CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-25.1-CAP:CAC

Collaborative Action Program to Reduce Liver Cancer Mortality in Texas: Collaborative Action Center

Competitive Renewal

Please also refer to the Instructions for Applicants document, which will be posted on February 22, 2024.

Application Receipt Opening Date: March 19, 2024

Application Receipt Closing Date: June 11, 2024

FY2025

Fiscal Year Award Period

September 1, 2024-August 31, 2025

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RFA VERSION HISTORY

2/22/24 RFA Released

1. BRIEF DESCRIPTION OF RFA

- This is a competitive renewal, supporting a single Collaborative Action Program to Reduce Liver Cancer Mortality in Texas: Collaborative Action Center (CAP:CAC).
- A competitive renewal application will address the expansion of administrative services, resources, and support to funded hepatocellular carcinoma research projects along with strong justification for the continuation of the FY19.2 CAP:CAC award.
- Applicants may request a maximum of $3,000,000 in total costs for a period of 5 years.
- Multi-Principal Investigators (MIs) are allowed under this Request for Applications (RFA). See the Information for Applicants (IFA) document for definition and eligibility of MIs.
- See application limitations for Principal Investigators (PIs)/MIs, regardless of whether the MI is from the prime institution or a subcontracted institution.
- **Note that CPRIT does not allow the use of the term Co-PI**.
- Minimum effort for the PI and/or MIs throughout the project period is required.
- FY25 salary cap is $225,000 per year.
- Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase.

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 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.

Established Principles:

- Scientific excellence and impact on cancer

- Increasing the life sciences infrastructure in all regions of the state
- Reducing disparities in cancer incidence and mortality

2.1. Academic Research Program Priorities

The program priorities for Academic Research adopted by the Oversight Committee include 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, early detection, risk assessment and interventions.
- Computational oncology and analytic methods
- Childhood and adolescent cancers
- Hepatocellular cancer (HCC)
- Expanding access to innovative clinical trials

3. PROGRAM DESCRIPTION

The goal of the **Collaborative Action Program to Reduce Liver Cancer Mortality in Texas** is to position Texas as a national leader in reversing the trajectory of liver cancer incidence and mortality.

Liver cancer, also known as HCC, is the fastest increasing lethal cancer in the United States, with an annual incidence that has tripled during the past 2 decades. The incidence of HCC is 3 times higher in men than women, and there are significant racial and ethnic differences in liver cancer occurrence and mortality.

Risk factors for liver cancer include viral hepatitis (hepatitis B virus and hepatitis C virus), nonalcoholic steatohepatitis (NASH), and alcoholic liver disease. Approximately 80% to 90% of HCCs occur in patients with underlying cirrhosis, making individuals with advanced cirrhosis at particularly high risk for developing HCC.

Texas has the highest incidence of HCC in the US, with an annual incidence that is nearly double the national average. The rise is particularly virulent among Texans of Hispanic ethnicity living along the US-Mexican border where HCC incidence and mortality is the highest in the nation.

While the reasons for the increase in HCC in this population are not fully understood, HCC development has been linked to multiple risk factors including genetic predisposition and socioeconomic factors, but significant gaps remain in knowledge about the relationship between HCC in high-risk populations compared to non-Hispanic whites.

To address this challenge, CPRIT invested in the **Collaborative Action Program (CAP) to reduce liver cancer mortality in Texas** and the CAP Research awards, which are now integrated into Individual Investigator Research Awards (IIRA).

The CAP-related IIRA Research Awards RFA (RFA 25.1 IIRAP and IIRA) support investigator-initiated research projects designed to do the following:

1. Identify risk factors for cirrhosis and HCC in Texas populations and predictors of high risk for progression of cirrhosis to HCC, including environmental and behavioral factors, genetic markers, and health disparities;
2. Identify and validate biomarkers and/or imaging methods that will enhance the surveillance and better stratify patients with cirrhosis leading to detection of HCC at an early stage;
3. Increase implementation of evidence-based interventions for the prevention and/or early detection of HCC among populations at high risk; and
4. Conduct health services research in populations at highest risk for developing cirrhosis and HCC designed to identify the most effective ways to address the disparities (eg, through systems change, outreach, access) and delivery of early detection and preventive care.

The CAP Collaborative Action Center Competitive Renewal RFA seeks to support a single Collaborative Action Center (Center) that will continue to catalyze interactions and enable data sharing among the awardees of the CAP IIRA Awards and forge innovative relationships among academic content experts, health providers, and policymakers in Texas to promote awareness and implementation of best practices for HCC prevention and early detection.

