CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-12-MIRA-1

Multi-Investigator Research Awards

FY 2012

Fiscal Year Award Period
September 1, 2011 — August 31, 2012

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RFA VERSION HISTORY

Rev 8/1/11   RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT); CPRIT may issue $3 billion in general obligation bonds over 10 years to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to:

- Create and expedite innovative work 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.

2. EXECUTIVE SUMMARY

CPRIT will foster cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research. This Request for Applications (RFA) solicits applications for integrated programs of collaborative and cross-disciplinary research among multiple investigators and will focus on critical research areas that will contribute meaningfully to advancing knowledge of the causes, prevention, and/or treatment of cancer. CPRIT encourages applicants who seek to apply or develop state-of-the-art technologies, tools, and/or resources for cancer research, including those projects with potential commercialization opportunities. 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 treatment and cure. To fulfill this vision, applications may address any research topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or cure.

3. MECHANISM OF SUPPORT

The Multi-Investigator Research Awards are intended to support the creation of integrated programs of collaborative and cross-disciplinary research among multiple investigators. The equivalent of program projects, centers, NCI SPOREs, shared instrumentation, core laboratories, clinical trials, or other types of collaborative interaction is appropriate. Teams will focus on critical areas of cancer research, especially those that have been inadequately addressed by research up to this point or for which there may be an absence of an established paradigm or technical framework. Laboratory research, translational studies, and clinical and epidemiological investigations may be supported. Awards are expected to promote a cooperative environment that fosters intensive interaction among members in all aspects of the research program. This approach is expected to transform the research process through the integration of basic and/or clinical disciplines, leading to the aggressive translation of scientific discoveries (including the development of databases and tissue banks) into tools and applications that have the potential to significantly impact cancer incidence, detection, treatment, and/or mortality.

While all investigators need not be trained specifically in cancer research, this award is intended to initiate sustainable, collaborative programs of cancer research that cannot be effectively addressed by an individual researcher or a group of researchers within the same discipline. It is aimed at research programs that, by their complexity and interdisciplinary nature, require a cross-disciplinary team approach to achieve significant progress and sustainability, thereby creating a culture for teaching and research that transcends traditional disciplinary boundaries. Clinical research or a clinical trial (Phase I, I/II, or II) may be included as part of the proposed program.

Investigators are expected to work together to develop the research plan, determine the management structure, and prepare the application. It should be clear that all investigators have a substantial level of intellectual input into the proposed program. Collectively, the members of the teams should represent the appropriate diversity of expertise necessary for addressing the research question. Effort is expected to be appropriately balanced among the investigators and their respective teams.

Applicants must present a clear plan for how they would manage and facilitate meaningful collaboration among the separate research teams to enable successful completion of the

proposed research. Participating institutions must be willing to resolve potential intellectual and material property issues/conflicts and remove institutional barriers to achieving high levels of cooperation.

NOTE TO APPLICANTS:

As a relatively new source of funding for cancer research in Texas, CPRIT offers an attractive opportunity for investigators to test new ideas, explore new areas, and/or implement new approaches. These types of applicant responses are desired and encouraged. However, CPRIT staff and external scientific review committees have noted a significant amount of overlap of investigators, i.e., some investigators proposing to lead or participate in several new activities, thereby making it difficult to discern where the investigators' interests truly lie. In addition, some investigators have submitted very ambitious applications requesting large sums of money but with minimal evidence of commitment to the project in terms of percentage effort. This RFA attempts to curb these practices while still avoiding excessively rigid rules that might stifle innovation; therefore, applications with deviations from guidelines stated in the RFA will be examined closely. Evidence of lack of commitment or excessive fragmentation will be a significant negative factor in funding decisions.

