

REQUEST FOR APPLICATIONS RFA C-25.2 SUPPLEMENTAL

Supplemental Awards for Product Development Research

Please also refer to the Instructions for Applicants document

Supplemental Award Application Receipt Opening Date: February 24, 2025 **Application Receipt Closing Date:** March 5, 2025

FY 2025

Fiscal Year Award Period September 1, 2024-August 31, 2025

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RFA VERSION HISTORY

Rev 2/24/2025 RFA release



1. EXECUTIVE SUMMARY

Texas created the Cancer Prevention and Research Institute of Texas (CPRIT) to identify and financially support innovative projects related to the prevention, detection, and treatment of cancer. CPRIT's mission includes investing in Texas-based startup and early-stage oncology companies to narrow the funding gap (sometimes referred to as the "valley of death") between discovery and commercial development.

Companies with current CPRIT awards that were funded prior to the 24.2 funding cycles (24.1 and earlier) may submit an application by the application deadline, which a panel of experts will review. If the application demonstrates sufficient progress on the current project and a justified need for supplemental funds, CPRIT will invite the company for an interview.

A company invited for an interview will present the proposed project to a panel of experts. If the panel recommends the company for potential CPRIT investment, the project will be presented to CPRIT committees before CPRIT makes a final award decision.

Applicants may request up to \$3 million in funding but can request no more than 30% of the company's original CPRIT budget to accelerate, augment, or supplement the currently funded CPRIT project. CPRIT provides funding via an award contract between CPRIT and the company. The contract includes a negotiated budget tied to agreed goals and objectives (G&Os) and project timeline, as well as revenue-sharing terms and regular reporting requirements on the use of CPRIT funds and project progress. CPRIT also requires companies receiving a Product Development Award to contribute the company's own funds toward the project contemporaneous with CPRIT's investment.

Please note that this RFA will use the terms "grant," "award," and "investment" interchangeably to denote the contractual commitment of CPRIT funds to support a company project recommended by an expert review panel and approved by CPRIT's Oversight Committee.

2. ABOUT CPRIT

A statewide vote of Texans in 2007 created CPRIT and constitutionally authorized the state to issue \$3 billion in taxpayer-backed general obligation bonds to fund cancer prevention and the research and development of innovative methods to prevent, detect, treat, and cure cancer. A

second statewide vote in 2019 reauthorized CPRIT and increased the total general obligation bond issuance by another \$3 billion, for a total of \$6 billion.

2.1. CPRIT's Statutory Mission

The Texas Legislature has charged CPRIT with the following:

- Create and expedite innovation in cancer research and product or service development,
 thereby enhancing the potential for a medical or scientific breakthrough in the prevention,
 treatment, and possible 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.
- Continue to develop and implement the Texas Cancer Plan by promoting the
 development and coordination of effective and efficient statewide public and private
 policies, programs, and services related to cancer and by encouraging cooperative,
 comprehensive, and complementary planning among the public, private, and volunteer
 sectors involved in cancer prevention, detection, treatment, and research.

2.2. CPRIT's Product Development Research Program Priorities

In addition to overarching principles that include scientific excellence, impact on cancer, and increasing the state's life science infrastructure. CPRIT's Oversight Committee establishes annual priorities for each of its 3 programs. The priorities guide CPRIT on the development of Request for Applications (RFAs) and the evaluation of applications considered for awards.

The Product Development Research Program's priorities for FY 2025 are as follows:

- Funding novel projects that offer therapeutic or diagnostic benefits; ie, disruptive technologies
- Funding projects addressing large or challenging unmet medical needs
- Investing in early-stage projects when private capital is least available
- Stimulating commercialization of technologies developed at Texas entities
- Supporting new company formation in Texas or attracting promising companies to Texas
 that will recruit staff with life science expertise, especially experienced C-level
 executives

• Providing appropriate return on Texas taxpayer investment

Information about CPRIT's program priorities is available at http://priorities.cprit.texas.gov/.

