

# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# REQUEST FOR APPLICATIONS RFA R-24.2-MIRA

# **Multi-Investigator Research Awards**

Please also refer to the Instructions for Applicants document, which will be posted on September 14, 2023

**Application Receipt Opening Date:** October 17, 2023 **Application Receipt Closing Date:** January 18, 2024

#### FY2024

Fiscal Year Award Period September 1, 2023-August 31, 2024

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#### RFA VERSION HISTORY

9/14/23 RFA release

10/17/23 Edited language throughout the document to clarify that the Lead PI should be the Contact PI for the application.

Section 1-Brief Description of RFA: Added the following language: "Multi-Principal Investigators (MI) (Required) Each research project and core resource within the overall research program must be directed by a single individual designated as an MI on the application for the overall research program. Each MI 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. Projects and cores located outside of the PI's institution must be supported through a subcontract with the applicant institution."

1/16/24 Revised to extend the submission deadline to 4 PM central time on January 18, 2024

# 1. BRIEF DESCRIPTION OF RFA

- Multi-Investigator Research Awards (MIRAs) support highly integrated programs of
  collaborative and cross-disciplinary research among multiple Texas investigators. MIRAs
  are expected to integrate basic and/or clinical disciplines leading to the aggressive
  translation of scientific discoveries into tools and applications that have the potential to
  make a significant impact on cancer prevention, detection, treatment, and/or survivorship.
- Applicants are encouraged to submit proposals that address the Cancer Prevention Research Institute of Texas' (CPRIT's) Academic Research Program Priorities (section 2.1).
- Applicants may request a maximum of \$4,500,000 total over a maximum period of 4 years (\$1,125,000 annually).
- Funds may be requested for research projects and administrative and technical cores.
- The MIRA RFA requires a Principal Investigator who serves as the contact PI and Multi-Principal Investigators who lead each research project and core resources within the overall research program.
- Contact Principal Investigator (Required): The Contact PI is responsible for the submission of the application, all reporting requirements, and all budgeting decisions.
- Multi-Principal Investigators (MI) (Required) Each research project and core resource within the overall research program must be directed by a single individual designated as an MI on the application for the overall research program. Each MI 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. Projects and cores located outside of the PI's institution must be supported through a subcontract with the applicant institution.
- An individual serving as the Contact Principal Investigator or Multi- Principal
   Investigators may submit only 1 application under this RFA and will not be eligible to
   participate as a Contact PI or an MI on another MIRA application (including subcontracts)
   in response to this RFA except for special circumstances as discussed under section 9.7.
- Note that CPRIT does not allow the use of the term Co-PI.
- Resubmissions of MIRA proposals previously reviewed under this RFA are not available under this RFA.
- Renewals are not available under this RFA.

• Minimum effort for the PI and MIs is required throughout the project period.

# 2. ABOUT CPRIT

The State of Texas has established CPRIT, which may issue up to \$6 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.

# 2.1. Academic Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency with regard to how the Oversight Committee directs the orientation of the agency's funding portfolio.

To accomplish CPRIT's long-term vision, the Oversight Committee has these 2024 priorities:

- Investing in the cancer research capacity of Texas institutions through recruitment of cancer scholars, investment in core facilities, and investment in individual investigator awards in all regions of the state;
- Building the Texas cancer life science ecosystem across Texas by bridging discovery and translational research into early-stage company products with high impact on cancer patient care and creating economic development for the State of Texas; and
- Increasing the capacity for Texas to have a significant impact on cancer prevention and early detection, ultimately decreasing cancer incidence and mortality.

# **Established Principles:**

- Scientific excellence and impact on cancer
- Increasing the life sciences infrastructure in all regions of the state
- Reducing cancer disparities

The program priorities for academic research adopted by the Oversight Committee include funding projects that address or utilize the following:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions and population research addressing cancer disparities.
- Computational oncology and analytic methods
- Childhood and adolescent cancers
- Hepatocellular cancer
- Expanding access to innovative clinical trials, particularly to regions of the state currently with limited access.

#### 3. RATIONALE

This MIRA mechanism is intended to support highly integrated programs of collaborative and cross-disciplinary research among multiple Texas investigators. Applications responding to this RFA that address one of the program priorities for academic research adopted by CPRIT's Oversight Committee are particularly encouraged.