4. RESEARCH OBJECTIVES

Because Multi-Investigator Research Awards, by definition, support collaborative research projects, this award mechanism will accommodate applications that encompass a wide variety of activities and administrative structures. Applicants may propose collaborative programs that are modest in size or those that are larger and more complex. *CPRIT encourages cancer investigators from Texas to bring their best ideas forward for consideration. Creative, collaborative projects that address critical questions should leverage cancer research taking place in Texas into a leadership position from both national and international perspectives. Federal programs should not be duplicated; rather, when possible, their impact in the State of Texas should be enhanced.*

5. CHARACTERISTICS OF MULTI-INVESTIGATOR RESEARCH AWARDS

5.1. Synergy

Successful Multi-Investigator Research Award recipient programs are characterized by an exceptionally synergistic theme. Applications in response to this RFA must bring together a strong group of research projects and necessary core resources that contribute to a common goal in cancer research as a single, coherent entity. Synergy between projects and cores to support the overall objective of the proposed program and the multidisciplinary focus of each project and core are essential aspects of the award mechanism.

It is envisioned that these research programs, once established, will interact extensively with each other and, if possible, with newly formed or established companies interested in bringing specific, Texas-based cancer discoveries to the market for the benefit of patients with cancer everywhere. To the extent possible, plans for such interactions should be developed and described. Applicants should consider requesting funds during the first year for videoconferencing equipment to enable multipoint interactions with other programs and with the CPRIT Scientific Review Office.

5.2. Leadership

5.2.1. Principal Investigator (PI)

The overall research program will be directed and overseen by a PI. The PI is responsible for developing and managing an integrated and collaborative research environment that permits uninterrupted progress of the research projects regardless of distinct geographic locations of collaborators within the State. The PI must direct the required administrative core (see Section 5.4).

5.2.2. Co-PI

Each research project and core resource within the overall research program must be directed by a single individual designated as a Co-PI on the application for the overall research program. The Co-PI will be responsible for the research activities of his or her research project(s) and/or core resource(s) within the framework and goals of the overall research program. The PI may also direct a research project and/or core resource.

5.3. Research Projects

Research projects (also referred to as "projects" in this RFA) will challenge existing paradigms; develop or employ novel concepts, approaches, methodologies, tools, or technologies for the proposed cancer research area; or address important under- or unexplored areas. CPRIT seeks to support original and innovative projects. The thrust of the Multi-Investigator Research Awards mechanism is to support research projects that lead to truly substantial advances in the field rather than add modest increments of insight. Projects that modestly extend current lines of research will not be considered for this award. Each project must be poised individually to make significant contributions to the field of cancer research as well as be complementary to the overall research program. Application of a single approach to multiple forms of cancer does not justify a request for multiple research projects.

The guidelines for research projects are as follows:

- Minimum: Three projects
- Maximum: Five projects
- Each research project must be directed by the PI or by a Co-PI. There is no restriction on the number of projects that the PI or a Co-PI can direct within one Multi-Investigator Research Award application.

5.4. Core Resources

Supporting core resources (also referred to as "cores" in this RFA) constitute integral components of multi-investigator research programs by providing the expertise and/or infrastructure essential to the completion of the individual research projects. Examples of core resources include, but are not limited to, administrative core, tissue/specimen core, sequencing/bioinformatics core, histopathology core, and imaging core. All applications submitted in response to this RFA must include an administrative core that comprehensively coordinates all activities proposed within the objectives of the projects and cores.

The guidelines for core resources are as follows:

- Minimum: Administrative core
- Maximum: Three technical cores
- A maximum of four cores is permitted, i.e., the administrative core and three technical cores.

- Each core must be directed by the PI or by a Co-PI. There is no restriction on the number of cores that the PI or a Co-PI can direct within one Multi-Investigator Research Award application. The administrative core <u>must</u> be directed by the PI.

- Cores should include clear descriptions of the projects they are designed to support.

- Projects and cores are subject to different review criteria (see Sections 11.5 and 11.6). Research projects must **not** be submitted as cores in an attempt to circumvent the limitation on the number of research projects that may be submitted as part of a single Multi-Investigator Research Award application.

5.5. Selection of Research Projects and Core Resources

The PI is expected not only to coordinate and develop the overall research program but also to *limit the number of projects and cores* to only those that are considered highly meritorious and significant within the context of the entire application. The collaborative impact, merit, and feasibility of all the projects—not the cores—will determine whether an application for a Multi-Investigator Research Award receives support. Investigators are strongly discouraged from including weaker projects in an effort to obtain a higher level of funding. Rather, inclusion of fewer, highly focused projects is strongly recommended.