3. FUNDING INFORMATION AND MATCHING FUNDS REQUIREMENT

3.1. Overview

Current CPRIT grantees have been provided project funding via a 3-year contract, with the opportunity to extend the contract duration based upon project progress. Funding is milestone driven, meaning that the company must fulfill the contractual G&Os associated with one funding tranche before receiving the next disbursement of funds. The current funding opportunity is provided for those current CPRIT grantees whose funding occurred before the 24.2 funding cycles and will be used to accelerate, augment, or supplement the currently funded CPRIT project

3.2. Funding Stage for Texas Company Supplemental Awards

The Supplemental Award for Product Development Research supports CPRIT awardee companies that have made significant progress during the pendency of the CPRIT award as evidenced by the attainment of G&Os that were approved in the initial CPRIT award. The purpose of the Supplemental Award is to enable the company to accelerate, augment, or supplement its current G&Os with respect to the CPRIT award. The funds can be used to reduce the time to attain specific current goal(s) and/or objective(s). The funds can be used to add goal(s) and/or objective(s) that will benefit the project as a whole, such as adding cohorts to an existing scheduled clinical trial or increasing the number of potential formulations or delivery systems for a given compound. The funds may also be used for revised G&Os based on new data to expedite attaining the objective of the grant.

3.3. Allowable Expenses

Companies may use CPRIT funds for expenses associated only with activities directly related to the specific project that CPRIT is funding. Allowable expenses include the following:

- Salary and fringe benefits
- Research supplies
- Equipment

- Clinical trial expenses
- IP acquisition and protection
- External consultants and service providers
- Travel in support of the project
- Other appropriate research and development costs, subject to certain limitations set forth by Texas law

Texas Health & Safety Code Section 102.203 limits the amount of awarded funds that a company may spend on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs).

3.4. Required Matching Funds

CPRIT requires each company receiving a CPRIT Supplemental Product Development Research Award to contribute funds under the company's control toward the overall project expenses. The company's expenditure of these "matching funds" must take place at the same time the company is drawing down CPRIT funds; there is no credit toward the matching funds requirement for inkind expenses or expenditures made prior to the CPRIT award. The amount that the company will contribute toward the project is dependent on the total amount of CPRIT funds committed to the company.

The company must demonstrate that it has available matching funds when CPRIT disburses funds under the contract, not when the company submits the CPRIT application.

See section 8.3 for more information about CPRIT's matching funds requirement.

4. ELIGIBILITY POLICY

4.1. Award Recipients Must Be Current CPRIT Award Recipients

Only companies with current CPRIT awards that were funded prior to the 24.2 funding cycle may submit an application. Companies with closed awards or awards in close out are not eligible.

4.2. Contributors to CPRIT Ineligible to Receive CPRIT Awards

An applicant is eligible to receive a grant award only if the applicant certifies that the company, including the company representative, any senior member or key personnel listed on the

application, or any company officer or director (or any person related to one 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.

4.3. Relatives of Oversight Committee Members Ineligible to Receive CPRIT Awards

An applicant is ineligible to receive CPRIT funding if the company representative, any senior member or key personnel listed on the application, or any company officer or director is related to a CPRIT Oversight Committee member.

4.4. Debarment/Termination of a Federal Grant May Affect Eligibility to Receive CPRIT Awards

The applicant must report whether the company, company representative, or any other individual who contributes to the execution of the proposed project in a substantive, measurable way, regardless of whether the individual receives salary or compensation under the grant award, is ineligible to receive federal grant funds or has had a grant terminated for cause within 5 years prior to the submission date of the grant application. If the applicant or any other individual is ineligible to receive federal grant funds or has had a grant terminated for cause, CPRIT will contact the applicant to provide more information to determine eligibility for CPRIT awards.

4.5. Only One Submission Per Applicant

Eligible applicants (a Company or PI) may apply for a single Supplemental Award in this funding cycle.

5. APPLICATION REVIEW PROCESS AND CRITERIA

5.1. Overview

CPRIT uses a 2-step process to review company projects proposed for funding. The steps include (1) application review and (2) interview for selected applications. The review will be conducted by an integrated panel of individuals with expertise in a wide variety of scientific fields including oncology as well as experts with experience in bringing products to market and those familiar with regulatory approval processes.

Based upon a review of the proposed utilization of the supplemental funds and its impact on the overall project, CPRIT may invite the company to an interview. Primary considerations will include accomplishments and progress on the project to date and how the supplemental funds will aid the company in executing and/or expanding its goals. If the review panel is favorably inclined to the application, an interview will be scheduled in which the review panel may ask questions of the company regarding the project and the proposed supplemental funding. The review process ends after application review for those applicants not invited to an interview.

CPRIT conducts all stages of the review in confidence to protect the applicant's technological, scientific, and proprietary information. Individuals involved in the review process operate under strict conflict-of-interest prohibitions and nondisclosure agreements. Applicants must not contact or discuss a pending application with anyone involved in making a final decision on the application unless specifically invited by CPRIT to provide information on the proposed project.