MIRAs 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 into tools and applications that have the potential to make a significant impact on cancer incidence, detection, treatment, and/or survivorship.

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 addressed effectively by an individual researcher or a group of researchers within the same discipline. It is aimed at interactive 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 1, 1/2, or 2) 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, and there should be evidence that the participants have a track record of collaboration. 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. CPRIT encourages the inclusion of early-stage investigators and recognizes the value of the inclusion of new technologies often contributed by these investigators, as well as the mentorship opportunities inherent in collaborative or multiproject research awards.

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 subcontracting issues and remove institutional barriers to achieving high levels of cooperation.

This funding mechanism 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, successful applications must demonstrate that the proposed research builds on a strong track record of existing interactions among the proposed projects, or if new research partnerships are being proposed, the application must provide compelling evidence that the new partnerships will catalyze significant synergies and impact.

# 4. RESEARCH OBJECTIVES

This RFA solicits applications for integrated programs of collaborative and cross-disciplinary research among multiple investigators that will contribute meaningfully to advancing knowledge of the causes, prevention, and/or treatment of cancer. CPRIT encourages applicants who seek to develop or apply state-of-the-art technologies, tools, and/or resources for cancer research, including those with projects having potential commercialization opportunities.

CPRIT expects outcomes of supported activities to benefit subsequent cancer research efforts directly and indirectly, cancer public health policy, or the continuum of cancer care—from

prevention to treatment and survivorship. While applications may address any research topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or quality of life, CPRIT encourages applications that address 1 or more of the priority areas that have been identified by the CPRIT Oversight Committee.

Because MIRAs, by definition, support collaborative research projects, this award mechanism will accommodate applications that encompass a wide variety of activities and administrative structures. 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. Successful applications will demonstrate a clear plan for sustainability of the research after the completion of the award period.

# 5. FUNDING INFORMATION

CPRIT anticipates having sufficient funds to support a limited number of only the most meritorious applications in response to this RFA.

Applicants may request a maximum of \$4,500,000 in total costs for a maximum period of 4 years. Exceptions to the maximum amount may be requested if extremely well justified. Funds may be used for salary and fringe benefits, research supplies, equipment, clinical costs, pilot projects, and travel to scientific/technical meetings or collaborating institutions. Funds may be used for core resources that provide support services necessary to achieve the goals of the MIRA projects. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism. 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.

In an attempt to reduce the administrative difficulties in submitting programmatic and financial reports, MIRAs will be submitted as a single application. The PI will lead the project through the Administrative Core, which will be housed at the applicant institution. Individual projects and cores must be handled through subcontracts if participating institutions are located outside of the applicant institution. The applicant institution will develop the overall program budget with the assistance of individual participating institutions. Therefore, the institution that leads the Administrative Core will be responsible for coordinating subcontracts, submission of progress reports, and all related annual and financial reports. There will not be a requirement for other participating institutions to submit these reports to CPRIT.

# 6. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism; these entities must use the appropriate award mechanism(s) under CPRIT's Product Development Research Program.
- The PI and MIs must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent. Individuals serving as a PI or MI must reside in Texas during the time the research that is the subject of the grant is conducted. (MIRA PI and MI roles are defined in sections 9.2.1 and 9.2.2.)
- An individual serving as a PI may submit only 1 application under this RFA and will not be eligible to participate as a PI or an MI on another MIRA application (including subcontracts) in response to this RFA except for special circumstances as discussed under section 9.7.
- An individual may participate as a MI on only 1 application under this RFA except for special circumstances as discussed under section 9.7.
- A major criterion for successful applications will be the evidence that the assembled team has established collaborations or complementary expertise that will be accelerated by participation in the MIRA. While CPRIT encourages the creation of teams composed of researchers from across Texas who have stellar reputations in their given areas of expertise, successful applications must demonstrate either a strong track record of collaboration or how newly proposed collaborations will contribute to the project as a whole.
- 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 institution may submit only 1 new application under this RFA during this funding cycle. An exception will be made for institutions submitting MIRAs that support research totally directed toward childhood and adolescent cancer; in this case,

# institutions may submit 1 childhood and adolescent cancer application and 1 additional application in another aspect of cancer research.