5.6. Commitment of Time and Effort

Investigators are expected to commit *significant percentage effort* to research projects and cores. As a strong guideline, the PI should commit 15-percent effort to the overall research program; this includes effort on the required administrative core that must be directed by the PI. A project/core lead, i.e., the PI or a Co-PI, should commit 10-percent effort for each project and/or core that he or she directs.

As examples:

- The PI of a multi-investigator research program who is leading only the administrative core—not any project or technical core on the application—should commit 15-percent effort.

- The PI of a multi-investigator research program who is also leading one project or one technical core on the application—in addition to the required administrative core—should commit 25-percent effort.

- A Co-PI who is leading a single project or a single core should commit 10-percent effort.

- A Co-PI who is leading a project and a core should commit 20-percent effort.

Note: CPRIT requires that the percentage effort of the PI and/or Co-PI(s) remain the same in every year of support requested unless there is a corresponding change in the budget and level of activity of the project/core directed by the PI or the Co-PI(s) in question.

CPRIT recognizes that multi-investigator programs will vary significantly in size and scope; thus, a single guideline for commitment of time and effort is not appropriate for all applications. Applications should exhibit a reasonable correlation between time commitment and funds requested unless there are special circumstances, which must be explained. In addition, it should be clear from the other support information provided that the investigator will be able to achieve the required percentage effort and what activities may have to be contracted or curtailed to achieve the required percentage effort for the application submitted.

5.7. Participation on More Than One Application

CPRIT is concerned that many investigators appear frequently as part of several different research programs, which makes it difficult to discern the investigators' commitment to a given project. CPRIT believes that this leads to weaker, less competitive applications. Therefore, CPRIT urges investigators to be named on only one Multi-Investigator Research Award application in a given funding cycle, regardless of their role. However, CPRIT recognizes that specific individuals directing and/or participating in core resources (e.g., biostatistics, bioinformatics, or histopathology cores) may be involved in multiple research studies. A common set of tools may be applied in more than one situation, leading to economies of scale (but **not** duplications of budgets). Thus, exceptions to investigators being listed on only one application may be made if prior permission is requested and granted. Such permission must be sought as part of the preapplication or as part of a letter of intent, where applicable (see Sections 11.2, 12.3, and 13.3). Compelling justification of the need for such exceptions and assurance of commitment (usually in the form of percentage effort) must be provided. Reductions in percentage effort will usually not be approved after an application is funded unless there have been major changes in scope and, therefore, in budget. All requests for exceptions must be received no later than the deadline for submitting the preapplication or the letter of intent. Late requests for exceptions are inappropriate for such a complex award mechanism and as such will not be entertained.

6. FUNDING INFORMATION

This funding mechanism is intended to accommodate a wide variety of applications and organizational structures. The maximum period of performance is 5 years; renewal applications will be accepted. No limit has been set on the maximum amount that may be requested if the amount is well justified. Funds may be used for salary and fringe benefits, research supplies, equipment, clinical costs, and travel to scientific/technical meetings or collaborating institutions. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism.

A major criterion for successful applications will be the level of expertise of the collaborative team that has been assembled. CPRIT encourages the creation of teams composed of researchers from Texas who have stellar reputations in their given areas of expertise (Texas "dream teams"). If necessary, applicants must eschew institutional and regional considerations to assemble the best qualified of the State's investigators on a given subject into a superb collaborative team. Competing applications in a single area may fragment and dilute the best talent available. While CPRIT recognizes the value of competition, assembly of researchers with the best expertise for large-scale programs is encouraged to facilitate the highest level of cancer research throughout the State.

7. RESPONDING TO THIS RFA

7.1. New Applications

All applicants wishing to submit a new application must submit a preapplication in response to this RFA (see Section 12). Preapplications will be reviewed and evaluated by CPRIT (see Section 11.2). Only applicants whose preapplications have been approved by CPRIT may submit an application.