4. COLLABORATIVE ACTION CENTER DESCRIPTION-CONTINUATION

Applicants are invited to propose a competitive renewal Center whose functions will be to continue to (1) promote interactions and collaboration across the hepatocellular cancer IIRA Research Awards; (2) provide opportunities for academic content experts, health care providers, and community stakeholders to exchange ideas and to explore new opportunities to impact the rise of HCC in Texas; (3) educate health care providers and the public on best practices to alter the trajectory of HCC in Texas; and (4) inform public health officials and influence, where possible, public health care policy to improve prevention, detection, and treatment of HCC.

To accomplish these goals, the Center will be expected to do the following:

- Demonstrate a compelling justification for continued CPRIT support of the Collaborative Action Center, based upon the scientific impact of current and continued CPRIT support.
- Quality and cost efficiency of the services alone are not sufficient justifications for continued CPRIT support. Renewal applications will be expected to demonstrate an exceptional record of impact on HCC research as measured by the following:
    - Utilization (number of PIs utilizing the Center; number of institutions served);
    - Publications that cite CPRIT support;
    - New peer-reviewed grant awards supported;
    - Clinical trials supported;
    - Patents supported;
    - Other metrics, such as practice-changing, or policy-influencing initiatives.
- Strong plan delineating how the Collaborative Action Center services provided will be developed further to advance HCC research.
- Provide current updates on the following FY2019 RFA deliverables and provide program expansion plans for the following:
    - Use of a steering committee consisting of the PIs and MIs of the funded HCC Research Awards to facilitate communications and interactions across these CPRIT-funded research projects;
    - Support collaborations across the HCC Research Projects by providing access to services that will facilitate data sharing among the HCC-funded research projects;

- Engage private and public entities across the state, (eg, representatives of health practices and health care systems, health insurers, pharmaceutical and biotech industry leaders, government agencies, etc), in policy considerations addressing issues critical to the reduction of HCC mortality in the state;
- Convene an annual scientific forum that will promote awareness of the burden of HCC, highlight CAP-supported research, and foster interactions with others whose research is relevant to HCC;
- Collect, synthesize, and disseminate findings and lessons learned from the CAP Research Awards and conduct an evaluation of the impact of the CAP program.

Applicants for this Center RFA are encouraged to identify additional assets that would leverage unique resources—such as established cohorts, biobanks, and annotated clinical data—that will provide additional opportunities and increase the impact of the *Collaborative Action Program to Reduce Liver Cancer Mortality in Texas*.

5. FUNDING INFORMATION

CPRIT plans to make 1 award to a single applicant in response to this RFA.

Applicants may request a maximum of $3,000,000 in total costs for a period of 5 years.

Applicants may request salary support and fringe benefits for a Center Contact PI, MIs, data analysts, and additional programmatic and support staff required to carry out the Center functions.

Funds may be used for research supplies, data management support, website development, production of educational materials (promotional marketing products such as pens, etc, are not allowable costs), and allowable costs associated with hosting annual symposiums.

CPRIT awards cannot be used to pay for food and beverages related to holding meetings/annual conferences.

Travel to attend scientific or technical meetings, to attend onsite meetings with CAP-supported research programs, and to meet health providers and policymakers is also an allowable expense for the PI and the Center's senior-level staff. Travel expenses related to the Center's mission and to support travel expenses of steering committee members to attend Center meetings and annual symposium are appropriate expenses.

Up to 10% of the Center's annual direct budget may be used to fund special projects recommended by the CAP steering committee to extend the impact of the individual CAP Research Awards to additional geographic areas and/or populations.

Requests for funds to support major equipment, 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.

6. ELIGIBILITY

- The application must come from a Texas-based entity. Any not-for-profit institution or organization is eligible to apply for funding under this award mechanism;
- Only institutions with an active CAP:CAC award may submit an application under this RFA.
- The PI must be the director of the proposed Center, must have requisite management experience, and must reside in Texas during the time the research that is the subject of the grant is conducted;
- The PI must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent. The PI should also hold a faculty position, preferably at the level of associate or full professor or the equivalent.
- The contact PI is required to maintain a minimum of **15%** level of effort through the duration of the entire award period. For applications that include MIs, **each** MI is required to maintain a minimum of **10%** effort through the entire duration of the award period.
- A PI may **not** submit applications to this RFA and to RFA R-25.1-IIRA, RFA R-25.1-IIRACSBC, RFA R-25.1-IIRACCA, RFA R-25.1-IIRACT, RFA R-2.1-IIRAP, or RFA R-25.1-IIRAEOC.
- A PI may **not** submit more than 1 application, either a new, resubmission, **or** renewal application under this RFA during this funding cycle.
- A PI may **not** be a part of more than 1 application, whether as a single applicant or as an MI on an application, under this RFA and RFA R-25.1-IIRA, RFA R-25.1-IIRACSBC,

