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CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

**REQUEST FOR APPLICATIONS**  
**RFA R-22.2-CTNA**

**Clinical Trials Network Award**

Please also refer to the Instructions for Applicants document,  
which will be posted on October 13, 2021

**Application Receipt Opening Date:** October 13, 2021

**Application Receipt Closing Date:** January 12, 2022

**FY2022**

Fiscal Year Award Period

September 1, 2021-August 31, 2022

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## **RFA Version History**

08/30/21 RFA release

Rev 08/31/21 Section 10 – Key Dates

- Edited to remove ambiguity regarding Award Notification Date and Anticipated Start Date

## **1. OVERVIEW**

The Cancer Prevention and Research Institute of Texas (CPRIT) aspires to develop a statewide clinical trials network to increase access by cancer patients in Texas to state-of-the-art clinical trials of new cancer treatment strategies. As an initial step in realizing this goal, CPRIT developed the Clinical Trials Network Award (CTNA) to support new clinical trials networks in Texas in order to provide oncologists and their patients who currently have limited access to cancer therapeutic trials and as a consequence limited opportunities to participate in cancer trials.

The CTNA will be made to a Lead Institution (LI) to develop and oversee a network of 2 cancer care facilities (Network Affiliates) (Stage 1). Once the initial network is satisfactorily demonstrated, the LI will be eligible to receive additional CPRIT funding to expand its network to 2 additional facilities located outside the LI current catchment (Stage 2).

LIs will provide their Network Affiliates access to phase 2 and phase 3 clinical trials appropriate for the patient population served by the affiliates. LIs and Network Affiliates are required to use a common institutional review board (IRB) either provided by the LI or a central IRB and to share access to a web-based clinical trials management support system (CTMS) and agree to implement appropriate legal and contractual agreements necessary to allow data sharing and clinical trial oversight. Ultimately, CPRIT intends to link successful LI networks into a statewide Texas Cancer Clinical Trials Network.

## **2. ABOUT CPRIT**

The State of Texas has established the Cancer Prevention and Research Institute of Texas (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 about how the Oversight Committee directs the orientation of the agency's funding portfolio.

Established Principles:

- Scientific excellence and impact on cancer
- Increasing the life sciences infrastructure

The program priorities for academic research adopted by the Oversight Committee include funding projects that address 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
- Computational biology and analytic methods
- Childhood cancers
- Hepatocellular cancer
- Expansion of access to innovative clinical trials

## **3. RATIONALE**

The past decade has spawned new strategies to treat patients with cancer. Technology has enabled scientists and clinicians to dissect individual patients' cancers down to the very genes that cause them to grow and progress, thereby opening new doors to the development of treatment specific for that patient. This Precision Cancer Medicine, as it has been named, requires tests or biomarkers to determine the gene/protein drivers of a given cancer and then new drugs that effectively target and block those drivers. Industry and academic centers have responded by developing new drugs that target these defective pathways, resulting in a plethora of new agents that need testing in patients. The sheer number of these new drugs and the requirement that they be tested only in the subset of patients harboring the gene/pathway alteration have made clinical testing of these new agents challenging. No longer do we test a new

drug on all patients or all patients with a specific disease like breast or colon cancer. Now these drugs must be tested on a much smaller subset of patients defined by the abnormal driver pathway in their tumor. This has resulted in the need to increase the number of patients going on clinical trials beyond the 3% to 5% of cancer patients that now participate in clinical research trials.

Another important issue is that many patients who could benefit or desire to participate in a new drug trial don't have access to those trials because (1) they are from an underserved or underinsured population without access to a cancer center, (2) they do not have close geographic access to an urban cancer center where most of these trials are offered, or (3) they can't afford to travel to another destination and stay there for the duration of the clinical trial. This problem often gives rise to a selection bias for the trial in that only insured, white, male, urban patients are studied in a clinical trial. It is recognized that different ethnic or racial groups may respond differently to a drug and need to be captured in early trials before a new drug enters the marketplace. Thus, solutions to address these issues must consider bringing the trials closer to the patients or providing support to bring the patients to the trial if it can't be done locally. These problems are particularly important in large states like Texas where patients are often hundreds of miles from an academic urban clinical research center offering state-of-the-art clinical trials of new and promising treatments.

