



Cancer Prevention & Research Institute of Texas

Request for Public Comments

CPRIT's Proposed Rules Regarding Grants for Cancer Prevention and Research

At its August 14th meeting, the Oversight Committee of the Cancer Prevention and Research Institute of Texas (CPRIT) approved a proposed set of rules to govern the process for awarding CPRIT grants. The attached set of proposed rules, "*Grants for Cancer Prevention and Research*," will be published in the August 28th edition of the *Texas Register*. The proposed rules cover all aspects of the CPRIT grant process, including topics such as the content of the Institute's request for applications, the peer review process, and awarding grants by contracts.

These proposed rules clarify the agency's statutory mandates and provide additional guidance regarding issues that may not be specifically addressed by the statute. In conjunction with the information provided in the formal request for applications, the final rules will establish the parameters that all successful grant applicants must follow.

CPRIT's goal is to create a grant process that identifies and awards the most innovative and creative projects representing the best science and prevention programs. At the same time, CPRIT is mindful that the Institute serves as the steward for the investment that Texas will make in these programs.

The public is invited to review the proposed rules and submit comments to CPRIT regarding the procedures and standards that will be implemented by the Institute. The most helpful comments will provide specific guidance on the areas discussed, including best practices that have been used elsewhere. If the proposed rules present barriers to identifying and awarding groundbreaking science, please point out the provisions and recommend changes. To the extent possible, address comments to specific rule provisions.

CPRIT will review all written comments and, if necessary, make changes to the proposed rules based upon the information received. At the conclusion of the public comment period, the Oversight Committee will consider a final order to officially adopt the rules. The final order will contain a summary of all comments received on the proposed rules.

Written comments should be submitted to Kristen Pauling Doyle, CPRIT General Counsel, on or before 5:00 p.m. on September 28, 2009. The comments will become part of the formal rulemaking record and provide guidance in crafting a final set of rules on CPRIT's grant process. The comments may be faxed (512/475-2563), sent by email (kdoyle@cprit.state.tx.us) or mailed to the Cancer Prevention and Research Institute of Texas, P.O. Box 12097, Austin, Texas, 78711.

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GRANTS FOR CANCER RESEARCH AND PREVENTION

§703.1. Purpose and Application.

- (a) Grants awarded by the Institute shall:
 - (1) Create and expedite innovation in the area of cancer research and enhance the potential for medical or scientific breakthrough in the prevention of cancer and cures for cancer;
 - (2) Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in Texas; and
 - (3) Develop and implement the *Texas Cancer Plan*.
- (b) This chapter applies to all grant proposals considered by the Institute for initial funding on or after September 1, 2009.

§703.2. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

- (1) Applicant -- the public or private institution of higher education, academic health institution, university, government organization, non-governmental organization, other public entity, private company, or individual that submits an application to the Institute for a grant funded by the Cancer Prevention and Research Fund. Unless otherwise indicated, this term includes the principal investigator.
- (2) Authorized expenses – items including honoraria, salaries and benefits, consumable supplies, other operating expenses, contracted research and development, capital equipment, construction or renovation of state or private facilities, travel, and conference fees and expenses, except as otherwise provided by this chapter.
- (3) Cancer Prevention and Research Fund -- the dedicated account in the general revenue fund consisting of patent, royalty, and license fees and other income received under a contract with a grant recipient, legislative appropriations, gifts, grants, and other donations, and earned interest.