RFA R-25.1-IIRACCA, RFA R-25.1-IIRACT, RFA R-25.1-IIRAP, or RFA R-25.2-IIRAEOC.

- **An individual may serve as a PI on no more than 3 active CPRIT Academic Research grants.** Recruitment Grants and Research Training Awards do not count toward the 3-grant maximum; however, CPRIT considers MIRA Project MIs 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 March 1, 2025).
- 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 (Texas Administrative Code, Title 25, Rule 703.3);
- 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 are 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. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

7. RESPONDING TO THIS RFA

7.1. 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 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 non-contact PI does not have to create a user account in CARS; the PI will be added to the application by the Center Contact PI. Please refer to the *Instructions for Applicants (IFA)* document for the instructions on adding Multi PIs to an application. The *IFA* document will be available when the application receipt system opens. Applications will be accepted beginning at 7 AM central time on March 19, 2024, and must be submitted by 4 PM central time on June 11, 2024. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

7.1.1. 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.

7.2. 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 for details. The IFA 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.

7.2.1. Abstract and Significance (5,000 characters)

Clearly present the organizational structure, content expertise, and unique qualifications that will enable the applicant to meet the requirements described in section 4 for the Center. Discuss special assets that the proposed Center will bring to the overall mission of the CAP program. State the added value that the Center will contribute to the projects supported by CAP Research Awards and discuss how the Center will (1) support collaborations across these CAP Research Awards, (2) engage private and public entities across the state in policy considerations that address issues critical to the reduction of HCC mortality in the state, and (3) educate health care providers and the public on best practices and new opportunities that will impact the trajectory of HCC in Texas.

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

Provide a layperson's summary of the proposed Center. Describe, in simple, nontechnical terms, the overall goals of the Center, how the Center will accomplish the requirements identified in section 4, and discuss any unique assets and/or experience that the Center will bring to the CAP program. 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 8) in evaluating the significance and impact of the proposed work.

7.2.3. Specific Aims and Subaims

Provide a list of specific aims and subaims for each year of the award. These aims will also be used in the initial assessment of the Center and in the evaluation of annual progress reports if the award is made.

7.2.4. Timeline (1 page)

Provide an outline (chart) of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications.

If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

7.2.5. Renewal Summary (3 pages)

Renewal applications must demonstrate a compelling justification for continued CPRIT support of the Center that is based upon the scientific impact of current and continued CPRIT support, as well as a strong plan delineating how the services provided will be developed further to advance HCC research. Renewal applications will be expected to demonstrate an exceptional record of impact on HCC research as measured overall and by administrative duties of the CAP:CAC as described in the FY19.2 CAP:CAC RFA. Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase. See section 8.

Overall Summary

Provide a summary of the Center's progress and accomplishments related to:

1. The identification of risk factors for cirrhosis and HCC in Texas populations and predictors of high risk for progression of cirrhosis to HCC, including environmental and behavioral factors, genetic markers, and health disparities;
2. The identification and validation of biomarkers and/or imaging methods that enhanced the surveillance and better stratification of patients with cirrhosis leading to detection of HCC at an early stage;
3. Details regarding the implementation of evidence-based interventions for the prevention and/or early detection of HCC among populations at high risk; and
4. Health services research projects in populations at highest risk for developing cirrhosis and HCC designed to identify the most effective ways to address the disparities (eg, through systems change, outreach, access) and delivery of early detection and preventive care.

Administrative Collaborative Action Center Summary:

1. Provide a roster of steering committee members, number of meetings, and actions executed;
2. Summarize the support provided to the CAP and IIRA-related research projects including, but not limited to, tissue collections and the facilitation of data sharing among the CAP-funded research projects;

3. Describe the engagement with private and public entities across the state in policy considerations addressing issues critical to the reduction of HCC mortality in the state;
4. Summarize annual scientific forums by number of participants, speakers, and forum outcomes; and
5. Discuss the responses to the Center's external evaluations conducted and summarize the lessons learned.