- 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 <a href="section 13">section 13</a> and <a href="section 14">section 14</a>. All statutory provisions and relevant administrative rules can be found at <a href="section 14">www.cprit.texas.gov</a>.

# 7. RESUBMISSION POLICY

Resubmissions of MIRA proposals previously reviewed under this RFA are not available under this RFA. PIs of previously reviewed, but unfunded, MIRAs are eligible to submit a MIRA award on a different topic.

#### 8. RENEWAL POLICY

Renewals are not available under this RFA. A project that was previously funded under the MIRA and would be a continuation of MIRA program activities is not eligible to be submitted under this RFA.

# 9. CHARACTERISTICS OF MULTI-INVESTIGATOR RESEARCH AWARDS

# 9.1. Synergy

Successful multi-investigator research 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. The overall program must provide greater value than the sum of its individual components.

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 and are major considerations of the review process. Applications are expected to demonstrate an existing track record of interactions among the proposed individual research programs and to discuss how the MIRA will accelerate existing synergies.

It is envisioned that most or all of the proposed research programs already interact with each other and that the MIRA will accelerate these interactions to bring Texas-based cancer discoveries to the market for the benefit of patients with cancer everywhere.

# 9.2. Leadership

# 9.2.1. Contact Principal Investigator (PI)

The overall research program will be directed and overseen by a Contact Principal Investigator (PI). The Contact 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 Contact PI <u>must</u> direct the required Administrative Core (see <u>section 9.4</u> and <u>section 10.2</u>). The Contact PI is responsible for the submission of the application, all reporting requirements, and all budgeting decisions. The PI may also direct a research project and/or core resource.

# 9.2.2. Multi-Principal Investigator (MI)

Each research project and core resource within the overall research program <u>must</u> be directed by a <u>single</u> individual designated as an MI on the application for the overall research program.

Each MI 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. Projects and cores located outside of the PI's institution must be supported through a subcontract with the applicant institution.

# 9.3. 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 underexplored or unexplored areas. CPRIT seeks to support original and innovative projects. The thrust of the MIRA 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: 3 projects

• Maximum: 5 projects

Each research project must be directed by the PI or by a participating MI. The PI and each
MI can direct only 1 project within the MIRA application.

# 9.4. 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, imaging core, and clinical trials core. All applications submitted in response

to this RFA <u>must</u> include an administrative core that comprehensively coordinates all activities proposed within the objectives of the projects and cores and is directed by the PI.

The guidelines for core resources are as follows:

- Minimum: Administrative Core
- Maximum: 3 technical cores
- A maximum of 4 cores is permitted (ie, the Administrative Core and 3 technical cores).
- Each core must be directed by the PI or by a participating MI. Each MI can direct 1 project and/or 1 technical core. The PI can direct 1 project and/or technical core in addition to the Administrative Core. The Administrative Core <u>must</u> be directed by the PI.
- Cores should include clear descriptions of the projects they are designed to support and the services to be provided.
- Core resources may propose new facilities not currently available in Texas or extend existing facilities. Cores that duplicate services already available at the institution will be considered nonresponsive. If support is requested for an existing facility, applicants must provide details on how CPRIT support will enhance its capabilities and improve access for MIRA investigators rather than simply replace ongoing institutional support.
- The program investigators are encouraged to consider the suitability of utilizing Core resources at other institutions within Texas, particularly those supported by CPRIT awards, to avoid establishing new services at new or existing core facilities that may not serve a larger group of investigators. Funds to purchase services at external core facilities within the State of Texas are considered allowable costs within the budget of research projects for this RFA.
- CPRIT strongly supports the development or adaptation of new technologies and resources
  that are made available to non-MIRA investigators at the host institution as well as at other
  institutions in Texas.
- Projects and cores are subject to different review criteria (see <u>section 11.3</u>). 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 MIRA application.

# 9.5. 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 MIRA 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.

# 9.6. Commitment of Time and Effort

Investigators are expected to commit *significant percent effort* to research projects and cores throughout the award funding period. A minimum time commitment of 20% effort is required for the PI. Research project and core resource MIs should commit at least 10% effort for each project and/or core that he or she directs.

