



CPRIT Product Development Research Award Program: FAQ

OVERVIEW

What is the CPRIT Product Development Research award program?

The Product Development Research Program at the Cancer Prevention and Research Institute of Texas (CPRIT) provides funding to Texas-based companies developing novel products or services intended to benefit patients with cancer. Applicant companies must either be based in Texas at the time of application or commit to relocate to Texas upon receipt of award. The funding provided by CPRIT is intended to assist companies in furthering the development of novel therapeutics, diagnostics/devices, and tools designed to lessen the burden of cancer.

PRODUCT DEVELOPMENT RESEARCH PROGRAM—AVAILABLE REQUESTS FOR APPLICATIONS

What awards are offered by the CPRIT Product Development Research program?

The CPRIT Product Development Research program currently offers 3 grant-funding mechanisms of support:

- Texas Company Product Development Research Award (TXCO)
- Relocation Company Product Development Research Award (RELCO)
- Seed Award for Product Development Research (SEED)

More details about these award mechanisms are covered in the FAQ below as well as on the [Apply for Funding](#) page of the CPRIT website.

How are Product Development Research awards made?

The selection process is similar across the Product Development Research award program and generally takes 6 months from application submission to award notification:

1. CPRIT posts a Request for Applications (RFA) defining application deliverables (see schedule below).
2. Companies submit applications electronically by the deadline. Applicants must pay an application fee.
3. [CPRIT's peer review panel](#) evaluates applications and selects firms to make in-person presentations. Applicants not selected are notified that they will not be moving forward in the process.
4. Invited firms present their proposed projects in person to the peer review panel. Peer reviewers score and select projects for due diligence review by outside experts. Applicants not moving forward for due diligence are notified shortly after the in-person presentations.
5. Due diligence is conducted on the technology, company, and commercial opportunity.
6. Peer reviewers assess the due diligence report and decide whether to recommend the company for funding.
7. CPRIT's Program Integration Committee and Oversight Committee vote to approve the applications recommended for funding.
8. CPRIT and the company execute a contract specifying terms and conditions for the award and funding.

How frequently does the Product Development Research program offer Requests for Applications?

CPRIT typically releases RFAs 2 times each year, with award announcements in February and August. Please refer to CPRIT's website for official RFA release schedules and deadlines.

Below is a planned schedule of current as well as tentative future award cycle dates:

Review Cycle	Award Mechanism	RFA Posting Date	Portal Opens for Submissions	Application Receipt Deadline	Award Notification
FY 2020, Cycle 2	TXCO, RELCO and SEED awards	November 20, 2019	December 4, 2019	January 29, 2020	August 2020
FY 2021, Cycle 1 (Tentative)	TXCO, RELCO and SEED awards*	May 2020*	June/July 2020*	August/September 2020*	February 2021*

*The award mechanisms and dates listed above are tentative and may be subject to change. Please refer to CPRIT's website for official RFA release schedule and deadlines.

How do the TXCO, RELCO, and SEED award programs work? Who is eligible to apply?

The TXCO, RELCO, and SEED award programs provide product development funding to select companies and projects in Texas. Companies interested in one of these awards apply and undergo CPRIT's [peer review process](#). Companies developing novel cancer therapeutics, diagnostics/devices, or tools may apply. There are no geographic criteria for applicants; however, successful awardees must meet [CPRIT's Texas location criteria](#) after receiving the award. This will entail relocation to Texas if the company is not already based in Texas.

What is the dollar amount for these awards?

SEED award applicants may request up to \$3.0 million for projects of up to 3 years in duration. TXCO and RELCO award applicants may request up to \$20 million for projects of up to 3 years in duration.

How do I decide whether the TXCO, RELCO, or SEED award mechanism is the best fit for my project?

CPRIT created the SEED award for companies that are very early in the product development timeline and may not be competitive for the TXCO or RELCO awards. The SEED award is designed to foster development of novel early-stage technologies that have demonstrated initial proof of concept (POC). SEED applicants are typically recently formed or early-stage startup companies.

In contrast, the TXCO and RELCO awards are designed for novel early-stage technologies that are in a later stage of product development in comparison to SEED award projects. TXCO and RELCO applicants are expected to have a more robust data package, regulatory strategy, and business/management team experience in comparison to the typical SEED company applicant.

While the TXCO and RELCO both target projects at the same stage of development, the key difference between these 2 mechanisms is the location of the company applicant at the time of application. The TXCO is designed for applicants that are already based in Texas, and the RELCO is designed for applicants that are based outside of Texas at the time of application and are committed to relocate the company to Texas upon receipt of award.