CPRIT makes funding decisions via the review process and review criteria described below. CPRIT's Administrative Rules, <u>Chapter 763</u>, <u>Sections 703.6 to 703.8</u> delineate the review process in more detail.

5.2. Review Process

5.2.1. Product Development and Scientific Review

CPRIT assigns applications to CPRIT Product Development review panel members for evaluation using the criteria described in <u>section 5.3</u> below. In addition to reviewing the written application, if the company is selected to attend an interview, the review panel may provide questions to the company prior to the interview. The company will address these questions during a virtual interview. To the extent that the company has had any interaction with regulatory agencies that it has not already submitted to CPRIT, the applicant should provide CPRIT with documents related to that interaction.

5.2.2. Program Integration Committee (PIC) Review

The CPRIT Program Integration Committee (PIC) meets to review the Product Development Review Council's final list of applications recommended for funding. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding when creating its comprehensive list of award recommendations for the Oversight Committee. By law, the PIC's list of recommended Product Development

Awards may not include any applications not also recommended by the Product Development Review Council.

5.2.3. Oversight Committee Approval

CPRIT's Chief Product Development Officer will present the PIC's award recommendations at a public meeting of the Oversight Committee for approval by two-thirds of the Oversight Committee members present and eligible to vote. By law, the Oversight Committee may not approve any Product Development Awards to applicants not also recommended by the Product Development Review Council and the PIC.

5.3. Review Criteria

The review of applications will consider the quality of the project conducted, the number of G&Os the company has attained, the continued commercial viability of the project, the revised project budget based on the supplemental funds requested, updated timeline and goals, and the company financials and ability to secure matching funds to the supplemental funds.

5.4. Confidential, Conflict-Free Review

CPRIT conducts each stage of application review confidentially and requires all CPRIT Product Development Review Panel members, Product Development Review Council members, PIC members, Oversight Committee members, and CPRIT employees with access to grant application information to sign nondisclosure statements regarding the contents of the applications. State law (Texas Health & Safety Code §102.262[b]) protects all technological and scientific information included in the application from public disclosure.

CPRIT will notify an applicant regarding the peer review panel assigned to review the grant application. CPRIT lists the review panel members on our website. Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Product Development Peer Review Panel members and Product Development Review Council members are non-Texas residents.

5.5. Reconsideration of an Application Review Decision Limited to Unreported Conflicts of Interest

CPRIT is committed to providing a fair, unbiased review process conducted by expert reviewers familiar with the science, development stage, and business challenges underlying the project

proposed for funding. That said, application review is a subjective process. **By applying, the** applicant agrees and accepts that the sole basis for reconsideration of an application is a reviewer's undisclosed conflict of interest as set forth in <u>CPRIT Administrative Rule 703.9</u>.

5.6. Prohibited Communication Between Applicant and Reviewers During Review

Except as noted below, CPRIT prohibits communication regarding any aspect of a pending application between the applicant or someone on the grant applicant's behalf and the following individuals: an Oversight Committee member, a PIC member, a Product Development Review Panel member, or a Product Development Review Council member: Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

- The communication prohibition begins at the time the applicant submits the application and extends until it receives notice regarding a final decision on the application. An applicant who has questions about the application process or the substance of the application should contact the CPRIT Product Development Program Manager.
- The communication prohibition does not apply when CPRIT staff or reviewers
 specifically invite the applicant to discuss the pending application for purposes of the
 review process, such as the in-person presentation or to respond to information requests.
 CPRIT will document communication between the applicant and CPRIT staff/reviewers,
 including the reason for the communication, as part of the grant review process records.

NOTE: The following individuals are members of the PIC: 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.

6. SUBMISSION GUIDELINES AND DEADLINES

By submitting an application, the applicant accepts the terms and conditions of the RFA.

Carefully review information in this section and the *Instructions for Applicants* document to ensure the accurate and complete submission of all components of the application. It is imperative that applicants allow sufficient time to familiarize themselves with the application format and instructions to avoid unexpected issues. CPRIT will administratively withdraw

without review any application that lacks one or more required components, exceeds the specified page or word limits, or fails to meet the eligibility requirements listed in section 4.

6.1. Online Application Receipt System

Applicants submit applications via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal are eligible for evaluation. Applicants must utilize a CARS user account to generate and submit the application. The *Instructions for Applicants* associated with this RFA provides information about establishing a user account.