**Note:** CPRIT requires that the percent effort of the PI and MIs 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 MI(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 percent effort and what activities may have to be contracted or curtailed to achieve the required percent effort for the application submitted.

# 9.7. Participation on More than 1 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, an investigator may participate as a PI or MI on only 1 MIRA application in a given funding cycle. However, CPRIT recognizes that specific individuals directing and/or participating in core resources (eg, biostatistics, bioinformatics, or pathology cores) may be involved in multiple research studies. Thus, exceptions to such investigators being listed on only 1 application as an MI may be made if compelling justification for such exceptions and assurance of commitment (usually in the form of percent effort) are provided. Reductions in percent level of effort will usually not be approved

after an application is funded unless there have been major changes in scope and, therefore, in budget.

# 10. RESPONDING TO THIS RFA

# 10.1. 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 Application/Authorized Signing Official (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. The MI does not have to create a user account in CARS; the MI will be added to the application by the PI. Please refer to the *Instructions for Applicants (IFA)* document for the instructions on adding MIs to an application. The IFA document will be available at the time of posting of this RFA or shortly thereafter. Applications will be accepted beginning at 7 AM central time on October 17, 2023, and must be submitted by 4 PM central time on January 18, 2024. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

#### 10.1.1. Submission Deadline Extension

The submission deadline may be extended 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 <u>Helpdesk</u> within 24 hours of the submission deadline. 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.

# **10.2.** Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the IFA document for details. Submissions that are

missing 1 or more components or do not meet the eligibility requirements listed in <u>section 6</u> will be administratively rejected without review.

# 10.2.1. Abstract and Significance (15,000 characters)

Clearly explain the question or problem to be addressed by the proposed overall 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. Indicate whether this research will address cancers associated with disparities in incidence or mortality in Texas. 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. Summarize the proposed core resources. Clearly state the project(s) that the core resources will support and the synergistic value the core resources provide to the goals of the research project(s).

**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).

# 10.2.2. Layperson's Summary (10,000 characters)

Provide a layperson's summary of the proposed program. Describe, in 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 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 11.1) in evaluating the significance and impact of the proposed work.

# 10.2.3. Specific Aims and Sub Aims (Maximum of 3 Aims and 3 Subaims per Aim for Each Project and Core)

Provide a list of specific aims and subaims for each year of the project. These aims and subaims will also be used during the submission and evaluation of progress reports and assessment of

project success. Aims and subaims should be listed for the overall project as well as for each project and core separately. Projects and cores should be labeled numerically (AC for the

Administrative Core, Project 1 to Project 5, and Core 1 to Core 3) and be clearly identified. Aims and subaims for cores should indicate the project(s) to be supported.

Aims and subaims for the overall project should be listed under Administrative Core and prepared by the PI.

# 10.2.4. Timeline (Maximum of 1 page per Project and Core)

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. Timelines should be listed for the overall program as well as for each project and core separately. Projects and cores should be labeled numerically (AC for the Administrative Core, Project 1 to Project 5, and Core 1 to Core 3) and be clearly identified. The timeline for the overall project should be listed under Administrative Core and prepared by the PI.

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.

# 10.2.5. Overview of Overall Program (10 pages)

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

**Research Strategy:** Describe the overall goals of the research program and briefly summarize each component project and core resource. Describe the significance, innovation, and impact of the proposed research. Indicate whether this research will address cancers associated with increased incidence and/or mortality in Texas or with population disparities.

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

# 10.2.6. Research Project Abstract (Maximum of 5,000 Characters per Project)

Clearly explain the question or problem to be addressed by the proposed project and the approach to its answer or solution. Provide the specific aims and brief description of experimental approaches. Indicate whether this research will address cancers associated with disparities.

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 project has to the overall research program and other projects and core resources in accomplishing the goals and objectives of the overall program.

# 10.2.7. Research Project Plan (Up to 25 pages for Each Project)

**Specific Aims and Subaims:** List specific aims and subaims for each year of the project. These aims and subaims will also be used during the submission and evaluation of progress reports and assessment of project success.

**Specific Aims:** Please provide a 1-page summary of the aims and subaims of the proposal. The Specific Aims page should identify the problem or gap in our current knowledge. It should present a hypothesis and briefly describe the aims and approaches. Address the proposal's innovation, novel approaches, and significance and impact on cancer research. Please also refer to the template located in *Current Funding Opportunities* for Academic Research Programs in CARS.