There are other barriers to increasing access to clinical trials other than patient financial and geographic concerns, and these relate in part to the medical care available in a smaller community:

1. Oncologists don't have the necessary resources or time to establish a clinical trials program that includes an experienced research pharmacist, research nurse, study coordinator, and other staff that are critical for a busy physician to enter patients on a clinical trial.
2. Community physicians may not have the experience, knowledge, or resources to carry out clinical trial research; for example, there are many regulatory requirements that need to be followed to ensure patient safety and to address other legal issues.
3. Community physicians may not be interested in this aspect of patient care.
4. Substantial regulatory and legal matters must be addressed to open clinical trials.

5. Certain trials such as sophisticated immune therapy trials with adoptive T-cell or CAR-T cell therapies, trials involving bone marrow transplantation, or those requiring repeated tumor biopsies to learn if the tumor is responding or resistant to therapy can only be done in experienced centers of excellence.

#### **4. RESEARCH OBJECTIVES**

The goal of the CTNA is to inaugurate new clinical trials networks in Texas in order to provide oncologists and their patients who currently have limited access to cancer therapeutic trials opportunities to participate in cancer trials. This mechanism will support access to phase 2 and 3 cancer therapeutic trials appropriate for a community oncology care setting. Clinical trials evaluating surgical or radiation cancer therapies or imaging are not appropriate for this mechanism. Clinical trials evaluating behavioral or prevention services are not appropriate for this mechanism.

To inaugurate this program, CPRIT plans to provide, on a competitive application basis, resources to **LIs with existing robust cancer clinical trials operations** to support development and operations of a clinical trials network with oncology care facilities that currently have limited access to clinical trials (**Network Affiliate**).

LIs will provide their Network Affiliates access to phase 2 and selected phase 3 trials that are appropriate for a community practice setting and meet the needs of that affiliate's patient population.

With award funds, the LI will provide their Network Affiliates access to a web-based protocol management system; consent forms tailored to meet the language, cultural, and socioeconomic needs of the patient population served; data safety and quality control monitoring; training of research personnel, including opportunities to receive CME, CNE, and ACRP maintenance certifications; and access to LI tumor boards with capability for virtual meeting participation to assess patient eligibility for clinical trials.

Network Affiliates are required to identify a physician champion (**physician leader**) who will provide overall leadership at their site, demonstrate onsite research pharmacy capability, and identify clinical research personnel responsible for patient eligibility determination, protocol registration, data collection, and adverse event reporting.

Network Affiliates will be expected to use the LI's IRB or a central IRB to ensure timely activation of clinical trials.

Network Affiliates will be expected to enter into appropriate legal and contractual arrangements with the LI to allow HIPAA business associate status, data sharing, and EMR access.

Network Affiliates will be expected to demonstrate capability for processing and storing plasma and biosamples.

Metrics of success include the following:

1. Ability to evaluate trial eligibility for all new patients and enter eligible patients on therapeutic trials.
2. Satisfactory performance on quality control and clinical protocol monitoring and audit evaluations.
3. Satisfactory staff training and demonstration of continued learning.
4. Ability of Network Affiliate to enroll patients with molecularly defined subsets.
5. Referral of Network Affiliate patients suitable for more complex trials to the LI.

Once the Stage 1 Network is satisfactorily demonstrated, the LI will submit to CPRIT the Stage 2 plan to support expansion of the LI's Network Affiliates to up to 2 additional community-based practices that are geographically located outside the LI catchment. Note that for the purpose of this award, the LI catchment is the geographic region where greater than 80% of the LI patients reside.

## **5. FUNDING INFORMATION**

Applicants may request a maximum of \$600,000 annually for Stage 1 and a maximum of \$900,000 annually for Stage 2. The maximum project period is 4 years.

