

INSTRUCTIONS FOR APPLICANTS

Texas Diagnostic and Devices Company Awards for Product Development Research RFA C-24.2-TDDC

Texas New Technologies Company Awards for Product Development Research RFA C-24.2-TNTC

Texas Therapeutics Company Awards for Product
Development Research
RFA C-24.2-TTC

SEED Awards for Product Development Research RFA C-24.2-SEED

FY 2024

Fiscal Year Award Period September 1, 2023-August 31, 2024

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VERSION HISTORY

Rev 12/1/2023 Instructions for Applicants document posted

1. INTRODUCTION

The Cancer Prevention and Research Institute of Texas (CPRIT) Application Receipt System (CARS) provides a means for the product development community (ie, applicants and Application/Authorized Signing Officials [ASOs]) to respond to CPRIT funding opportunities electronically over the Internet through a secure connection. This document provides instructions and guidance to applicants on how to successfully submit an application in response to CPRIT's Requests for Applications (RFAs) for FY 2024 Cycle 2. Preliminary applications must be submitted by December 11, 2023, 4 PM central time, and invited full applications must be submitted by February 13, 2024, 4 PM central time.

2. SUMMARY INSTRUCTIONS

- **Technical Support:** Applicants are strongly advised to carefully read this document in its entirety before starting an application. The CPRIT Helpdesk (section 18.1) is available to answer technical questions and guide applicants with application submission. This *Instructions* document will be updated as necessary. Revisions will be listed in the *Revision History*.
 - Note that CARS is not compatible with mobile technology (eg, Surface Pro, iPad). It is recommended that applicants use a PC to complete the application submission process.
- User Accounts: The applicant (Principal Investigator [PI]; the person responsible for the overall performance of the project) and an ASO (a person authorized to sign for the organization) will each need to create user accounts in CARS. These are 2 different roles, and an account for each is required in order for an application to be submitted. NOTE: Future tabs of the application, including the budget, will be prepopulated with the applicant's information, and should a contract be awarded, the applicant will serve in the role of PI. If your company is not listed in the dropdown menu, please email the Helpdesk (contact information in section 18.1) and provide the information noted in section 6.2; please allow up to 5 business days to complete this request. The same person may serve as both the applicant and the ASO; however, a separate account (with a separate username and password) must be set up for each role. An application cannot be submitted without ASO approval.

- **Document Format for Uploaded Files:** Use Portable Document Format (PDF) only.
 - Do NOT password protect documents.
 - o Do NOT submit documents that are bound together in a single PDF package.
- Font Type/Size: Arial (11 point), Calibri (11 point), or Times New Roman (12 point).
- **Page Format:** Single spacing, 0.75-inch margins in all directions.
- **Templates:** Templates are located in in the *My Applications: Summary* tab. The application template named "Product Development Research Programs: Biographical Sketches" should be used for biographical sketches. The template named "Product Development Research Programs Capitalization Table" must be used for the capitalization table.

• Submission Process:

- Application submission requires both a preliminary application and a full application.
 A full application may not be submitted unless it has been invited following preliminary application review.
- The applicant completes/finalizes a series of numbered tabs of the application.
- o Finalized tabs can be reset by the ASO.
- Once all tabs are finalized, the ASO reviews, approves, and submits the application to
 CPRIT by the deadlines indicated.

• Tab Finalization and Reset:

Application information saved as "draft" can be edited at a later time. Once
 application information is "finalized for ASO approval," it can be edited only after an
 ASO has reset the section to draft mode at the request of the applicant.

3. APPLICATION SUBMISSION DEADLINES

Preliminary applications must be submitted by December 11, 2023, 4 PM central time. Following review of the preliminary application, it is anticipated that invitations to submit a full application will be issued by January 24, 2024. The full application submission deadline is February 13, 2024, 4 PM central time.

4. APPLICATION PREPARATION AND SUBMISSION PROCESS

- Application submission is a 2-step process requiring both a preliminary application and a
 full application. A full application may not be submitted unless it has been invited
 following preliminary application review.
- To submit an application, the applicant completes all sections except Tab 5 in a
 preliminary application or Tab 6 in a full application. The system then automatically
 sends an email forwarding the application to the ASO for review and final submission to
 CPRIT.
- Finalized tabs can be reset by the ASO as needed.
- Once all tabs are finalized, the ASO reviews, approves, and submits the application to CPRIT.
- Preliminary and full applications must be submitted by an ASO by the deadlines indicated.
- **NOTE:** CARS will be unavailable the third Thursday of each month between 7 PM and 9 PM central time for routine system maintenance.

5. PERSONNEL AND APPLICATION ROLES IN CARS

5.1. Required Personnel

- **Applicant (PI):** The applicant oversees the project and is responsible for the overall performance of the funded project. The applicant completes and finalizes a series of numbered tabs of the application. The applicant starts the application in CARS.
- Application/Authorized Signing Official (ASO): The ASO is the organization's representative that is authorized to officially submit the application to CPRIT. The ASO is identified by the applicant in CARS, can reset applicant-finalized tabs to draft at the request of the applicant, and submits the application. The ASO submits the application in CARS.
- Grants Contract/Office of Sponsored Projects Official (GC/OSPO): The GC/OSPO manages the grant contract if the award is made. The GC/OSPO is identified by either the applicant or ASO in CARS. The GC/OSPO must be entered in CARS but does not have a required role in application submission.