7.2.6. Center Description (10 pages)

Overview and Capabilities

Provide an overview of the continuation award Center proposal in the context of the overall CPRIT Collaborative Action Program to Reduce Liver Cancer Mortality in Texas indicating how the Center will continue to facilitate, enhance, and support the research of the CAP Research Awards and **promote collaborations among the CAP program participants and others in Texas such that the whole is greater than the sum of the parts.**

Highlight any unique approaches or special assets the Center will bring to the overall CAP program.

Expertise and capabilities

Summarize the collective capabilities of the Center personnel, recent accomplishments, etc, in areas vital to the role of Center, including expertise relevant to liver cancer, including early detection and surveillance, development and validation of biomarkers including imaging approaches, dissemination and implementation research, health services research, and outreach and education.

Plans and Approaches to required Collaborative Action Center Functions

Describe a plan for continued evolution and operation of the Center that addresses all the functions of the Center identified in section 4. The plan should address (but is not limited to) the following aspects:

- *Program Coordination.* Describe how the Center will (1) Provide organizational and logistical support for CAP Steering Committee meetings and additional program meetings as needed; (2) maintain or expand the Center's role in promoting collaborations

by identifying synergistic research opportunities among the funded CAP Research Awards, especially collaborations that involve different regions of the state; (3) plan activities that will facilitate collaborations between the CAP Research Awards and other Texas research programs (eg, CPRIT-, NIH-, DOD-funded research) addressing HCC prevention and early detection; and (4) convene representatives of private and public entities across the state to address policy issues critical to reduction of HCC mortality in the state.

- *Research Support.* The Center should plan to develop uniform protocols for specimen and data collection; coordinate, when feasible, the sharing of biospecimens (blood, other body fluids and, when feasible, liver tissue) across the CAP Research Awards; and support the Steering Committee's selection of special projects designed to extend the impact of the CAP Research Awards.
- *Outreach and education*. Describe a plan to enhance initiatives to build awareness among health care providers and the public of cirrhosis and HCC risk factors and best practices for preventive measures and treatment; describe a plan to engage private and public entities across the state, (eg, representatives of health practices and health care systems, health insurers, pharmaceutical and biotech industry leaders, government agencies, etc), in public policy considerations addressing issues critical to the reduction of HCC in the state.
- *Evaluation and dissemination of new findings.* Describe how the Center will evaluate the impact of the *Collaborative Action Program to Reduce Liver Cancer Mortality in Texas* and how the Center will disseminate new findings from the individual CAP Research Awards as well as policy recommendations from the CAP-sponsored statewide policy considerations.

Applicants are encouraged to describe any additional assets that would leverage unique resources—such as established cohorts, biobanks, and annotated clinical data—for the benefit of the CAP program.

7.2.7. Human Subjects (2 pages)

If human subjects or human biological samples will be used, please use this section to provide any additional details that may have not been covered in the description of the Center.

7.2.8. Publications/References

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

7.2.9. Budget and Justification

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 maximum annual salary (also referred to as direct salary or institutional base salary) that an individual may request under a CPRIT award for FY 2025 is $225,000; CPRIT FY 2025 is from September 1, 2024, through August 31, 2025. 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.

Applicants may request salary support and fringe benefits for a Center contact PI, MIs, data analysts, and additional programmatic and support staff required to carry out the Center functions.

Funds may be used for research supplies, data management support, website development, production of educational materials (promotional marketing products such as pens, etc, are not allowable costs), and allowable costs associated with hosting annual symposiums.

CPRIT awards cannot be used to pay for food and beverages related to holding meetings/annual conferences.

Travel to attend scientific or technical meetings, to attend onsite meetings with CAP-supported research programs, and to meet health providers and policymakers is also an allowable expense for the PI and the Center's senior level staff. Travel expenses related to the Center's mission and

to support travel expenses of steering committee members to attend Center meetings and annual symposium are appropriate expenses.

Up to 10% of the Center's annual direct budget may be used to support special projects recommended by the CAP steering committee to extend the impact of the individual CAP Research Awards to additional geographic areas and/or populations.

7.2.10. Biographical Sketches for Key Personnel (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, if applicable, any additional MIs (for an MI application), as required by the online application receipt system. Up to 5 **additional** biographical sketches for key personnel may be provided; these should be concatenated into a single PDF with a 25-page limit. **Each biographical sketch must not exceed 5 pages.** The NIH biosketch format is appropriate.