**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. The inclusion of preliminary data that support the proposed hypothesis is recommended.

**Synergy:** Describe how the project provides synergistic value to the entire research program. Describe interactions with other components of the MIRA and the potential for enriching the program.

**Biographical Sketches:** A biographical sketch must be provided for each individual leading a project. Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 5 pages. The NIH biosketch format is appropriate.

**Vertebrate Animals and/or Human Subjects:** 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 IRB approval or exemption and recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

**Publications/References:** Provide a concise and relevant list of publications/references cited for the research project.

**Budget and Justification:** While there will be 1 budget for the entire program, an individual budget and budget justification must be included for each project. A 4-year budget table with a justification of budget expenses should be sufficient. This budget should not be as detailed as the overall program budget but rather a high-level budget that allows reviewers to evaluate project expenses.

# 10.2.8. Core Resource Abstract (Maximum of 5,000 characters per Core Resource)

Clearly explain the question or problem to be addressed by the proposed core resource and the approach to its answer or solution. Describe the services to be provided and which projects the core resource will support. Describe new technologies and approaches or resources to be developed to support the needs of the MIRA projects. Address how the core will have a major impact on the field of cancer research or on the care of patients with cancer. State the synergistic value that the core resource has to the overall research program and other projects and core resources in accomplishing the goals and objectives of the overall program.

# 10.2.9. Core Resource Plan (Up to 25 pages for Each Core Resource)

**Background:** Present the rationale and need for the facility, emphasizing the pressing problems in cancer research that will be addressed by the technologies/services provided. Address the projects served and if researchers at other institutions will have access to these services and technologies. Describe how the proposed facility does not duplicate services provided by existing facilities. Address how the proposed facility addresses CPRIT priorities.

**Support Strategy:** Describe the services to be provided, the projects utilizing the services, and new technologies or resources that may be developed or adapted to support the goals of the projects proposed in the MIRA. Describe training and education initiatives that will be provided by the core resource, if relevant. Describe how access to the core will be made available and how the core services will be sustained. 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.

**Biographical Sketches:** A biographical sketch must be provided for each individual leading a core resource. Applicants should provide a biographical sketch that describes their education and

training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 5 pages. The NIH biosketch format is appropriate.

**Vertebrate Animals and/or Human Subjects:** 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 IRB approval or exemption and recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

**Publications/References:** Provide a concise and relevant list of publications/references cited for the core resource.

**Budget and Justification:** While there will be 1 budget for the entire program, an individual budget and budget justification must be included for each core. A 4-year budget table with a justification of budget expenses should be sufficient. This budget should not be as detailed as the overall program budget but rather a high-level budget that allows reviewers to evaluate core expenses.

# 10.2.10. Administrative Core Plan (7 pages)

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

*Pilot Projects:* Up to \$100,000 may be requested annually to support pilot projects that address new hypotheses related to the focus of the MIRA or extend the scope of the existing projects.

If pilot project funds are requested, describe the goals of this initiative and the components of an application, including total allowable budget request. Describe the review criteria and the processes for selecting, funding, and managing the pilot projects.

External Advisory Board (EAB): Each MIRA must recruit external experts who will serve as scientific advisors to the program leadership. This EAB, consisting of 3 to 5 individuals, will advise the MIRA on ongoing research and strategic planning for future research directions. The EAB should convene at least annually (either in person or virtually) and provide a written report to leadership. EAB members may reside in Texas or outside of the state. Describe the composition of the EAB and the expertise provided relevant to the focus of the MIRA program. Honoraria and travel costs are considered allowable costs for this RFA.

# 10.2.11. Synergy Illustration (3 pages)

Provide a detailed narrative and diagrammatic representation of interactions among the Administrative Core, all research projects, and all core resources of the proposed research program.

# 10.2.12. Sustainability Plan (2 pages)

Provide a detailed narrative that discusses a sustainability plan for how the progress of the MIRA will be continued after the conclusion of the CPRIT award. For example, the MIRA may lead to follow-on funding as P01s, SPOREs, or multi-investigator R01s; development of a new center or other institutional mechanisms that recognize and support a multi-investigator program; new faculty recruitment; identification of a new lead compound; the proof-of-principle leading to a clinical trial; or impact on public policy.