7.2. Resubmissions

A preapplication is not required for resubmission of an application; however, applicants wishing to resubmit a previously not funded application are required to submit a letter of intent (see Section 13).

8. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted once. More than one resubmission is not permitted. This policy is in effect for all applications submitted to date. Applicants preparing a resubmission must outline the approach to the resubmission as stated in Sections 14.7, 15.4, 16.3, and 17.1. *All resubmitted applications must conform to the structure and guidelines outlined in this RFA.*

9. KEY DATES

RFA

RFA release	August 1, 2011

Preapplication (all new submissions)

Online preapplication opens	August 4, 2011, 7 a.m. Central Time
Preapplications due	September 7, 2011, 3 p.m. Central Time
Preapplication review	Continuous
Preapplication notification	No later than September 13, 2011

Letter of Intent (all resubmissions)

HelpDesk opens	August 4, 2011, 7 a.m. Central Time
Letters of intent due	September 7, 2011, 3 p.m. Central Time

Application

Online application opens	September 29, 2011, 7 a.m. Central Time
Applications due	November 22, 2011, 3 p.m. Central Time
Application review	February/March 2012

Award

Award notification	March 2012
Anticipated start date	May 2012

10. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. Companies may participate as collaborators in the programs described in this RFA, but the PI must not be a company employee.

- The PI and Co-PIs must have a doctoral degree, including M.D., Ph.D., D.D.S., D.M.D., Dr.P.H., D.O., D.V.M., or equivalent. The PI must reside in Texas during the time the research that is the subject of the grant is conducted.

- Collaborations are permitted and encouraged, and collaborators, including Co-PIs, may or may not 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 non–Texas-based organizations are not eligible to receive CPRIT funds.

- An individual should be listed on only one application submitted under this RFA during this funding cycle, regardless of his or her role (note exceptions stated in Section 5.7).

- A PI may resubmit an application that was previously not funded (see Section 8).

- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas State 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 familiarize themselves with these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in Sections 24 and 25. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

11. APPLICATION REVIEW

11.1. Outline

All eligible applications will be reviewed using a three-stage process: (1) Preapplication review, (2) peer review, and (3) programmatic review.

11.2. Preapplication Review

The purpose of the preapplication is to permit CPRIT to discourage applications that will not be competitive, align its peer review committees with the applications to be received, offer suggestions about optimal responses to the RFA, and/or encourage and suggest collaborations to assemble the best qualified researchers from Texas for such large-scale projects (see Sections 3, 4, and 6). Preapplications will be evaluated by the CPRIT Scientific Review Council, and applicants will be invited to submit a complete application if the proposed program meets the guidelines outlined in Sections 3 and 4. Preapplications may be submitted from August 4 through September 7, 2011. Applicants are urged to submit their preapplications as soon as

possible; CPRIT will respond to preapplications as quickly as possible, without waiting for the September 13 preapplication notification date. Deviations from guidance regarding commitment of time and effort and/or participation in more than one application must be noted and defended in the preapplication. The same issues should be addressed in letters of intent for those investigators submitting revised applications.

Following preapplication review, all applications will be evaluated by an independent scientific merit review committee using the criteria listed in sections 11.5 and 11.6. Applications judged to be most meritorious by review committees will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the merit review committees and programmatic priorities.

11.3. Confidentiality of Review

Each stage of application review is conducted completely confidentially, and all council and committee members are required to sign nondisclosure statements regarding the contents of the applications. All council and committee members will be non-Texas residents and operate under strict conflict of interest prohibitions. Under no circumstances should institutional personnel and/or individual applicants initiate contact with any member involved in the peer review process (with the exception of members of the CPRIT Scientific Review Office), the CPRIT executive director, or any member of the CPRIT Oversight Committee regarding the status or substance of the application. Violations of this prohibition will result in the administrative withdrawal of the application. Any communication regarding the application should be directed to the CPRIT HelpDesk and/or CPRIT's Scientific Review Office.

