CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-21.2-CTNA

Clinical Trials Network Award

Please also refer to the Instructions for Applicants document, which will be posted on September 16, 2020

Application Receipt Opening Date: September 16, 2020

Application Receipt Closing Date: January 27, 2021

FY2021

Fiscal Year Award Period

September 1, 2020-August 31, 2021

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RFA Version History

Rev 08/05/20 RFA release

Rev 9/24/20 Section 9.2.5 – Network Description – B. Lead Institution

- Added the following requirement: "Lead Institution must document the mechanism(s) in place for assuring oversight of the scientific aspects and patient safety of the clinical trials available to Network Affiliates."

1. OVERVIEW

The Cancer Prevention and Research Institute of Texas (CPRIT) aspires to develop a statewide clinical trials network that functions to speed development of new promising drugs and to increase access by cancer patients in Texas to state-of-the-art clinical trials of new treatment strategies. The Clinical Trials Network Award (CTNA) will be made to Lead Institutions (LIs) 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. LI and Network Affiliates are required to use a common institutional review board (IRB) either provided by the lead institution or a central IRB and to share access to a Web-based clinical trials management support system (CTMS). 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. 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 **Lead Institutions (LIs)** 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. Agreements to use a common IRB must be in place prior to initiating the CTNA contract.

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 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 LI Networks are satisfactorily demonstrated, LI's will submit to CPRIT their plans 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 9.2.8).
- 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 13).

- Please see section 9.2.8 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.**
- 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 award. 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, 2021).
- 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 a Co-PI.

- 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 12 and section 13. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

7. RESUBMISSION POLICY

Not applicable as this is a new CPRIT RFA.

8. RENEWAL POLICY

Not applicable as this is a new CPRIT RFA.

9. RESPONDING TO THIS RFA

9.1. 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 September 16, 2020 and must be submitted by 4 PM central time on January 27, 2021. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

9.1.1. 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.

9.2. 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.

9.2.1. 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. Clearly address how the LI will oversee the proposed network and how the performance of the Network Affiliates will be monitored and evaluated.

9.2.2. 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 10.1) in evaluating the significance and impact of the proposed work.

9.2.3. 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.

9.2.4. 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.

9.2.5. 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. **The LI is encouraged to propose telemedicine approaches to evaluate eligibility and to invite patient participation in a clinical trial at the Network Affiliate.**

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.
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 affiliate.
3. Agreement by the LI and Network Affiliates to use a common IRB (section 9.2.6).
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. Lead Institution must document the mechanism(s) in place for assuring oversight of the scientific aspects and patient safety of the clinical trials available to Network Affiliates.

C. Network Affiliates:

1. Identify the Network Affiliate sites and any established affiliation or 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 Affiliate has agreed to use the LI IRB or a central IRB.
5. 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.
6. Provide the plan for protocol access, patient registration, and drug access at each Network Affiliate (include information on the CTMS).
7. Discuss how Network Affiliate performance metrics will be monitored.
8. Discuss how the LI and Network Affiliates will ensure inclusion of women and underrepresented populations (eg, rural, elderly, low socioeconomic status individuals) in the clinical trials offered.

9.2.6. Institutional Review Board agreement

Provide documentation that the LI and Network Affiliates will use a common IRB. Certification of approval of these plans by the IRB will be required before funding can occur.

9.2.7. Publications/References

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

9.2.8. 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. 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 may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.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 2021 is $200,000; CPRIT FY 2021 is from September 1, 2020, through August 31, 2021. 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.

9.2.9. 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.

9.2.10. 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, the Co-PI must be provided. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

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

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

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

9.3. 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.

10. APPLICATION REVIEW

10.1. 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 10.2. 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.

10.2. 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.

10.3. 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.**

10.3.1. 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:

Significance and Impact: Will the proposed network expand patient access and geographic proximity to innovative clinical trials? Will the proposed network increase the diversity of the patients participating in the LI sponsored clinical trials portfolio?

Research Plan: Does the plan for the proposed network document a process for rapid and efficient access to clinical trials and does the plan incorporate best practices to ensure timely clinical treatment decisions and the output of high-quality data? Does the LI have a well-defined plan and an appropriate governance structure to coordinate activities related to the Network? Does the LI demonstrate the potential to overcome critical barriers for robust accrual to advance progress in the field? Does the LI have a history of timely activation of clinical trials? Are the LI infrastructure and policies in place to support accrual to clinical trials? Does the LI have active programs to recruit minorities and underserved patient populations to clinical trials? Do proposed Network Affiliates demonstrate a commitment to providing their patients' access to clinical trials? Is environment and setting of the proposed

Network Affiliates adequate to support a robust clinical trial program where 10% of new patients seen will be eligible to enroll on trials?

Applicant 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?

Relevance: Does the proposed research have a high degree of relevance to cancer research? This is a critical criterion for evaluation of projects for CPRIT support.

10.3.2. 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?

11. KEY DATES

RFA

RFA release	August 5, 2020

Application

Online application opens	September 16, 2020, 7 AM central time
Application due	January 27, 2021, 4 PM central time
Application review	January 2021 to August 2021

Award

Award notification	August 18, 2021
Anticipated start date	August 31, 2021

12. 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. 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.

13. 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.

14. CONTACT INFORMATION

14.1. 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

14.2. 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: Help@CPRITGrants.org

Website: www.cprit.texas.gov