#### 10.2.13. Publications/References

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

# 10.2.14. 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:

• One budget will be submitted on behalf of the entire program and will include costs for individual projects and cores. While there will be 1 budget for the entire program, individual budget breakdowns must be included for each project and core resource as a part of the research or core resources plan. For programs that have outside institutions participating, a subcontract must be executed for that institution to receive CPRIT funds.

- 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 <a href="www.cprit.texas.gov">www.cprit.texas.gov</a>. 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 2024 is \$200,000; CPRIT FY 2024 is from September 1, 2023, through August 31, 2024. 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.

# 10.2.15. Biographical Sketches for Key Personnel (5 pages Each)

Up to 10 additional biographical sketches for key personnel may be provided. Each individual biographical sketch must not exceed 5 pages. The NIH biosketch format is appropriate.

Biographical sketches for Project and Core MIs must be submitted as part of the research project or core resource plans. Biographical sketches must be provided for members of the EAB.

# 10.2.16. 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. Note that support information is not needed for members of the EAB. 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 and MIs must be provided.

# 10.2.17. Institutional/Collaborator Support and/or Other Certification (15 pages)

Applicants are encouraged to provide letters of institutional support, collaborator and EAB member support, and/or other certification documentation relevant to the proposed project. A maximum of 15 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.

#### 11. APPLICATION REVIEW

#### 11.1. Full Peer Review

Applications submitted in response to the MIRA RFA will undergo a full peer review using a 2-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. 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 based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by Scientific Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the CPRIT 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.

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

# 11.2. 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 prior to the opening of CARS. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

#### 11.3. Review Criteria

Peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review panels will evaluate and score each project and core individually according to the primary criteria 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.

# 11.3.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work in each project and core as well as the overall program as described in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include the following:

Significance and Impact of Overall Program: What is the innovative potential of the program? Does the program propose new paradigms or challenge existing ones? Does the program develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important underexplored or unexplored areas? If successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? For MIRAs that involve translational research, is there the potential to impact the standard of care? Does the program address cancers with disparities and/or cancers that are particularly relevant to the cancer burden of Texas? 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. Programs that modestly extend current lines of research will not be considered for this award.

**Research Plan for Research Projects:** 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 9.1.

**Project Leader for Research Projects:** 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 (percent 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 9.6?

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

**Sufficiency and Capability of Core Resources:** 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? Is there a mechanism for prioritizing the work of the core?

**Core Resources 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 (percent effort) to this resource?

Administrative Core Plan: Is the proposed organizational and management structure capable of comprehensively overseeing and coordinating all aspects and activities, including scientific oversight, of the proposed research program? If funds are requested for pilot projects, is there an appropriate plan described for soliciting and selecting scientifically sound and impactful projects?

**Administrative Core Leader:** Does the core leader demonstrate the required expertise and experience to direct the research program? Has the core leader devoted a sufficient amount of his or her time (percent effort) to this activity? Are there plans for coordination of the program and for facilitating interactions among the program components?

# 11.3.2. 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, facilities, 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 research team and 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?

# 12. KEY DATES

# **RFA**

RFA release September 14, 2023

# **Application**

Online application opens October 17, 2023, 7 AM central time Application due January 18, 2024, 4 PM central time

Application review February 2024 to August 2024

Award notification August 2024

Anticipated start date August 31, 2024

#### 13. 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 <u>chapter 701</u>, 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 <a href="https://www.cprit.texas.gov">www.cprit.texas.gov</a>. 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 <a href="https://www.cprit.texas.gov">www.cprit.texas.gov</a>.

# 14. 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, <a href="https://chapter.703.section.703.11">chapter.703</a>, <a href="https://ceetion.703.11">section.703.11</a>, for specific requirements regarding demonstration of available funding.

# 15. CONTACT INFORMATION

# 15.1. 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 through Friday, 8 AM to 6 PM central time

**Tel:** 866-941-7146

Email: Help@CPRITGrants.org

# 15.2. Scientific and Programmatic Questions

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

**Tel:** 512-305-8491

Email: research@cprit.texas.gov

Website: www.cprit.texas.gov