7.2.11. Current and Pending Support

State the funding source and duration of all current and pending support for the PI, MIs, and 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 key personnel must be provided.

7.2.12. Institutional/Collaborator Support and/or Other Certification (10 pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed Center. A maximum of 10 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 withdrawn without review.

7.3. 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 may be submitted as part of the 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. URLs of publications referenced in the application may be included.

  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.

8. APPLICATION REVIEW

8.1. Preliminary Evaluation

Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase. All eligible applications submitted in response to the CAP

Collaborative Action Center RFA will be evaluated 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 in section 8.3. Applicants will be notified of peer review panel assignments prior to the peer review meeting dates. Peer review panel membership can be found on the CPRIT website. In the second stage, applications judged to be most meritorious by the peer review panel will be evaluated and recommended for funding by the CPRIT Scientific Review Council (SRC) who will take into consideration how well the Center's expertise and attributes complement the top-ranked HCC individual investigator research awards.

The SRC recommendations 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.

8.2. Confidentiality of Review

Each stage of the application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, SRC 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 SRC members are non-Texas residents.

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 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.

8.3. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Peer review committees will evaluate and score each primary criterion and subsequently assign an overall score that reflects a complete 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 merit of each application is within the sole discretion of the peer reviewers.**

8.3.1. Primary Criteria

The 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 project. Primary criteria include the following:

Significance and Impact: Has the Center achieved the goals outlined in the initial FY19 RFA? Has the Center been impactful in advancing collaborations and research on HCC? Has the Center developed resources that advance HCC research or care? How well does the proposed Center address the responsibilities described in the RFA? Will the Center effectively engage the CAP Research Awardees and create new opportunities for collaboration? Will the Center bring unique advantages or capabilities to the CAP? Will the Center provide statewide leadership and engage appropriate stakeholders in advancing policies and practices that will impact HCC in Texas? Does the Center include plans for developing outreach to health care providers, policymakers, and

others whose participation will increase the likelihood of success, and has the Center been effective in their current effort?

Will the overall impact of the Center lead to a program whose whole is greater than the sum of the individual components?

Technical Expertise: Is there sufficient technical expertise to carry out the duties of the Center?

Institutional Commitment: Is there clear institutional commitment for support of the Center? Has the host institution provided appropriate space and infrastructure support?

Center Personnel: Are the PI and other key personnel well suited to their roles in the Center? Do they have appropriate experience and training, and have they demonstrated significant experience with coordinating collaborative clinical research and implementation science? Is the leadership approach, governance, plan for conflict resolution, and organizational structure appropriate for the Center?

8.3.2. Secondary Criteria

Secondary criteria contribute to the overall 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 facilities and access to resources to accomplish all aspects of the Center? Are the levels of effort of the key personnel appropriate?

Human Subjects: If human biological samples are included in the proposed research, is the human subjects plan adequate and sufficiently detailed? Note that certification of approval by the institutional IRB 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?

9. KEY DATES

RFA

RFA release	February 22, 2024

Application

Online application opens	March 19, 2024, 7 AM central time

Application due	June 11, 2024, 4 PM central time
Application review	June 2024-February 2025

Award

Award notification	February 2025
Anticipated start date	March 1, 2025

10. 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 documented in the grant award contract and address plans for the upcoming year. In addition, fiscal reporting and human studies reporting will be required as appropriate.

CPRIT will review annual progress reports and continuation of funding is contingent upon the timely receipt of these reports and documentation of sufficient progress toward completing

project goals. 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.

11. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

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

12. CONTACT INFORMATION

12.1. Helpdesk

The Helpdesk will answer queries submitted via email within 1 business day. Helpdesk support is available for questions regarding user registration, online submission of applications as well as page limitations, formatting and how to upload application components/subsections in the appropriate tabs of the CPRIT Application Receipt System. Helpdesk staff cannot answer scientific questions and/or Academic Research programs aspects of an application. Before contacting the Helpdesk, please refer to the *Instructions for Applicants* document, which provides a step-by-step guide on using CARS.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time
Tel: 866-941-7146
Email: Help@CPRITGrants.org

12.2. Scientific and Programmatic Questions

Scientific and Programmatic Questions-should be directed to the CPRIT Director of Academic Research. **Before contacting CPRIT, please refer to the *Instructions for Applicants* document and contact the Helpdesk for any items related to the Application Receipt System (CARS), page limitations, formatting, etc.**

Email: research@cprit.texas.gov

Website: www.cprit.texas.gov