11.4. Application Review

The overall Multi-Investigator Research Award application will receive a composite score that reflects the review committee's evaluation of the entire proposed research program's potential to make a significant contribution to cancer research. This composite score is based on:

- The scientific impact and merit of the individual research projects;
- The necessity and sufficiency of the core resources in supporting the research projects;
- The synergy between the research projects and also between the research projects and core resources; and
- The leadership and the organizational structure of the research program.

11.5. Review of Research Projects

Peer review of individual research projects 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 is an overall assessment of the project. **The global score will not be an average of the scores of individual criteria; rather, it reflects the reviewers' overall impression of the research project. Evaluation of the scientific merit of each research project is within the sole discretion of the peer reviewers.**

11.5.1. Primary Review Criteria

Primary criteria will evaluate the scientific merit of the proposed work contained in the research project. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study.

Significance and Impact: What is the innovative potential of the project? Does the project propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important under- or unexplored areas? If successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Investigators and biomedical personnel must want and need to know the results of CPRIT-funded research because such knowledge will change the ways in which they conduct their own research or approach and care for their patients. Projects that modestly extend current lines of research will not be considered for this award.

Research Plan: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined hypothesis or goal that is supported by sufficient preliminary data and/or scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed? Does the proposed project provide strong synergistic activities as part of a multidisciplinary collaboration? See Section 5.1.

Project Leader: Does the project leader demonstrate the required creativity, expertise, experience, and accomplishments to achieve the goals of the research project? Has the project leader devoted a sufficient amount of his or her time (percentage effort) to this project?

Synergy and Collaborative Teams: Does the proposed project provide strong synergistic activities as part of a multidisciplinary collaboration? That is, is the value of this program significantly greater than the sum of its parts? If core facilities are described, are they necessary and sufficient to support the project in achieving the overall goals proposed? Has the project

assembled the best qualified collaborative and multidisciplinary teams to achieve the proposed goals? Are the levels of effort of the key personnel appropriate, as outlined in Section 5.6?

Relevance: Does the proposed research have a high degree of relevance to cancer research? This will be an important criterion for evaluation of projects for CPRIT support.

11.5.2.   Secondary Review Criteria

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

Research Environment: Does the research team have the needed expertise, facilities, and resources to accomplish all aspects of the proposed research project? Is there evidence of institutional support for the research team and the project?

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

Budget: Is the budget requested appropriate for the proposed work?

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

11.6.   Review of Core Resources

Peer review of individual core resources will be based on two scored criteria, listed below. Review committees will evaluate and score each criterion and subsequently assign a global score that is an overall assessment of the core. The appropriateness of the budget requested for each core will also contribute to the overall impression of the core resource. **The global score will not be an average of the scores of individual criteria; rather, it reflects the reviewers' overall impression of the core resource. Evaluation of the scientific merit of each core resource is within the sole discretion of the peer reviewers.**

11.6.1.   Core Resources

Sufficiency and Capability: Is the proposed core resource necessary? Does it have the needed facilities and sufficient resources to support the proposed research project(s) in accomplishing the proposed goals? Does it provide strong synergistic activities as part of a multidisciplinary collaboration?

Core Leader: Does the core leader demonstrate the required expertise and experience to direct the core resource in supporting the research project(s)? Has the core leader devoted a sufficient amount of his or her time (percentage effort) to this resource?

11.6.2. Administrative Core

Administrative Plan: Is the proposed organizational and management structure capable of comprehensively overseeing and coordinating all aspects and activities of the proposed research program?

Core Leader: Does the core leader demonstrate the required expertise and experience to direct the core resource in supporting the research project(s)? Has the core leader devoted a sufficient amount of his or her time (percentage effort) to this resource?

12. SUBMISSION GUIDELINES: PREAPPLICATION

12.1. Online Application Receipt System

A preapplication is required of those investigators submitting a new application. Applicants must submit a preapplication via the CPRIT Application Receipt System (https://CPRITGrants.org). Preapplications will be accepted beginning at 7 a.m. Central Time on August 4, 2011. Only preapplications submitted at this portal will be considered eligible for evaluation. The PI must create a user account in the system to start and submit a preapplication. Submission of a preapplication is considered an acceptance of the terms and conditions of the RFA.

