally, or personally from either a positive or negative evaluation of the grant proposal.

Financial:

A SRPP committee member has a financial conflict of interest if the SRPP committee member, his or her spouse, parent, domestic partner, child, or any other person with whom the member has a common financial interest:

- (1) Is an employee of either the applicant or the Principal Investigator on an application.
- (2) Is under active consideration for a faculty or administrative position at an applicant institution.
- (3) Stands to receive a financial benefit of any amount from an application under review.
- (4) Owns or controls, directly or indirectly, an ownership interest of five percent or more in a business entity or other organization receiving money from the Institute. Interests subject to this provision include sharing in profits, proceeds, or capital gains. Examples of ownership or control include, but are not limited to, owning shares, stock, or otherwise, and are not dependent upon whether voting rights are included.
- (5) Has received a financial benefit from an applicant institution or organization unrelated to the proposal of over \$5,000 per year. This total includes fees, stock and other benefits. It also includes current stock holdings, equity interest, intellectual property or real property interest, but does not include diversified mutual funds.
- (6) Is a member of the board of directors, other governing board or any committee of the applicant, or serves as an elected or appointed officer of the entity.

Professional:

An SRPP committee member has a professional conflict of interest if:

- (1) A person listed on the grant application as Principal Investigator or an individual who will receive salary from the grant has been at any time within the past three years a professional associate, such as a former student or post-doctoral fellow, or someone with whom the SRPP committee member serves on an advisory board for a commercial entity.
- (2) The SRPP committee member was a student or postdoctoral associate in the applicant's laboratory research group within the past six years.

- (3) The SRPP committee member and a primary member of the research or prevention team of an application are engaged in, or are planning to be engaged in, collaboration.
- (4) An applicant is someone with whom the SRPP committee member has had long-standing scientific differences or disagreements that are known to the professional community and could be perceived as affecting the member's objectivity.

Personal:

An SRPP committee member has a personal conflict of interest if:

- (1) A family member or close personal friend is an applicant.
- (2) An applicant is someone with whom the member has had long-standing personal differences.

Duty to Report and Process for Recusal:

At the time that the SRPP committee member becomes aware of a possible conflict of interest including, but not limited to, those described above, the reviewer must notify the committee chair and the CPRIT Chief Scientific Officer or Chief Prevention Officer, as may be applicable. Except under exceptional circumstances as described below, any member of an SRPP committee who has a real or apparent conflict of interest with respect to an application may not review or vote on the application and must leave the room when that application is discussed.

In exceptional cases, the CPRIT Executive Director, working in conjunction with the Chief Scientific Officer and/or the Chief Prevention Officer and the CPRIT General Counsel may decide that the need for special expertise of the reviewer outweighs any possible bias posed by a real or apparent conflict of interest. Under these circumstances, the SRPP committee member's interest shall be disclosed in writing before the SRPP committee meeting and the SRPP committee member shall be permitted to participate in the discussion but will not be permitted to vote on the application or participate in the scientific scoring.

All reviewers must sign a post-review statement that they did not participate in the discussion or review of any application for which they might have a conflict of interest.

I understand the conflict of interest policies of CPRIT and will report any and all conflicts of interest that I have with respect to applications submitted to my assigned SRPP committee for review.

Signature: _____ Date: _____

**NON-DISCLOSURE AGREEMENT FOR CPRIT SCIENTIFIC RESEARCH AND
PREVENTION PROGRAM (SRPP) COMMITTEE MEMBERS**

Peer review of applications submitted to the Cancer Prevention and Research Institute of Texas (CPRIT) may require a Scientific Research and Prevention Program committee member (Committee Member) to view information that is considered confidential and proprietary, either by the applicant for the CPRIT funding award or by Systems Research and Applications (SRA) Corporation, or both.

The Committee Member is able to view such confidential and proprietary information for the sole purpose of the evaluation of the applications for CPRIT funding awards in accordance with the terms and conditions contained in this Non-Disclosure Agreement (Agreement). Public disclosure of the confidential and proprietary information may cause irreparable harm to the applicant or to SRA.

This Agreement governs the responsibilities and obligations of the Committee Member with regard to the use and handling of confidential and proprietary information in the course of the review process. By signing the agreement, the Committee Member accepts and agrees to abide by the provisions of this agreement in exchange for the ability to participate in the peer review process for CPRIT research funding awards.