- (4) Cancer prevention and control program -- a program designed to mitigate the incidence of all types of cancer in humans.
- (5) Cancer research -- research into the causes and cures for all types of cancer in humans, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer in humans.
- (6) Chief Prevention Officer -- the individual employed by the Institute to oversee the scientific and program review and evaluation of the grant applications for cancer prevention activities.
- (7) Chief Scientific Officer -- the individual employed by the Institute to oversee the scientific review and evaluation of the grant applications for cancer research activities.
- (8) Encumbered funds -- funds that are designated by a recipient for a specific purpose.
- (9) Indirect costs -- the expenses of doing business that are not readily identified with a particular grant, contract, project, function, or activity, but are necessary for the general operation of the organization or the performance of the organization's activities.
- (10) Prevention Review Council -- the group of individuals designated as chairs of the prevention program committees created to review cancer prevention program applications.
- (11) Recipient -- the public or private institution of higher education, academic health institution, university, government organization, non-governmental organization, other public entity, private company, or individual that is awarded a grant funded by the Cancer Prevention and Research Fund.
- (12) Scientific research and prevention program committee -- one or more groups of experts in the field of cancer research and prevention appointed by the Executive Director and approved by the Oversight Committee for the purpose of reviewing grant applications and making recommendations to the Executive Director regarding the award of cancer research and prevention grants. For purposes of this chapter, the Scientific Review Council and the Prevention Review Council are scientific research and prevention program committees. This term shares the same meaning as "peer review group" and "scientific review group" as defined in §702.3(18) of this title (relating to Definitions).

- (13) Scientific Review Council -- the group of individuals designated as chairs of the scientific research and prevention program committees created to review cancer research applications.

§703.3. Grant Applications.

- (a) The Institute will accept grant applications for cancer research and prevention programs to be funded by the Cancer Prevention and Research Fund in response to standard format requests for applications that will be publicly issued by the Institute at least annually. The requests for applications will be announced and available through a web-based electronic system managed by the Institute.
- (b) The Institute reserves the right to modify the format and content requirements for the requests for applications at any time. Notice of the modification will be announced through a web-based electronic system.
- (c) Cancer research grant applications may address, but are not limited to, the following areas:
- (1) Short-term, high-impact programs;
 - (2) Individual investigator awards;
 - (3) Multiple investigator awards, including collaborative projects, centers, core facilities, shared instrumentation, and infrastructure;
 - (4) Recruitment to the state of new, emerging, and established investigators;
 - (5) Training; and
 - (6) Implementation of the *Texas Cancer Plan*.
- (d) Cancer prevention grant applications may address, but are not limited to, the following areas:
- (1) Innovation awards;
 - (2) Education, outreach and training;

- (3) Evidence based prevention programs and services;
 - (4) Collaborative projects;
 - (5) Infrastructure/capacity building grants; and
 - (6) Implementation of the *Texas Cancer Plan*.
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- (e) An applicant must disclose all contractors, including subcontractors that the applicant intends to use to carry out the work of the awarded grant. The applicant has a continuing duty to supplement this information as it becomes known to the applicant.
 - (f) An applicant has a duty to ensure that the design, conduct, and reporting of the research or prevention program will not be biased by conflicting financial interest of the applicant or any individuals associated with the grant. This duty is fulfilled by providing an appropriate written, enforced conflict of interest policy that governs the applicant institution and by complying with any other provisions that may be set forth in the request for applications.
 - (g) The applicant shall not initiate contact with scientific research and prevention programs committee members regarding the status or substance of the grant application.
 - (h) Failure to comply with the requirements set forth in the request for applications may serve as grounds for disqualification from further consideration of the grant application by the Institute.

§703.4. Grants Management.

The Institute may engage third-party grants management services to assist in some or all aspects of the grant application process, as determined by an agreement with the Institute.

§703.5. Scientific Research and Prevention Programs Committee Members.

- (a) The Executive Director, with approval of a simple majority of the Oversight Committee, will appoint experts in the field of cancer research and prevention to serve as members of a scientific research and prevention program committee for terms designated by the Executive Director.
- (b) An individual appointed to serve as a member of a scientific research and prevention

program committee may be a resident of another state.