12.2. Preapplication Submission Deadline

Preapplications must be submitted by 3 p.m. Central Time on September 7, 2011.

12.3. Preapplication Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the preapplication. Submissions that are missing one or more of these components or do not meet the eligibility requirements listed in Section 10 will be administratively withdrawn without review. Applicants are required to submit the following information:

- Application title.
- Period of performance.
- Name, title, and institutional affiliation of the PI.
- Name, title, and institutional affiliation of each Co-PI.
- Biographical sketches of the PI and Co-PIs.
- Listing of research projects and core resources.
- Lead investigator (i.e., the PI/Co-PI) of each project and core; the PI <u>must</u> lead the administrative core.

- Specific aims of the overall research program as well as specific aims of each project and core (2 pages).

- Major goals of the proposed work (2 pages).

- Tabular summary of approximate budget to be requested for each project and core for each year for the entire period of performance of the overall research program (1 page).

- Tabular summary of percentage effort to be dedicated to this program for all key personnel (1 page); deviations from guidelines must be explained and justified (see Section 5.7).

13. SUBMISSION GUIDELINES: LETTER OF INTENT

13.1. HelpDesk

A letter of intent is required of those investigators preparing a resubmission. Letters of intent will be accepted beginning August 4, 2011 and must be submitted via e-mail to the CPRIT Research HelpDesk (ResearchHelp@CPRITGrants.org; see Section 26.1).

13.2. Letter of Intent Submission Deadline

Letters of intent must be submitted by 3 p.m. Central Time on September 7, 2011.

13.3. Letter of Intent Components

Letters of intent must be submitted in Portable Document Format (PDF) and must not exceed 1 page. Applicants are required to include the following information:

- Application title.

- Prior application ID.

- Period of performance.

- Total award amount.

- Name, title, and institutional affiliation of the PI.

- Number of research projects and core resources.

- If applicable, justification and request for permission for deviations from guidelines for commitment of time and effort and/or participation in more than one application (see Section 5.7).

14. SUBMISSION GUIDELINES: APPLICATION

14.1. Online Application Receipt System

Applications will be accepted beginning at 7 a.m. Central Time on September 29, 2011. **Only applications submitted at this portal will be considered eligible for evaluation. Further, only applicants with preapplications approved by the CPRIT Scientific Review Office or those preparing resubmissions are eligible to submit an application.** The PI must create a user account in the system to start and submit an application. Co-PIs must also create user accounts to participate on the application. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

14.2. Application Submission Deadline

Applications must be submitted by 3 p.m. Central Time on November 22, 2011.

14.3. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Submissions that are missing one or more of these components or do not meet the eligibility requirements listed in Section 10 will be administratively withdrawn without review.

14.4. Abstract and Significance (5,000 characters)

Clearly explain the question or problem to be addressed by the proposed research program and the approach to its answer or solution. Address how the proposed research, if successful, will have a major impact on the field of cancer research or on the care of patients with cancer. Summarize how the proposed research creates new paradigms or challenges existing ones. State the synergistic value that the individual research projects and core resources present to the goals of the overall application.

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

Provide a layperson's summary of the proposed program. Describe in very simple, nontechnical terms the overall goals of the proposed program, the type(s) of cancer addressed, the potential significance of the results, and the impact of the program on advancing the field of cancer research. 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.

14.6.   Overall Goals and Timeline (1 page)

Outline the specific aims of the overall research program. Indicate an approximate timeline for accomplishment of these aims. 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.

14.7.   Resubmission Summary (1 page)

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original research program review, applicants are advised to address all concerns noted. Changes to individual projects and cores should be outlined in the description of the project/core, as stated in Sections 15.4, 16.3, and 17.1.

14.8.   Overview of Research Program (5 pages)

Background: Present the rationale behind the proposed research program, emphasizing the pressing problem in cancer research that will be addressed.

Research Strategy: Describe the objectives of the research program, and briefly summarize each component project and core resource.

Synergy: Describe how individual component projects provide synergistic value to the research program.

14.9.   Publications/References

Provide a concise and relevant list of publications/references cited for the overall research program.