Potential applicants are encouraged to visit the [Apply for Funding](#) page of the CPRIT website for more information. There you can find open as well as closed RFAs for the TXCO, RELCO and SEED awards.

What stage of technology/business development is necessary to apply for a SEED award?

The typical applicant for the SEED award is a startup company that has been recently formed. At a minimum, the company has a preliminary management team.

The ideal applicant will be a company that has developed compelling discovery-stage data around a novel compound, diagnostic, device, computational tool, etc, that warrants further development efforts to establish POC on the road to commercialization.

The objective is to start with an interesting technology and to further develop it into a commercially viable business opportunity, ie, make it more attractive to private funding agents. Typically, applicants have completed the following minimum activities:

- Identified a novel technology: therapeutic, diagnostic, device, computational tool, or other nontraditional oncology technology and shown research applicability
- Shown the product can be consistently produced at a research scale
- Assessed the business opportunity and have a clear understanding of the value proposition
- Organized a preliminary business plan that addresses key development issues (eg, clinical utility/unmet need, competition, value proposition, IP strategy, technical challenges, formulation, manufacturing scale-up, clinical trial, and regulatory strategies)
- Initiated a patent application
- Established a company

As an example, in the case of drug development, the SEED award is geared toward applicants that plan to file an IND in the third CPRIT-funded project year.

As another example, in the case of medical devices, the SEED award is geared towards applicants that have developed an initial research prototype and are at a minimum able to demonstrate compelling bench data.

As another example, in the case of diagnostics, the SEED award is for applicants with a novel technology with compelling research data targeting the development of an LDT or CLIA product.

What type of work does the Seed Award fund?

The objective of a Seed Award is to fund technology product development work necessary to position the company to be attractive for private capital investment.

While the example below relates to drug development, CPRIT also funds appropriate costs for product development and validation activities associated with devices, diagnostics, computational tools, and other nontraditional oncology products or services.

As an example, in the case of drug candidates, the Seed Award funds specific technical activities such as:

- Performing target validation
- Conducting lead optimization
- Performing target and cellular potency studies
- Exploring activity in xenograft models and determining PKs and exposure; testing whether concentrations that result in significant cell death in vitro can be achieved safely in vivo
- Evaluating biopharmaceutical properties (absorption in rodents and nonrodents, clearance, and bioavailability)
- Optimizing synthetic/bioengineering route; developing prototype clinical formulation

- Expanding preclinical safety characterization; performing PK and PD assessments
- Evaluating biodistribution

What stage of technology/business development is necessary to apply for a TXCO or RELCO award?

The typical applicant for the TXCO/RELCO award is a startup or established company that has been in operation for some time and has a well-developed management team.

Strong candidates for the TXCO and RELCO awards will need to present a sufficiently robust data package, regulatory strategy, value proposition, and experienced business/management team to warrant the amount of award funding requested. For example, an ideal candidate for a TXCO or RELCO award might include in their application the following:

- A significant data package establishing robust POC in multiple relevant studies
- Initial data supporting safety of the product (if applicable)
- Significant demonstration of manufacturability and scale-up potential
- Robust clinical and regulatory strategies
- Strong value proposition clearly communicated within a business plan
- Management team with significant industry experience as appropriate for the technology type
- Significant IP portfolio
- Typically licenses have been completed at the time of application

As an example, in the case of drug development, a strong candidate for consideration for a TXCO or RELCO might be a company that is approximately 12 months or less from filing their IND.

As another example, in the case of medical devices, the TXCO/RELCO award is geared towards applicants that have developed a fieldable prototype and are able to demonstrate compelling clinical research data, biocompatibility analysis, and animal data, and targeting first-in-human trials.

As another example, in the case of diagnostics, a strong applicant for consideration for a TXCO/RELCO might be a company that is able to demonstrate compelling human clinical data on sensitivity (with disease) and specificity (without), in addition to competitive comparable performance data to support conversion to IVD (501k or PMA).

What type of work is funded by a TXCO or RELCO award?

CPRIT funds novel approaches to drug development, diagnostic applications, medical device development, and other nontraditional oncology applications. CPRIT seeks to maximize the clinical impact of CPRIT funding.