Allowable costs include the following:

- Funds may be used for personnel salary and fringe benefits, research supplies, equipment, CTMS licensing fees, cost for central IRB review, and travel of personnel between LI and Networks sites (see [section 8.2.9](#)).

- Support up to 20% effort for the LI PI and 10% effort for the Network Affiliate physician leader are required up to a maximum full-time salary of \$200,000/year.
- Subject participation costs including diagnostic or interventional procedures associated with participation in a clinical trial and not considered routine standard of care should be supported by other mechanisms and are not appropriate for this award but may be counted toward the required matching funds (see [section 12](#)).
- Please see [section 8.2.9](#) and the IFA for additional information.

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. The 5% indirect cost expenditures may be distributed between the LI and the Network Affiliate(s); however, in no case may the actual indirect costs reported exceed 5% of grant funds expended. The LI determines whether or not a portion of the 5% indirect costs may be claimed on grant expenses submitted by a Network Affiliate to the LI.

## **6. ELIGIBILITY**

- The LI and Network Affiliates must be Texas-based entities. The LI and Network Affiliates may be institutions, organizations, or other entities (including physician groups) that conduct clinical research; however, a public or private company operating as a clinical research organization (CRO) is not eligible for funding under this award mechanism.
- An entity may only submit 1 application as the LI under this RFA. Network Affiliates may be listed on 1 application submitted under this RFA.
- An entity may hold only 1 active CTNA.
- The Principal Investigator (PI) must have an MD or DO and must be a full-time resident of Texas at the time the application is submitted and during the entire time the grant is active.
- An individual may serve as a PI on no more than 3 active CPRIT Academic Research grants at the time of CTNA. Recruitment and Research Training Awards do not count toward the 3-grant maximum; however, CPRIT considers MIRA Project Co-PIs equivalent to a PI. For the purpose of calculating the number of active grants, CPRIT will

consider the number of active grants at the time of the award contract effective date (for this cycle expected to be August 31, 2022).

- A PI may submit both an application to this RFA and a new or renewal application to another RFA during this funding cycle.
- This award does not allow Multiple PIs. Coinvestigators are allowed.
- Collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but those organizations outside Texas are not eligible to receive CPRIT grant funds.
- 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 gift or grant to CPRIT or to any nonprofit organization specifically created to benefit CPRIT.
- Texas law prohibits a LI or Network Affiliate from receiving CPRIT grant funding if a CPRIT Oversight Committee member or the spouse of a CPRIT Oversight Committee member is employed by the LI or Network Affiliate, participates in the management of the LI or Network Affiliate, or owns or controls, directly or indirectly, an interest in the LI or Network Affiliate.
- The applicant must report whether the LI or Network Affiliate, 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 or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the

CPRIT contract are listed in [section 11](#) and [section 12](#). All statutory provisions and relevant administrative rules can be found at [www.cprit.texas.gov](http://www.cprit.texas.gov).

## 7. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted and must follow all resubmission guidelines. An application is considered a resubmission if the proposed LI is the same as presented in the original submission. Note that the PI and Network Affiliates can be changed in a resubmission.

## 8. RESPONDING TO THIS RFA

### 8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (<https://CPRITGrants.org>). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and apply. Furthermore, the Application 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. Applications will be accepted beginning at 7 AM central time on October 13, 2021 and must be submitted by 4 PM central time on January 12, 2022. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

#### 8.1.1. Submission Deadline Extension

The submission deadline may be extended upon a showing of extenuating circumstances. A request for a deadline extension based on the need to complete multiple CPRIT or other grants applications will be denied. All requests for extension of the submission deadline must be submitted via email to the CPRIT [Helpdesk](#) 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.

## **8.2. 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 *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in [section 6](#) will be administratively withdrawn without review.