14.10.   Budget and Justification

Provide an overall budget and a compelling justification of the budget for the entire proposed period of support for all the projects and core resources, including indirect costs. See Section 19 for additional details and for guidance regarding indirect costs.

14.11.   Components: Research Projects and Core Resources

Each project and core must be submitted individually (Sections 15–23), as directed in the CPRIT Application Receipt System. Projects and cores should be labeled numerically (Project 1 to Project 5, Core 1 to Core 3). The administrative core should be labeled as such and should not be numerically labeled.

15. SUBMISSION GUIDELINES: RESEARCH PROJECTS

The following items (Sections 15.1–15.6) and items listed in Sections 18–21 are required for each of the proposed research projects. Sections 22 is optional. Section 23 should be completed if applicable.

15.1. Abstract (2,500 characters)

Clearly explain the question or problem to be addressed and the approach to its answer or solution. Address how the proposed project, if successful, will have a major impact on the field of cancer research or on the care of patients with cancer. Summarize how the proposed research creates new paradigms or challenges existing ones. State the synergistic value that the individual research project presents to the goals of the overall application.

15.2. Layperson's Summary (1 page)

Provide a layperson's summary of the proposed work. Describe in very 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. 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.

15.3. Overall Goals and Timeline (1 page)

Outline the specific aims of the research project. 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.

15.4. Resubmission Summary (1 page)

Applicants preparing a resubmission of a research project must describe the approach to the resubmission. If a summary statement was prepared for the original project review, applicants are advised to address all concerns noted.

Note: A research project previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Submissions that

received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh research plan or modify the original research plan and mark the changes. However, all resubmissions should be carefully reconstructed; a simple revision of the prior submission with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

15.5. Research Plan (10 pages)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data that support the proposed hypothesis are encouraged but not required.

Human Studies: If human subjects or human biological samples will be used, provide a plan for IRB approval or exemption and for recruitment of participants or acquisition of samples that will meet the time constraints of this award mechanism.

Synergy: Describe how the project provides synergistic value to the entire research program.

15.6. Synergy Illustration (1 page)

Provide a diagrammatic representation of synergistic interactions between this project and other research projects and/or core resources of the proposed research program.

16. SUBMISSION GUIDELINES: CORE RESOURCES

The following items (Sections 16.1–16.5) and items listed in Sections 18–21 are required for each of the proposed core resources. Sections 22 is optional. Section 23 should be completed if applicable.

16.1. Abstract (2,500 characters)

Summarize the proposed core resource. Clearly state the project(s) that the core will support and the synergistic value it provides to the goals of the research project(s).

16.2. Overall Goals and Timeline (1 page)

Outline the specific aims of the core resource. Indicate the projects that will be supported. 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.

16.3. Resubmission Summary (1 page)

Applicants preparing a resubmission of a core resource must describe the approach to the resubmission. If a summary statement was prepared for the original core review, applicants are advised to address all concerns noted.

Note: A core resource previously submitted to CPRIT but not funded may be resubmitted <u>once</u> after careful consideration of the reasons for lack of prior success. Submissions that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh resource plan or modify the original resource plan and mark the changes. However, all resubmissions should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

16.4. Resource Plan (5 pages)

Background: Present the rationale behind the proposed core resource.

Support Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data demonstrating the capabilities of the core are encouraged but not required.

Synergy: Describe how the core resource provides synergistic value to the research program.

16.5. Synergy Illustration (1 page)

Provide a diagrammatic representation of synergistic interactions between this core and other research projects and/or core resources of the proposed research program.

17. SUBMISSION GUIDELINES: ADMINSTRATIVE CORE

In addition to the items listed in Sections 17.1–17.3, items listed in Sections 19–21 are required for the administrative core. Section 18 is not required. Section 22 is optional. Section 23 should be completed if applicable.

17.1. Resubmission Summary (1 page)

Applicants preparing a resubmission of the administrative core must describe the approach to the resubmission. If a summary statement was prepared for the original core review, applicants are advised to address all concerns noted.