As an example, in the case of drug development, CPRIT investment may include the following eligible stages:

- Studies that establish preclinical POC
- GLP studies to support INDs
- Phase 1 to establish safety and a maximally tolerated dose
- Phase 2 studies to determine safety and efficacy in initial targeted patient populations (up to 100 patients)

HOW FUNDS MANAGEMENT WORKS

Which project expenditures will the TXCO, RELCO, and SEED awards reimburse?

Most expenditures related to developing the technology are reimbursable subject to [CPRIT standard policies](#). Companies may use CPRIT funds to support salaries and benefits, use of external consultants, laboratory expenses, manufacturing costs, equipment, facilities costs, and travel. Specific activities and milestones will vary by category.

How are funded awards managed?

CPRIT disburses funds according to a contract with the company that includes agreed-upon project goals, objectives, and timelines. Typically, CPRIT provides company funding in tranches. The first tranche is advanced after contract execution and subsequently with the accomplishment of specific project goals and objectives. Companies must submit periodic updates; continued release of funds is contingent upon the company making satisfactory progress toward project objectives. Companies [must contribute “matching funds”](#) of at least half of the award amount toward the project. All CPRIT contracts include a revenue-sharing agreement. Typically [CPRIT receives a royalty-based return](#) when the CPRIT-funded products are commercialized. CPRIT does not take a board seat.

Do I need to raise capital before applying?

No, but the company must certify it will contribute 50% of the amount of the first-year budget toward the project in matching funds before CPRIT will disburse any funds. After the first year and for each subsequent year, the company must verify that it has spent its matching funds totaling at least one-half of the award amount on the project.

TEXAS LOCATION CRITERIA

Does a company need to be located in Texas to apply?

No, the applicant may be located outside of Texas when the application is submitted and reviewed. However, the applicant must commit to relocating to Texas as a condition of executing the award contract. All companies receiving CPRIT awards must be based in Texas during the entire contract term and remain in the state for at least 3 years after the contract ends.

What does it mean to be a “Texas-based” company?

An applicant is considered to be Texas-based if it meets a majority of [CPRIT’s Texas location criteria](#).

Does a wholly owned subsidiary located in Texas or willing to relocate to Texas qualify for a product development grant if the subsidiary’s parent corporation is based outside of Texas?

Yes, as long as the subsidiary meets [CPRIT’s Texas location criteria](#) during the contract term and for at least 3 years after the contract ends.

What happens if a company that receives a CPRIT award leaves Texas after the CPRIT contract has ended?

A company that receives a CPRIT grant must remain Texas-based company for at least 3 years after the contract has ended or repay all CPRIT funds as a penalty.

Is it required for the technology to have been developed originally at a Texas research institution?

No; however, the company developing the technology must be based in Texas and continue to operate in the state once it has received a Product Development award.

How much of the CPRIT award amount is allowable to be spent on goods and services purchased outside of the state of Texas?

A grantee that expends more than 40% of grant funds budgeted in a grant year on goods and services purchased outside of Texas must provide a written explanation of the good faith efforts the grantee used to purchase in-state goods and services. CPRIT may deny reimbursement or require repayment of grant funds if the grantee fails to sufficiently explain the reasons for doing so in the annual HUB and Texas Supplier form. The annual Texas Supplier information is not cumulative; it should reflect only purchases made during the relevant grant year. If purchases made from suppliers outside of Texas during the grant year do not rise to the 40% reporting threshold, the form should indicate “purchases less than 40% of budgeted grant funds in the grant year.”

Please refer to the CPRIT [Policies and Procedures Guide](#) for additional information.

APPLICATION FAQs

Where in the application does an applicant have to demonstrate availability of matching funds, and how should that information be presented? Which types of sources for matching funds are acceptable?

A company is not required to have raised the entire matching amount at the time of application. If your application is successful and ultimately recommended for funding, availability of matching funds will be documented and verified during the contract initiation process. If an application is successfully awarded, the grantee will need to have raised at least the Year 1 matching amount and be able to show proof of match for their Year 1 budget before CPRIT can release the Year 1 tranche of funds.

According to CPRIT's Administrative Rules, Chapter 703, [Section 703.11](#), matching funds may include both federal funds (eg, NCI) and nongovernmental funds (including private funds, foundation grants, gifts, and donations). To view additional information regarding matching funds, please visit www.cprit.texas.gov and search for Administrative Rules.

We are a new company applying for a product development research award. The company is currently based in a different state, but we would move to Texas if awarded the contract. On Tab 2, what should I indicate as the State Senate District and State House District?

Applicants not currently based in Texas should enter the State Senate and State House districts of their proposed new location.