### **8.2.1. Abstract and Significance (5,000 characters)**

Describe the proposed clinical trials network including a description of the LI and proposed Network Affiliates for Stage 1 of the network plan. Discuss the clinical trial capabilities of the LI and the criteria for selection of Network Affiliates. Discuss opportunities for expansion of the network in Stage 2. Identification of the Stage 2 Network Affiliates is not required at the time of application. Address how the LI will oversee the proposed network and how the performance of the Network Affiliates will be monitored and evaluated. Provide a clear and concise plan to implement the legal and operational agreements to allow the data sharing, EMR access, and HIPAA business associate contracts necessary to establish the network.

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

Provide a layperson's summary of the proposed clinical trials network including description of the participant sites and patient populations served. Describe, in simple, nontechnical terms, how the network will facilitate access to clinical trials, the type(s) of trials proposed for the network, and the expected impact on patient access to clinical trials. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. **Do not include any proprietary information in the layperson's summary.** The layperson's summary will also be used by advocate reviewers ([section 9.1](#)) in evaluating the significance and impact of the proposed work.

### **8.2.3. Goals and Objectives**

List specific goals and objectives for each year of the CTNA including the plan for launching Stage 1 and for implementing Stage 2 by Year 3 of the award. These goals and objectives will also be used during the submission and evaluation of progress reports and overall assessment of project success.

#### **8.2.4. Timeline (1 page)**

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

#### **8.2.5. Resubmission Summary (1 pages)**

An application previously submitted to CPRIT but not funded may be resubmitted after careful consideration of the reasons for lack of prior success. Applicants preparing a resubmission must describe the approach to the resubmission and address all noted concerns raised in the review of the original application.

#### **8.2.6. Network Description (10 pages)**

##### **A. Principal Investigator**

Discuss the qualifications and the role of the Principal Investigator.

##### **B. Lead Institution**

Describe the LI and its commitment to development of a clinical trials network. Provide an overview of the LI including a description of the LI catchment area, the LI organizational capabilities, clinical research portfolio, and the LI overall commitment to the award.

Document the LI's ability to meet the goals of the CTNA including the following:

1. Access to phase 2 and selected phase 3 trials that are appropriate for a community practice setting and meet the needs of the patients served by the proposed Network Affiliates. Describe the LI current trial portfolio and summarize accruals to therapeutic clinical trials for the LI.
2. Access to a clinical trials management system that includes web-based eligibility review and central registration and access to electronic consent forms tailored to meet the language and cultural needs of patients served by the proposed affiliates.

3. Strategies to overcome barriers to clinical trial participation.
4. Safety and quality control monitoring capability.
5. Training for Network Affiliate personnel and opportunities for network personnel to receive CME, CNE, and ACRP maintenance certification.
6. Tumor boards with capability for virtual meeting participation by Network Affiliate personnel.
7. Oversight of the clinical trial scientific aspects and patient safety of the clinical trials available to Network Affiliates.

#### **C. Network Affiliates:**

Describe how the Stage 1 Network Affiliate sites were selected and discuss how future Stage 2 Network Affiliate sites will be selected. For the Stage 1 Network Affiliates, do the following:

1. Identify the Stage 1 Network Affiliates and indicate if there are any established affiliation or other existing agreements with the LI.
2. Identify and describe the qualifications and responsibilities of the physician leader who will oversee each Network Affiliate site.
3. Discuss the patient population and geographic region served and document the cancer patient volumes and principal cancers seen for each Network Affiliate.
4. Document that the Network Affiliates have agreed to use the LI IRB or a central IRB.
5. Document that the Network Affiliates have agreed to use the CTMS provided by the LI for protocol access, patient registration, and data monitoring at each Network Affiliate (include information on how the CTMS will be accessed).
6. Document the intent and capability to establish an onsite research pharmacy capability and to recruit a clinical research coordinator responsible for eligibility determination, data collection, and to assist with IRB submissions, industry contracts, and other regulatory documentation.
7. Discuss how Network Affiliate performance metrics will be monitored.

### **8.2.7. Legal and Contractual Agreements**

Provide documentation that the LI and Network Affiliates will use a common IRB.