Note: An administrative core previously submitted to CPRIT but not funded may be resubmitted <u>once</u> after careful consideration of the reasons for lack of prior success. Submissions that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh administrative plan or modify the original administrative plan and mark the changes. However, all resubmissions should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

17.2. Administrative Plan (5 pages)

Describe the organizational and management structure that will be established to efficiently, effectively, and comprehensively manage all aspects of the research program. State how the leaders of individual projects and cores, i.e., the PI and the Co-PIs, will communicate and discuss results, report progress, and resolve potential problems throughout the duration of the research program.

17.3. Synergy Illustration (1 page)

Provide a diagrammatic representation of interactions between the administrative core and all research projects and core resources of the proposed research program.

18. PUBLICATIONS/REFERENCES

For each research project and core resource, provide a concise and relevant list of publications/references cited. This list is not required for the administrative core.

19. BUDGET AND JUSTIFICATION

For <u>each</u> research project and core resource (including the administrative core), provide a budget and 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, other expenses, and indirect costs. Applicants are advised NOT to interpret the absence of a maximum allowable budget as an indication that the budget can be expanded to any level. Reasonable

budgets clearly work in favor of the applicant. Poorly justified requests of this type will likely have a negative impact on the overall evaluation of the project/core and, by extension, on 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 State law limits the amount of grant funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent 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 (e.g., sponsored programs fee; 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 2012 is $200,000; CPRIT FY 2012 is from September 1, 2011 through August 31, 2012. Salary does not include fringe benefits and/or facilities and administrative (F&A) 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.

20. BIOGRAPHICAL SKETCHES

A biographical sketch is required for the individual leading each project/core (i.e., the PI/Co-PI). Up to two additional biographical sketches for other key personnel on the project/core may be provided. The biographical sketch should describe the individual's education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 2 pages.

21. 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 for each project/core. For each award, provide the title, a two-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 project/core lead must be provided.

22. INSTITUTIONAL/COLLABORATOR SUPPORT AND/OR OTHER CERTIFICATION

For each project and core, applicants may provide relevant letters of institutional support, collaborator support, and/or other certification documentation. A maximum of 4 pages may be provided for each research project; a maximum of 2 pages may be provided for each core resource (including the administrative core).

23. COMMERCIALIZATION PLAN

If the proposed research will lead to the development of a product that requires regulatory filing, applicants must complete a commercialization plan. Applicants have the option of submitting a commercialization plan for the entire application and/or for individual projects/cores.

- If two or fewer projects/cores have the potential for commercialization, then a commercialization plan for only those projects/cores will suffice.
- If three or more projects/cores have the potential for commercialization, then the applicants should consider submitting a commercialization plan for the projects and cores in question and also a commercialization plan for the entire application. This decision is at the discretion of the PI and Co-PI(s).

Applications that are missing one or more of these components, exceed the specified page, word, or budget limits, or do not meet the eligibility requirements listed in Section 10 will be administratively rejected without review.

24. AWARD ADMINISTRATION

Texas law requires that CPRIT research awards be made by contract between the applicant and CPRIT. Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, and terms

relating to intellectual property rights. These contract provisions are specified in CPRIT's administrative rules, which are available at www.cprit.state.tx.us.

All CPRIT awards will be made to institutions, not to individuals. Applicants who change their institutional affiliation during the time period of the award must submit a written request to CPRIT to transfer the award to the new institution.

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 receipt of these reports. Forms and instructions will be made available at www.cprit.state.tx.us.

25. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires the CPRIT award recipient to 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, not when the application is submitted.

26. CONTACT INFORMATION

26.1. HelpDesk

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

Dates of operation (excluding public holidays):

Preapplication:	August 1, 2011 to September 7, 2011
Letter of Intent:	August 1, 2011 to September 7, 2011
Application:	August 1, 2011 to November 22, 2011
Hours of operation:	Monday through Friday, 7 a.m. to 4 p.m. Central Time
Tel:	866-941-7146
E-mail:	ResearchHelp@CPRITGrants.org

26.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Scientific Review Office:

Tel:	512-305-8491
E-mail:	ResearchHelp@CPRITGrants.org
Web site:	www.cprit.state.tx.us