We were wondering whether there were any guidelines/restrictions on the proportion of requested funding that can be applied to our relocation costs. (For example, only 5% of the total grant could be spent on relocation costs.) Also, could you provide any guidance on the types of expenses that can be included in the relocation costs?

There is no official limit or maximum percentage of funding allowed for relocations costs. The types of expenses that can be included in the relocation costs do NOT include relocating personnel but DO include recruiting costs (with some restrictions) and the cost of transporting equipment from your current facility. CPRIT limits the amount of indirect expenses that can be reimbursed with grant funds to 5% of the CPRIT award. Rent and utilities cannot be directly tied to the product development project, so these costs are subject to the 5% indirect cost limit.

Our company does not have a sponsored programs office with a designated ASO. Can the applicant also be assigned as the ASO on the same application?

Yes, it is acceptable (and not uncommon) for the applicant to also serve as the designated ASO. However, if the applicant intends to also serve as the ASO, the system requires that the Applicant and the ASO have 2 different accounts and user names. When submitting your application, it is critical to allow enough time to create these different accounts.

Are applicants required to select a Grants Contract/Office of Sponsored Projects Official (GC/OSPO) for the application? What is the purpose of that role?

The GC/OSPO is indeed a required application role. However, the GC/OSPO does not have any responsibility for application submission. The proper individual, who must be assigned by the Applicant, would serve primarily as an assistant to the ASO in the event that a grant contract is executed.

The annual salary that an individual may receive under a CPRIT award is currently \$200,000. Does this mean an individual cannot have a base salary greater than \$200,000 or that the most an individual can

request is up to \$200,000 of their base salary based on effort on project?

The maximum direct salary that an individual can request is \$200,000. Thus, an individual with a base salary of \$250,000 can request the salary cap of \$200,000 with 100% effort. The same individual that contributes 50% effort may request \$100,000.

Are cost adjustments (ie, 3% salary increase) to capped salaries allowed for multiyear awards?

No, cost adjustments to capped salaries are not allowed.

What percentage of the requested funding can be used for indirect costs?

Texas state law limits the amount of awarded funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs).

My company is newly formed and does not yet have a DUNS number. Is a DUNS number a required part of the application?

While a DUNS number may be submitted as part of the application, provision of a DUNS number is not required. However, if your company is selected for an award, the company will need to supply a DUNS number during contracting.

MISCELLANEOUS

Can Product Development Awards be made to nonprofit entities?

Yes, if the entity intends to bring a product to market.

Does CPRIT consider all proposal content to be confidential to the proposing company? Will any element of the proposal content be publicly released?

By law, the name and address of the applicant, the amount of funding requested, and the type of cancer addressed by the application are not confidential and must be released if CPRIT receives a request for that information. State law protects the confidentiality of information in the applications submitted to CPRIT. If you have a specific question about the confidentiality of information submitted to CPRIT or how CPRIT treats confidential information in the review process, please contact CPRIT's general counsel at 512-463-3190.

Must CPRIT receive our Product Development Review Fee (\$1,000 for TXCO or RELCO, \$500 for SEED) by the application submission deadline?

No, the application fee does not have to be received by the application submission deadline. However, unless a request to submit the application fee late has been approved by CPRIT, the fee must be received by CPRIT within 7 business days of the application deadline or CPRIT will withdraw the application from the review cycle, and it will not be considered for an award.

Are resubmission applications required to pay the application fee?

Yes, an applicant must pay the Product Development Review fee for every application submission, whether it is a new application or a resubmission.

I submitted a grant application that did not go through peer review. Will CPRIT refund the fee I paid for that application?

If an application was withdrawn by the applicant or CPRIT during the administrative review process and was not reviewed by the peer review committee, CPRIT will refund the application fee. The applicant should send a written request (email is acceptable) to CPRIT for a refund. However, if the application proceeds to peer review and the applicant chooses to withdraw the application after peer review has commenced, the application is not eligible for refund.

Our company applied unsuccessfully for a CPRIT award in the past. Is it considered a resubmission if our company submits a new project that is different from the project application that was previously rejected?

If your application describes a completely new project, then CPRIT considers this a new application and not a resubmission. However, if the application describes the same or substantially similar project that was proposed previously to CPRIT within the past 2 years, then your application would be considered a resubmission. More information on resubmission guidelines can be found in the Resubmission Policy described in the TXCO, RELCO, and SEED RFAs.

For more information, please visit www.cprit.texas.gov or contact:

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