- (c) Scientific research and prevention programs committee members are responsible for reviewing the scientific research and prevention program grant applications assigned to the individual member's committee.
- (d) Scientific research and prevention programs committee members may receive an honorarium.
- (e) A member of a scientific research and prevention programs committees is prohibited from attempting to use the committee member's official position to influence a decision to approve or award a grant or contract to the committee member's employer.
- (f) A member of a scientific research and prevention programs committee must comply with the requirements set forth in §702.11 (of this title relating to Recusal and Conflicts of Interest). The disclosure required by §702.11 of this title must be submitted in writing to the Executive Director.
- (g) If a member of a scientific research and prevention programs committee has a conflict of interest as described §702.11 of this title, the member shall recuse himself or herself from the committee's deliberations and actions on the matter and shall not participate in the committee's decision on the matter.
- (h) Nothing in this section prohibits the Scientific Review Council and the Prevention Review Council from adopting additional standards and reporting requirements relating to prohibited conflicts of interest that may be more rigorous than set forth in the Act or in this chapter. Members of scientific research and prevention programs committees must comply with additional standards upon adoption.

§703.6. Grants Review Process.

- (a) The Institute will endeavor to ensure that the most creative, most innovative projects representing the best science are funded. This will be accomplished through a rigorous peer review process of grant applications supervised by the Chief Scientific Officer and the Chief Prevention Officer in coordination with the Scientific Review Council and the Prevention Review Council.
- (b) To the extent possible, priority for funding for cancer research and prevention applications will be given to proposals that:
 - (1) Could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer;

- (2) Strengthen and enhance fundamental science in cancer research;
 - (3) Ensure a comprehensive coordinated approach to cancer research and prevention;
 - (4) Are interdisciplinary or interinstitutional;
 - (5) Address federal or other major research sponsors' priorities in emerging scientific or technology fields in the area of cancer prevention or cures for cancer;
 - (6) Are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;
 - (7) Use Cancer Prevention and Research funds to obtain additional cancer research and prevention funding from other sources;
 - (8) 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;
 - (9) Have a demonstrable economic development benefit to this state;
 - (10) 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
 - (11) 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.
- (c) Based upon the results of the peer review process and in consideration of the standards described in subsection (b) of this section, as applicable, an individual research and prevention program committee will agree upon a recommendation for grant proposal funding for grant applications reviewed by the committee.
- (d) Grant funding recommendations made by individual research and prevention program committees will be evaluated by the Scientific Review Council or the Prevention Review Council, as may be appropriate.

- (e) Pursuant to a schedule developed by the Executive Director, the Scientific Review Council and the Prevention Review Council will submit a prioritized list of grant funding recommendations to the Executive Director. The list of grant funding recommendations will include a statement of how the grant applications recommended for funding meet one or more standards of subsection (b) of this section.
- (f) The decision to recommend a grant application for funding is entirely within the purview of scientific research and prevention programs committee to which the grant application has been assigned, and, if applicable, to the Scientific Review Council or the Prevention Review Council.

§703.7. Executive Director’s Funding Recommendation.

The Executive Director shall submit to the Oversight Committee a prioritized list of applications to be awarded cancer research grants and cancer prevention program grants substantially based upon the lists submitted by the Scientific Review Council and Prevention Review Council.

§703.8. Overriding the Executive Director’s Funding Recommendation.

- (a) The Oversight Committee shall consider the Executive Director’s funding recommendations as a comprehensive slate.
- (b) The Executive Director’s slate of funding recommendations is approved by the Oversight Committee unless two-thirds of the members of the Oversight Committee vote to disregard the slate of recommendations.
- (c) If the Oversight Committee votes to disregard the slate of funding recommendations, the Executive Director may re-submit recommendations for consideration by the Oversight Committee pursuant to a process and time table established by the Oversight Committee.

§703.9. Limitation on Review of Grant Process.

- (a) The decision to recommend a grant application for funding is based upon the sufficiency of the grant application, the results of the initial peer review by the individual scientific research and prevention program committee and, if applicable, the results of the review conducted by the Scientific Review Council or the Prevention Review Council.

