

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS_

REQUEST FOR APPLICATIONS RFA R-17-CFSA-1

Core Facilities Support Awards – Competitive Renewal

Please also refer to the "Instructions for Applicants" document, which will be posted August 11, 2015.

Application Receipt Opening Date: August 11, 2015 **Application Receipt Closing Date:** October 13, 2015

FY 2017

Fiscal Year Award Period September 1, 2016–August 31, 2017

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RFA VERSION HISTORY

Rev 07/06/15 RFA release



1. ABOUT CPRIT

The state of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or 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 the state of Texas; and
- Develop and implement the Texas Cancer Plan.

Research Program Priorities 1.1.

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The principles and priorities of the Scientific Research program will guide CPRIT staff, peer reviewers, and the Scientific Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs. The program priorities for research adopted by the Oversight Committee include funding projects that address the following:

- A broad range of innovative, investigator-initiated research projects;
- Prevention and early detection;
- Rare and intractable cancers, including childhood cancers;
- Cancers of importance in Texas;
- Computational biology and analytic methods; and
- Infrastructure development

2. RATIONALE

Core Facility Support Awards seek to facilitate the further development or improvement of core facilities that will provide valuable services to support and enhance scientifically meritorious cancer research projects. A user group of Texas-based investigators must be identified, each of

whom should have supported cancer research projects that will make use of the requested facility. This requirement is not intended to exclude early career—stage investigators who have not yet secured peer-reviewed grant support. Successful applicants should show that the proposed continuation of the program demonstrates a high likelihood of continued success based on initial results and outcomes of the project.

3. RESEARCH OBJECTIVES

CPRIT will foster cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research. This RFA solicits applications from institutions to continue funding for existing core facilities that will directly support cancer research programs to advance knowledge of the causes, prevention, and/or treatment of cancer or improve quality of life for patients with and survivors of cancer.

CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to survivorship. To fulfill this vision, applications may address any topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, cure, or quality of life. This award provides cancer researchers access to appropriate research infrastructure, instrumentation, and technical expertise necessary to achieve their research objectives. Funds may be requested to continue activities of an existing facility that directly supports and impacts cancer research programs at the institution and in the region.

4. FUNDING INFORMATION

The maximum duration for this award mechanism is 5 years. Eligible applicants may request up to the total amount that was originally awarded not to exceed \$5,000,000 in total costs. Exceptions to these limits may be granted, but only if exceptionally well justified. Allowable expenses include the cost of instruments (preferably expended in the first 2 years), installation and/or necessary renovation expenses in the first year (installation/renovation expenses not to exceed 10% of the total first-year request), and maintenance/service contracts.

Installation/renovation expenses can be requested in the first year only. Equipment should be purchased within the first 2 years. In addition, applicants may request salary support and fringe benefits for the facility director, data analysts, and technical staff; travel to scientific/technical meetings or collaborating institutions is also an allowable expense for these individuals. *All of these costs and expenses must be prorated for direct use in cancer research efforts*. Also

allowable are funds to support the use of the facility by qualified cancer research investigators for relevant projects (research supplies and services, clinical research costs, etc). Institutions must describe the process to be used to disburse funds to support use of the facility by cancer investigators. Finally, some fraction of available funds may be used by the facility director for development of new or improved approaches to technical challenges. State law limits the amount of award funding that may be spent on indirect costs to no more than 5% of the total award amount.

5. ELIGIBILITY

- This competitive renewal RFA is open only to projects that were funded in 2012 pursuant to RFA R-12-CFSA-1 with a contract end date of November 30, 2016.
- The Principal Investigator (PI) must be the director of the facility and must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and must reside in Texas during the time the research that is the subject of the grant is conducted. The PI should also hold a faculty position, preferably at the level of associate or full professor or the equivalent.
- This award must be directed by the PI. Co-PIs are not permitted.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Collaborators should have specific and well-defined roles. 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 non-Texas-based organizations are not eligible to receive CPRIT funds. In no event shall equipment purchased under this award leave the state of Texas.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.

- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds because of scientific misconduct or fraud or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

RESUBMISSION POLICY 6.

Resubmission applications will not be accepted in response to this RFA. Applications submitted previously under any CFSA RFA, but not funded, should be submitted in response to RFA R-16-CFSA-2.

RENEWAL POLICY 7.

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be listed in the renewal summary.

8. RESPONDING TO THIS RFA

8.1. **Application Submission Guidelines**

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be **considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. Furthermore, the Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on August 11, 2015, and must be submitted by 3 PM central time on October 13, 2015. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

8.1.1. Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. A request for a deadline extension based on the need to complete multiple CPRIT or other grants applications will be denied. All requests for extension of the submission deadline must be submitted via email to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records. Please note that deadline extension requests are very rarely approved.

Application Components 8.2.

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in section 5 will be administratively rejected without review.

8.2.1. Abstract and Significance (5,000 characters)

Clearly explain the proposed program, including a summary of the facility to be used, an outline of the goals of the research projects that will be supported, and an overview of institutional infrastructure and commitment. The specific aims of the application must be obvious from the

abstract although they need not be restated verbatim from the Core Facility Plan. Clearly address how the proposed project, if successful, will have a major impact on cancer.

Note: It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. Applicants should not waste this valuable space by stating obvious facts (eg, that cancer is a significant problem, that better diagnostic and therapeutic approaches are needed urgently, or that the type of cancer of interest to the PI is important, vexing, or deadly).

8.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention, or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding.

Do not include any proprietary information in the Layperson's Summary. The Layperson's Summary will also be used by advocate reviewers (section 9.1) in evaluating the significance and impact of the proposed work.

8.2.3. Goals and Objectives

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

8.2.4. Timeline (1 page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.5. Institutional Support (2 pages)

Each application must be accompanied by a letter of institutional support from the president or provost or equivalent indicating commitment to the program. Furthermore, the letter should indicate support of the facility for activities not related to cancer research. An additional letter should be submitted by the person to whom the facility director reports, ensuring that the facility will be operated in a superior fashion and discussing how this will be ascertained.

8.2.6. Renewal Summary (2 pages)

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Please provide a brief summary of the progress of the project, results obtained to date, problems/issues encountered and actions taken, and include information about any publications, patents, and/or economic impact. Information provided should be based around the stated specific aims and goals as set forth in the original Scope of Work as approved.

8.2.7. Core Facility Plan (5 pages)

Background: Present the rationale and need for the facility, emphasizing the pressing problems in cancer research that will be addressed.

Instrument Details: Provide details of the equipment/instruments, if any, that will be acquired.

Technical Expertise: Describe the qualifications of the facility director and other key personnel that make them suitable to oversee the establishment and operations of the facility.

Administrative Plan: Clearly describe the plan under which the operation, sharing, time allocation, and maintenance of the facility will be administered.

Training Plan: Describe the plan to train users to use the facility and also to evaluate the results obtained.

8.2.8. Vertebrate Animals and/or Human Subjects (1 page)

If vertebrate animals will be used, provide an outline of the appropriate protocols that will be followed. If human subjects or human biological samples will be used, provide a plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

8.2.9. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

8.2.10. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Applicants are advised not to interpret the maximum allowable request under this award as a suggestion that they should expand their anticipated budget to this level. Reasonable budgets clearly work in favor of the applicant.

However, if there is a highly specific and defensible need to request more than the maximum amount in any year(s) of the proposed budget, include a special and clearly labeled section in the budget justification that explains the request. Poorly justified requests of this type will likely have a negative impact on the overall evaluation of the application.

In preparing the requested budget, applicants should be aware of the following:

- Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. So-called grants management and facilities fees (eg, sponsored programs fees; grants and contracts fees; electricity, gas, and water; custodial fees; maintenance fees) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.
- The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2016 is \$200,000; CPRIT FY 2016 is from September 1, 2015, through August 31, 2016. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income

that an individual may be permitted to earn outside of his or her duties to the applicant organization.