6.2. Application Submission Deadlines; Other Key Dates

An applicant may submit an application via CARS at any time on or after February 24, 2025, through March 5, 2025. CPRIT will assign all applications to a review panel.

Key dates for the review cycle are as follows:

FY 2025.2 Review Cycle

Application Deadline	March 5, 2025, 4:00 PM central time	
Interview (virtual)	Week of April 7, 2025	
Oversight Committee Meeting	August 21, 2025	

6.3. Submission Deadline Extensions

Review schedules are set in advance and do not accommodate receipt of an application days after the deadline. Therefore, potential applicants that are unable to meet the application deadline because of travel, sabbaticals, conferences, prolonged illness or other leave, etc, should not request additional time to file an application.

In exceptional instances CPRIT may extend the submission deadline for an application upon a showing of good cause, usually for technology problems related to CARS. In this event, the applicant should submit a request to extend the submission deadline via email to the CPRIT Helpdesk within 8 hours of the submission deadline. If CPRIT approves the applicant's request for extension, then CPRIT will reopen CARS for a 2-hour window to allow an applicant with an unsubmitted application to complete and submit it. CPRIT will document submission deadline extensions, including the reason for the extension, as part of the grant review process records.

CPRIT urges applicants to initiate the application process in CARS several business days prior to

the deadline to ensure enough time to complete and apply. The applicant's failure to adequately

review application instructions and plan accordingly to avoid unexpected issues is not sufficient

grounds to justify approval for a late submission.

6.4. **Product Development Review Fee for Full Applications**

All applicants submitting an application must pay a nonrefundable fee of \$500 to partially offset

the cost of reviewing Product Development Award applications. The application review fee must

be postmarked by the application submission deadline unless CPRIT approves a request to

submit the fee after the deadline.

Applicants should make the payment by check or money order payable to "Cancer Prevention

and Research Institute of Texas." On the check or money order, please indicate the new (this

submission) grant application ID and the name of the applicant (PI) of the application. CPRIT

cannot accept electronic or credit card payments.

Applicants using the US Postal Service to mail the application review fee should send it to

CPRIT's PO Box (see address below) DO NOT use CPRIT's physical address when mailing

checks via the US Postal Service.

Cancer Prevention and Research Institute of Texas

PO Box 12097

Austin, TX 78711

Contact name: Michelle Huddleston

Phone 1-512-305-8420

For those applicants using a delivery service (eg, FedEx, UPS) to send the application review

fee, CPRIT's physical address is as follows:

Cancer Prevention and Research Institute of Texas

Wm B Travis State Office Building

1701 N Congress Ave Ste 6-127

Austin, TX 78701

Contact name: Michelle Huddleston

Phone 1-512-305-8420

7. APPLICATION COMPONENTS

7.1. Project Narrative

The application shall consist of a project narrative of no more than 20 pages and can be arranged as text, graphs, and/or charts that will have 3 main sections: (1) a summary of the funded CPRIT project up to the submission date, including the progress made on the current G&Os of the project, (2) a detailed description of the how the requested funds will be spent and the impact the spend will have on the project, and (3) a detailed budget that is integrated into the current budget.

The section 1 summary should provide a history of the project from its inception through the current date and should provide the progress made on each of the G&Os of the current CPRIT award. Address any challenges or delays that might have occurred during the project and how those challenges or delays have been remediated. This section should also provide any updates in the competitive landscape, regulatory interactions, and any insight into how the marketing plan or reimbursement plan has changed. Section 2 of the application should provide the details of how the funds requested will be used to expedite or augment the current project. The section should outline any additional project G&Os and/or explain how the funds will be used to provide additional data or to provide additional support for the project. The third section should have a detailed budget for the funds requested that highlights where the additional funds will be spent over the current budget. This section should also provide an explanation of the company's current finances and run rate, as well as an explanation of ongoing fundraising efforts and whether the company currently has the additional match for the requested funds.

Applicants may request up to \$3 million in funding but can request no more than 30% of the company's original CPRIT budget to accelerate, augment, or supplement the currently funded CPRIT project.