Provide documentation that the Network Affiliates will allow the data sharing, EMR access, and LI personnel HIPAA business associate status, necessary for the LI personnel to carry out trial monitoring and oversight at the Network Affiliate site. While legal and contractual agreements are not required until an award is recommended by the CPRIT Oversight Committee, both the LI and Network Affiliate Leadership should address plans to enter into these agreements in their letters of support for the CTNA ([section 8.2.12](#)).

**Certification of these agreements will be required before funding can occur.**

### **8.2.8. Publications/References**

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

### **8.2.9. Budget and Justification**

Provide a detailed justification of the budget for the entire proposed period of support for both the LI and each Network Affiliate in Stage 1 (maximum total costs of \$600,000 for Years 1 and 2) and Stage 2 (maximum total costs of \$900,000 for Years 3 and 4), including salaries and benefits, supplies, and equipment. All clinical trial sites supported by a CPRIT award under this RFA must be in Texas. Salaries can be budgeted for the Network Affiliate for Research Nurse or Coordinator. CPRIT will not reimburse personnel expenses for employees of the LI or Network Affiliate residing outside of Texas.

Note that patient care costs associated with the conduct of a clinical trial are not appropriate for this mechanism.

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

- Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that maybe spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available

at [www.cprit.texas.gov](http://www.cprit.texas.gov). 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 2022 is \$200,000; CPRIT FY 2022 is from September 1, 2021, through August 31, 2022. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

#### **8.2.10. Biographical Sketches (5 pages each)**

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI and each Network Affiliate Lead (as required by the online application receipt system). Each biographical sketch must not exceed 5 pages. The NIH biosketch format is recommended.

#### **8.2.11. Current and Pending Support**

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a 2-line summary of the goal of the project, and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI and, if applicable, any Coinvestigators, must be provided. Refer to the sample current and pending support document located in [Current Funding Opportunities](#) for Academic Research in CARS.

#### **8.2.12. Institutional/Collaborator Support and/or Other Certification (4 pages)**

Applicants must provide letters of institutional support, including Network Affiliate's support. A maximum of 4 pages may be provided.

### **8.2.13. Previous Summary Statement**

If the application is being resubmitted, the summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission. The applicant is not responsible for providing this document.

**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.**

## **8.3. Formatting Instructions**

Formatting guidelines for all submitted CPRIT applications are as follows:

- **Language:** English
- **Document Format:** PDF only
- **Font Type/Size:** Arial (11 point), Calibri (11 point), or Times New Roman (12 point)
- **Line Spacing:** Single
- **Page Size:** 8.5 x 11 inches
- **Margins:** 0.75 inch, all directions
- **Color and High-Resolution Images:** Images, graphs, figures, and other illustrations must be submitted as part of the appropriate submitted document. Applicants should include text to explain illustrations that may be difficult to interpret when printed in black and white.
- **Scanning Resolution:** Images and figures must be of lowest reasonable resolution that permits clarity and readability. Unnecessarily large files will NOT be accepted, especially those that include only text.
- **References:** Applicants should use a citation style that includes the full name of the article and that lists at least the first 3 authors. Official journal abbreviations may be used. An example is included below; however, other citation styles meeting these parameters are also acceptable if the journal information is stated. Include URLs of publications referenced in the application.

Smith, P.T., Doe, J., White, J.M., et al (2006). Elaborating on a novel mechanism for cancer progression. *Journal of Cancer Research*, 135: 45–67.

- **Internet URLs:** Applicants are encouraged to provide the URLs of publications referenced in the application; however, applicants should not include URLs directing reviewers to websites containing additional information about the proposed research.
- **Headers and Footers:** These should not be used unless they are part of a provided template. Page numbers may be included in the footer (see following point).
- **Page Numbering:** Pages should be numbered at the bottom right corner of each page.
- All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded in PDF format.

## **9. APPLICATION REVIEW**

### **9.1. Application Review**

Applications will undergo 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 in [section 9.3](#). 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 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 Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC.

The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, [chapter 703, sections 703.6 to 703.8](#).

### **9.2. Confidentiality of Review**

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to

sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

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

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website.