- (b) Grounds for reconsideration of a grant application are limited to conflict of interest concerns regarding a member of the scientific research and prevention program committee that reviewed the application or a member of the Scientific Review Council or Prevention Review Council, if the grant application was considered by the Scientific Review Council or Prevention Review Council.
- (c) The applicant shall file a request for a review of the grant process with the Executive Director no later than 30 days from the date of the notification to the applicant that the grant application was not recommended for funding.
- (d) The request for review shall include all information related to the allegation of a conflict of interest.
- (e) If the Executive Director finds that no conflict of interest affecting the review of the grant application, then the applicant will be notified that the request for review is rejected. For purposes of this section, if the reviewer fully complied with the requirements under §702.11 (of this title relating to Recusal and Conflicts of Interest) and §703.5 (f - h) of this Chapter (relating to Scientific Research and Prevention Programs Committee Members) if applicable, then no conflict of interest exists.
- (f) If the Executive Director finds that a conflict of interest exists, the application shall be re-submitted to a different scientific research and prevention programs committee for review.

§703.10. Awarding Grants by Contract.

- (a) The Oversight Committee may not award more than \$300 million in grants from the Cancer Prevention and Research Fund in a fiscal year.
- (b) The Oversight Committee shall negotiate on behalf of the state regarding the awarding of grant funds, and enter into a written contract with the grant recipient.
- (c) The Oversight Committee may delegate contract negotiation duties to a team that includes at least the Executive Director, the General Counsel for the Institute, and an Oversight Committee member designated by the Presiding Officer.
- (d) The contract between the Institute and the grant recipient shall include the following provisions:
 - (1) If any portion of the grant has been approved by the Oversight Committee to be used to build a capital improvement, the contract must specify that:
 - (A) The state retains a lien or other interest in the capital improvement in proportion to the percentage of the grant amount used to pay for the

capital improvement.

(B) The grant recipient agrees to repay to the state the grant money 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.

- (2) Terms relating to intellectual property rights consistent with the standards established by the Oversight Committee pursuant to §102.256, Health and Safety Code;
- (3) Terms related publication of material created with grant funds or related to the research that is the subject of grant funds, including to acknowledgement of Institute funding and copyright ownership, if applicable;
- (4) Repayment terms, including interest rates, to be enforced if the grant recipient has not used grant money for the purposes for which the grant was intended;
- (5) A statement that the Institute 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 are under the scope and direction of the recipient;
- (6) A statement that 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;
- (7) Standards established by the Oversight Committee pursuant to §102.258 and §102.259, Health and Safety Code, to ensure that grant recipients purchase goods and services from suppliers in this state and from historically underutilized businesses as defined by Chapter 2161, Government Code, and any other state law;
- (8) An agreement by the grant recipient to submit to regular inspection reviews of the grant project;
- (9) An agreement by the grant recipient to present progress reports to the Executive Director on a schedule specified by the contract that includes information on a grant-by-grant basis quantifying the amount of additional research funding, if any, secured as a result of Cancer Prevention and Research funding;
- (10) 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 this state, to the extent possible; and

- (11) 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.
- (e) The grant recipient is under a continuing obligation to notify the Executive Director of any adverse conditions that materially impact milestones and objectives included in the contract.
- (f) The Oversight Committee may not award grant funds after August 31, 2020.

§703.11. Requirement to Demonstrate Available Funds.

- (a) At the time of award, a cancer research grant recipient must certify that encumbered funds equal to one-half of the amount of the total grant are available and not yet expended for research that is the subject of the grant. Recipients receiving multiple grant awards may provide certification at the institutional level.
- (b) For purposes of the certification required by subsection (a) of this section, a recipient may use the following categories to classify available funds that are dedicated to cancer research:
 - (1) Cancer biology and genetics, including oncogenesis and collection and characterization of tumors (genomics, proteomics, other "omics");
 - (2) Cancer immunology, including vaccines;
 - (3) Cancer imaging and diagnostics;
 - (4) Cancer epidemiology and outcomes research; and
 - (5) Cancer treatment, including drug discovery and development and clinical trials.
- (c) Recipient available funds sufficient to fulfill the requirement of this section may include but are not necessarily limited to:
 - (1) Federal funds (including American Recovery and Reinvestment Act of 2009 funds);
 - (2) State of Texas funds;
 - (3) Other States' funds;