7.2. Regulatory Correspondence

Applicants must upload as a single, standalone document copies of any meeting minutes, communications between the company and regulatory agencies, and summaries of interactions with regulatory authorities (eg, FDA, EMA, NMPA, CDSCO) related to the product that is the subject of the CPRIT application. This is a continuing obligation that extends over the course of the review process. If the applicant receives meeting minutes after submitting the application but

before CPRIT has made a final decision on the application, the applicant should contact the CPRIT <u>Helpdesk</u> for assistance on filing the additional information.

7.3. Personnel and Collaborators

List all project personnel in the appropriate tab in CARS, including any C-level executives, employees, collaborators, consultants, and advisors, paid or unpaid, who will provide input on this project. The list should include all individuals identified by name in any section of the application. The purpose of this section is for reviewers to be able to determine if they have any conflicts of interest with any of the listed individuals, at which point they would be required to recuse themselves from the review of the application. This list should be as complete as possible, as it is used by reviewers before they are given access to the application.

8. AWARD CONTRACTS

8.1. Overview

Texas law requires that CPRIT award grant funds via a contract between the company and CPRIT. Contract negotiation commences after the CPRIT Oversight Committee votes to approve an application for a grant award. Texas law specifies several contract terms that CPRIT must include in the executed agreement, including terms relating to revenue sharing and IP rights, matching funds, and required reporting for fiscal, progress, and compliance.

CPRIT recommends that applicants review CPRIT's Administrative Rules and its related Policies & Procedures Guide (available at www.cprit.texas.gov) for information describing contractual requirements, fiscal and program progress reporting, and limitations on the use of CPRIT grant funds. This RFA highlights information regarding revenue sharing and matching funds below.

8.2. Revenue Sharing Terms

The contract will include a revenue-sharing agreement. CPRIT publishes its standard revenue-sharing terms on its website at https://cprit.texas.gov/our-programs/product-development-research. CPRIT will include these standard revenue-sharing terms in the award contract unless parties negotiate different revenue-sharing terms that are in the interest of the state and the company.

8.3. Matching Funds

CPRIT requires a company receiving a CPRIT Product Development Research Award to pay a portion of the overall project expenses using money under the company's control. The company's expenditure of these "matching funds" must take place at the same time the company is drawing down CPRIT funds; there is no credit toward the CPRIT matching funds requirement for in-kind expenses or expenditures made prior to the CPRIT award. The company may fulfill its matching funds commitment on a year-by-year basis.

The company demonstrates that it has available matching funds when CPRIT disburses funds pursuant to an executed award contract, <u>not</u> when the company submits the CPRIT application.

CPRIT sets the amount of matching funds the company must contribute toward the project based on the total amount of CPRIT funds committed to the company:

- For companies receiving \$20 million or less from CPRIT (inclusive of previous CPRIT awards), the company must dedicate to the project \$1 of funds under the company's control for every \$2 of CPRIT grant award funds.
- A company approved for one or more CPRIT product development grants that together total a commitment of more than \$20 million must increase their matching fund obligation to \$1 for every \$1 contributed by CPRIT.
 - The increased matching fund obligation applies to the grant award that caused the grantee to exceed the \$20 million threshold. For example, a company receives 3 product development grant awards of \$3 million, \$15 million, and \$8 million (in that order) over the course of several years. Under CPRIT's matching funds policy, the company must dedicate \$8 million in matching funds to the \$8 million project (a dollar-for-dollar match obligation) because that project caused it to exceed the \$20 million threshold.
- A company approved for one or more CPRIT product development grants that together total a commitment of more than \$30 million must contribute \$2 for every \$1 provided by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the \$30 million threshold.

9. CONTACT INFORMATION

9.1. Helpdesk

The Helpdesk will answer queries submitted via email within 1 business day. Helpdesk support is available for questions regarding user registration and online submission of applications; Helpdesk staff cannot answer questions regarding scientific and product development aspects of applications. Before contacting the Helpdesk, please refer to the *Instructions for Applicants* document, which provides a step-by-step guide on using CARS. For "Frequently Asked Technical Questions," please go here.

Hours of operation: Monday through Friday, 8:00 AM to 6:00 PM central time

Tel: 866-941-7146 (toll free in the United States only - international applicants

should use the email address below)

Email: Help@CPRITGrants.org

9.2. Programmatic Questions

The CPRIT Product Development Program Manager will answer questions regarding CPRIT's Product Development Program Awards and review process, including questions regarding the scientific, product development, and business aspects of applications. For "Frequently Asked Programmatic Questions," please go here.

Tel: 512-305-7676

Email: proddey@cprit.texas.gov

Website: www.cprit.texas.gov