8.2.11. User Group (8 pages)

Provide concise descriptions of the research projects of major users of the facility. Provide a tabular summary of all users of the requested facility. List the names of all researchers, their academic appointment and affiliation, funded project title(s)/number(s) (wherever applicable), a brief description of the project(s), and approximate percentage use of the facility for direct use in cancer research efforts.

8.2.12. Biographical Sketches (2 pages each)

The PI should provide a biographical sketch that describes his/her education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI (as required by the online application receipt system). Up to 5 additional biographical sketches for key personnel from the user group may be provided. Each biographical sketch must not exceed 2 pages.

8.2.13. Current and Pending Support

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a 2-line summary of the goal of the project, and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI must be provided.

8.2.14. Institutional/Collaborator Support and/or Other Certification (4 pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 4 pages may be provided.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively rejected without review.

9. **APPLICATION REVIEW**

Review Process Overview 9.1.

All eligible applications will be evaluated using a 2-stage peer review process: (1) Peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council and CPRIT Program Integration Committee (PIC). In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers, using the criteria listed below. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council and CPRIT PIC based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by the Scientific Review Council will be forwarded to the CPRIT PIC for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

9.2. **Confidentiality of Review**

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Peer Review Panel members and Scientific Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. **By submitting** a grant application, the applicant agrees and understands that the only basis for

reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee Member, a PIC Member, a Scientific Review Panel member, or a Scientific Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when RFAs are announced and CARS opens. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

9.3. Review Criteria

Peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.

9.3.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the request for the instrument/equipment. Primary criteria include the following:

Justification of Need/Value: Is the need for the facility justified? Is it necessary and appropriate for the research projects? Will the state-of-the-art facility directly support and impact cancer research programs at the institution and in the region? How will the availability of the facility offer incipient research projects by investigators at various career stages the opportunity to develop? Will the facility make the user group more competitive for external funding?

Quality and Significance of research projects supported: Does the facility support a significant number of different, independently funded users? Are the projects at the forefront of cancer research? Are the projects of significance in reducing cancer incidence, morbidity, or mortality?

Technical Expertise: Is there sufficient technical expertise for optimal use of the facility? How well qualified is the user group to take optimal advantage of the facility and evaluate the research results for the proposed projects? How will the facility be maintained? Is there a satisfactory training plan for new users?

Administration: Is there assurance that the facility will be managed and operated in a superior fashion? To whom does the facility director report? Is that person committed to appropriate oversight (a letter of commitment should be submitted)? Is there an adequate plan for the management of the facility, including an appropriate system for charging for services and subsidy of user fees for specific cancer-related projects and individuals (especially early career—stage investigators)? How will facility time be allocated among the projects? Have biosafety issues been addressed? Are there criteria and is there a mechanism for prioritization of user requests? Are there appropriate advisory committees?

Institutional Commitment: Is there clear institutional commitment for support of the facility for cancer research and, if applicable, for noncancer research efforts as well? Has the host institution provided an appropriate site for the facility?

9.3.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed project.

Secondary criteria include the following:

Research Environment: Does the team have the needed expertise and resources to accomplish all aspects of the project? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support for the project?

Vertebrate Animals and/or Human Subjects: If vertebrate animals and/or human subjects are included in the proposed research, certification of approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

Budget: Is the budget appropriate for the proposed work?

Duration: Is the stated duration appropriate for the proposed work?

10. KEY DATES

RFA

RFA release July 6, 2015

Application

Online application opens August 11, 2015, 7 AM central time

Application due October 13, 2015, 3 PM central time

Application review November 2015 to March 2016

Award

Award notification May 2016

Anticipated start date December 2016

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements regarding demonstration of available funding.

13. CONTACT INFORMATION

13.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific aspects of applications.

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time

Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Senior Manager for Research.

Tel: 512-305-8491

Email: Help@CPRITGrants.org