**By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in Texas Administrative Code RULE §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 Research Officer, and the Commissioner of State Health Services.

The prohibition on communication begins on the first day that grant applications for the grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

### **9.3. Review Criteria**

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. **The overall assessment will not be an average of the scores of individual criteria; rather, it will**

**reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.**

### **9.3.1. Primary Criteria**

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include the following:

**Lead Institution:** Does the LI document a robust clinical trials program? Will the proposed network expand patient access and geographic proximity to the LI's cancer therapeutic clinical trials? Do plans for the network operation incorporate best practices to ensure timely trial oversight and monitoring to ensure patient safety and the output of high-quality data? Will the LI provide training for network personnel and opportunities for network personnel to receive CME, CNE, and ACRP maintenance certification?

**Network Affiliates:** Do the Network Affiliates proposed for Stage 1 demonstrate a commitment to providing their patients' access to clinical trials and is the environment and setting of the proposed Network Affiliates adequate to support a clinical trial program? Will the proposed network increase the diversity of the patients with access to the LI sponsored clinical trials? Has a physician leader who will provide overall leadership at the Network Affiliate site been identified?

**Network implementation:** Do the LI and Network Affiliates agree to use the LI IRB or a central IRB? Do the leadership of the LI and Network Affiliates agree to enter into the legal and contractual agreements necessary to allow the data sharing, EMR access, and LI personnel HIPAA business associate status, necessary for LI personnel to carry out trial monitoring and oversight at the Network Affiliate site? While final legal and contractual agreements are not required until an award is recommended by the CPRIT Oversight Committee, letters of institutional commitment from LI and Network Affiliate Leadership should address their commitments to enter into these agreements.

**Principal Investigator:** Does the applicant investigator demonstrate the required expertise and experience to lead the network? Has the applicant devoted enough of his or her time (percent effort) to this project?

### 9.3.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed research. Secondary criteria include the following:

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

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

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

## 10. KEY DATES

RFA

RFA release August 30, 2021

## Application

Online application opens	October 13, 2021, 7 AM central time
Application due	January 12, 2022, 4 PM central time
Application review	January 2022 to August 2022

## Award

Award notification August 17, 2022  
Anticipated start date August 31, 2022

## **11. AWARD ADMINISTRATION**

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

Such use shall be in accordance with CPRIT's electronic signature policy as set forth in [chapter 701, section 701.25](#).

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

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

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate.

Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of award contract. Forms and instructions will be made available at [www.cprit.texas.gov](http://www.cprit.texas.gov).

## **12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS**

Texas law requires that prior to disbursement of CPRIT grant funds, the grant 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. A grant recipient that is a public or private institution of higher education, as defined by §61.003, Texas Education Code, may credit toward the grant recipient's matching funds obligation the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the grant recipient and the 5% indirect cost limit imposed by §102.203(c), Texas Health and Safety Code. Grant applicants are advised to consult CPRIT's Administrative Rules, [chapter 703](#).

[section 703.11](#), for specific requirements regarding demonstration of available funding. 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.

CPRIT recognizes that an LI and/or Network Affiliate may not be considered a public or private institution of higher education or may have an FIDC rate credit that is less than 55%. If that is the case, non-CPRIT funds (eg, federal grants, industry contracts, philanthropic funds, institutional funds, etc) paid to support the clinical trials that are the subject of this award may be used to fulfill the matching funds requirement. CPRIT will also allow the grant recipient to count funds paid for the non-research-related patient care costs toward the matching funds requirement. The grant recipient must submit documentation to CPRIT supporting all matching fund expenses.

## **13. CONTACT INFORMATION**

### **13.1. Helpdesk**

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not able 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](mailto:Help@CPRITGrants.org)

### **13.2. Scientific and Programmatic Questions**

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

**Tel:** 512-305-8491

**Email:** [research@cprit.texas.gov](mailto:research@cprit.texas.gov)

**Website:** [www.cprit.texas.gov](http://www.cprit.texas.gov)