- (4) Non-governmental funds (including private funds, foundation grants, gifts and donations); and
- (5) Unrecovered indirect costs not to exceed 10 percent of the grant award amount, subject to the following conditions:
 - (A) These costs are not otherwise charged against the grant as the five percent indirect funds amount allowed under §703.12(c) of this chapter (relating to Limitations on Use of Funds);
 - (B) Recipient must have a documented federal indirect cost rate or an indirect cost rate certified by an independent accounting firm; and
 - (C) The allowance for unrecovered indirect costs must be specifically approved by the Executive Director.
- (d) The following items do not qualify as funds sufficient to fulfill the requirement of this subsection:
 - (1) In-kind costs;
 - (2) Volunteer services furnished to the grant recipient;
 - (3) Noncash contributions;
 - (4) Income earned not available at the time of award;
 - (5) Pre-existing real estate including building, facilities and land;
 - (6) Deferred giving such as a charitable remainder annuity trust, a charitable remainder unitrust, or a pooled income fund; or
 - (7) Other items as may be determined by the Oversight Committee.

§703.12. Limitation on Use of Funds.

- (a) A grant recipient may use the money only for cancer research and prevention programs consistent with the purpose of the Act, and in accordance with the contract between the grant recipient and the Institute.
- (b) Money awarded from the Cancer Prevention and Research fund must be used for authorized expenses. Additional guidance regarding authorized expenses for a

specific program may be provided by the terms of the contract between the grant recipient and the Institute.

- (c) A recipient of funds for cancer research may not spend more than five percent of the money awarded for indirect costs.
- (d) Not more than five percent of the money awarded from the Cancer Prevention and Research Fund may be used for facility purchase, construction, remodel, or renovation purposes during any year. Any funds awarded that are expended for facility purchase, construction, remodel, or renovation are subject to the following conditions:
 - (1) The funds must be specifically approved by the Oversight Committee during the grants review process in §703.6 of this Chapter (relating to Grants Review Process); and
 - (2) Money spent on facility purchase, construction, remodel, or renovation projects must benefit cancer prevention and research.
- (e) Not more than 10 percent of the money awarded under from the Cancer Prevention and Research Fund may be used for cancer prevention and control programs during any year. For purposes of this subsection, the Institute is presumed to award the full amount of funds available from the Cancer Prevention and Research Fund.
- (f) Grant funds may not be used for purposes other than those purposes for which the grant was awarded.

§703.13. Audits.

The Institute shall have the right to request and receive from the recipient any and all documents and other information related to the grant at any time during or after the term of the grant. This right includes, but is not limited to, the right to review all financial books and records of the recipient related to the grant and to perform an audit or other accounting procedures of all expenses related directly or indirectly to the grant.

§703.14. Termination of Grants.

- (a) The Executive Director may terminate grants prior to the expiration of the contract between the Institute and the grant recipient on the grounds that the recipient has

failed to meet contractual obligations.

- (b) The Executive Director shall notify the grant recipient in writing of the intent to terminate funding at least 30 days before the intended termination date.
- (c) The notice shall state the reasons for termination and the procedure for seeking reconsideration of the decision to terminate.

§703.15. Multiyear Projects.

- (a) The Oversight Committee may grant funds for a multiyear project subject to the requirement that all funds for the multiyear project are awarded in the state fiscal year that the project is approved by the Oversight Committee.
- (b) Only those funds to be expended during the fiscal year will be distributed to the multiyear grant recipient.
- (c) Funds approved by the Oversight Committee for multiyear projects not expended during the fiscal year shall be maintained in an escrow account until such time that the funds are distributed for subsequent years of the project.
- (d) A recipient awarded a grant for a multiyear project may fulfill the certification requirements set forth in §703.11 of this Chapter (relating to Requirement to Demonstrate Available Funds) on a year-by-year basis at the time of the annual progress review or upon a schedule established by the contract between the Institute and the recipient.