1. CONFIDENTIAL OR PROPRIETARY INFORMATION.

For purposes of this Agreement, and subject to the limitations set forth in Paragraph 2, all information disclosed in writing by applicants for CPRIT funding awards or by SRA that is clearly marked and labeled “Confidential” shall be deemed to be "Confidential or Proprietary Information."

In addition, whether or not so marked, Confidential or Proprietary Information shall be deemed to include any trade secret, information, business and financial data, patent disclosures, patent applications, structures, models, techniques, processes, safety information, compositions, compounds and apparatus relating to the same, invention, idea, sample, media and/or cell line and procedures and formulations for producing any such sample, media and/or cell line, process, formula, or test data relating to any research project, work in process, future development engineering, manufacturing, marketing, servicing, financing or personnel matter relating to the applicant or to SRA, its present or future products, sales, suppliers, clients, customers, employees, investors or business, whether in oral, written, graphic, physical or electronic form disclosed by the parties or through observation or examination of information or developments, as well as information or data generated or derived as a result of the research project, but only to the extent that such information is maintained as confidential by the applicant or SRA.

2. INFORMATION NOT CONSIDERED CONFIDENTIAL.

The term “Confidential or Proprietary Information” as used in this Agreement shall not include any information:

- In the public domain at the time of disclosure by applicant or by SRA;
- Published or otherwise comes into the public domain after its disclosure through no violation of this Agreement by Committee Member;
- Disclosed to Committee Member by a third party not under an obligation of confidence;
- Already known by Committee Member at the time of its disclosure as evidenced by written documentation Committee Member existing prior to such disclosure; or
- Independently developed by Committee Member through persons who have not had, either directly or indirectly, access to or knowledge of the Confidential or Proprietary Information, as evidenced by written documentation of Committee Member.

3. AUTHORIZED USE.

Committee Member may use such Confidential or Proprietary Information only to the extent required to accomplish the peer review of the application. Committee Member shall maintain all Confidential or Proprietary Information in trust and confidence.

Committee Member may disclose Confidential or Proprietary Information to the agents, consultants, advisors, or attorneys for CPRIT or SRA who have a need to know such information and such individuals are or will be bound by obligations of confidentiality and non-use no less restrictive than those set forth in this Agreement.

4. OBLIGATIONS.

By executing this Agreement, Committee Member agrees to treat as confidential and maintain in trust all Confidential or Proprietary Information made available to him/her as a result of the peer review process. The obligations imposed herein remain in force for a period extending three (3) years from the application submission date. Consistent with this agreement, Committee Member agrees that he/she:

- Shall not disclose or use Confidential or Proprietary Information for any purpose other than to evaluate the application, whether or not a final CPRIT funding award contract results.
- Shall not use Confidential or Proprietary Information disclosed on an application or in the review process for any unauthorized purpose or in any manner that would constitute a violation of any federal or state laws or regulations, including without limitation the export control laws of the United States.
- Shall not reproduce in any form Confidential and Proprietary Information except as required to accomplish the peer review process and specifically directed by SRA.

Committee Member acknowledges that such use or disclosure of Confidential and Proprietary Information as described in this Agreement may constitute insider trading in violation of federal law, resulting in severe sanctions on individuals and the corporate entities involved in insider trading.

4. REMEDY FOR BREACH OF AGREEMENT.

Committee Member acknowledges and agrees that a breach of this Agreement by Committee Member would cause an applicant or SRA to suffer irreparable damage that could not be adequately remedied by an action at law. The Committee Member therefore agrees that the applicant, SRA, and/or CPRIT acting on behalf of the applicant shall have the right to seek and obtain immediate injunctive relief from the breach or threatened breach of this Agreement. Such relief includes specific performance of the obligations provided herein to enjoin the breach or further breach of this Agreement, in addition to all other rights and remedies available at law, in equity, or otherwise.

If any of the rights or restrictions contained in this Agreement shall be deemed to be unenforceable by reason of the extent, duration or geographic scope, or other provision hereof, then the Committee Member hereto agrees that the court shall reduce such extent, duration, geographic scope or other provision hereof and enforce the provisions in reduced form for all purposes in the manner contemplated hereby.

5. RETURN OF DOCUMENTS.

Upon request from SRA, Committee Member shall promptly return all originals and copies of Confidential or Proprietary Information as well as permanently delete all electronically or otherwise stored Confidential or Proprietary Information from all systems containing such Confidential and Proprietary Information, and in any event, upon completion or termination of this Agreement.

I understand the obligations and responsibilities imposed by this Non-Disclosure Agreement and will abide by these requirements.

Signature: _____ Date: _____