Note that in some organizations without an Office of Sponsored Projects, the roles of the applicant and/or ASO as well as Grants Contract Official may be assigned to the same individual. However, this individual will need to have separate accounts in CARS to carry out each of these distinct roles (see <u>section 6.1</u> below).

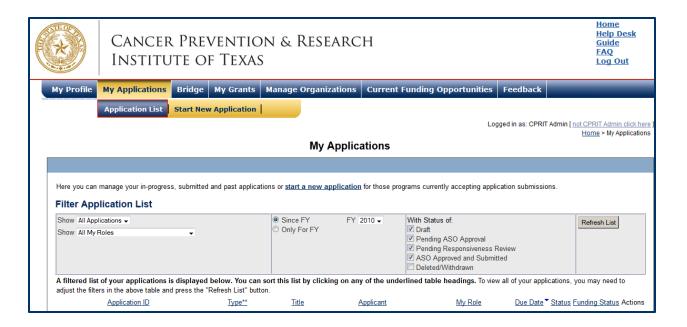
5.2. Optional Personnel

- Co-Applicant (Co-I): The co-applicant assumes equal responsibility with the applicant
 for overall performance of the funded project. The co-applicant can start the application
 in CARS.
- Alternate Submitter: The alternate submitter is designated by the applicant to complete applicant tasks in CARS. *The alternate submitter can start the application in CARS*.
- Alternate ASO: The alternate ASO is designated by the ASO to complete ASO tasks in CARS.

6. REGISTRATION AND "MY PROFILE" SETUP

6.1. User Registration

Applicants begin the application process by registering or logging in to CARS (https://CPRITGrants.org). All users can register for an account in the Sign In/Register section of the home page. To register, select the Register here link and complete the required information. applicants, co-applicants, and alternate submitters should register as an applicant (or someone who works for one). An ASO, alternate ASO, or GC/OSPO should register as an ASO (or someone who works for one). New organizations should set up both an Applicant account and an ASO account at this time. Upon successful login to the system, the applicant will be presented with the My Applications page screen shown below:



All previously submitted applications by the applicant are listed on this page. After initial registration or after login, all users are encouraged to complete/verify the information under the *My Profile* link on the top left corner of this screen. All profile information should be completed before a user is added to an application.

6.2. Organization Registration

If your organization does not appear in the dropdown list during registration, please contact the <u>Helpdesk</u> for assistance. In order to create or reactivate an organization, the Helpdesk will need the following information, which should be sent in an email to <u>help@cpritgrants.org</u>:

- Organization Name (exactly as you want it to appear in our system)
- Employer Identification Number (EIN)
- Organization Type (academic or nonacademic)
- Fiscal year end date (for example, CPRIT's fiscal year ends on 8/31/2024)
- What deadline do you need to meet?
- To which mechanism will you be applying?

Applicants are advised that CPRIT cannot guarantee that a request to add an organization in CARS will be approved immediately. **Please allow up to 5 business days for approval of your request**.

If your organization does not yet have an EIN, please visit https://www.irs.gov/businesses/small-businesses-self-employed/apply-for-an-employer-identification-number-ein-online to get one. The EIN application process should take about 15 to 20 minutes and must be completed in a single session. The EIN will be provided immediately upon successful completion of the process.

6.3. My Profile

Profiles contain contact information for individuals and organizations. The user profile contains information that will be used to autofill some of the fields in the application.

6.4. ORCID iD

Applicants may link their CARS profiles to their ORCID iDs on an optional basis so that CPRIT can have access to the applicant's ORCID profile at the time of application submission.

Upon a user's first login in this review cycle, the user will be prompted with a modal window (see below) announcing support for ORCID authentication with the ability to opt out of any further notifications. If the user selects "Do not show this window again," the user will not be prompted again.

As directed by the modal window displayed below, during the initial login, on the "My Profile" page, the user is displayed a description of the authentication process and is invited through an ORCID-branded link to correlate his/her CARS and ORCID profiles. Note that the system will also provide identical functionality within the "Contacts" tab of all new applications.



Upon clicking on the ORCID-branded link, the system will open a new tab on the user's browser that will direct the user to enter his/her ORCID username and password. <u>Users without an ORCID account can initiate one from this window.</u>

Upon a successful login to the ORCID system, the user will be directed to a modal window that explicitly requests permission from the user to share his/her public ORCID profile with CARS.

If permission to correlate the 2 accounts has been provided by the authenticated user, the system then returns the user to the page from which the authentication started (ie, either the "My Profile" page or the "Contacts" tab of a new application). The system will then display a brief message confirming the authentication and replacing the ORCID-branded link with a new button that directs the user to his/her specific ORCID profile page.

7. STARTING A NEW OR RESUBMISSION APPLICATION

7.1. Starting a New Preliminary Application

New preliminary applications can be started in 1 of 2 ways:

- My Applications (this is the default post-login page) → click Start New Application →
 FY 2024 Product Development Research Programs → select the appropriate Preliminary
 Application RFA → click New Application or
- Current Funding Opportunities → click FY 2024 Product Development Research
 Programs → select the appropriate Preliminary Application RFA → click Start New
 Application

Upon starting a new preliminary application, applicants are required to enter the title (160-character limit, including spaces; can be edited later) and select the submitter role. Do NOT use symbols or special characters (eg, Greek letters, bullets)—these will not be transmitted correctly.

Applicants are advised to carefully read the information on the summary page before moving on to the numbered tabs.

- Tab 1 (Contacts) **must** be completed/finalized before Tab 3 (Project Personnel & Collaborators).
- Tab 2 (Application Information) must be completed/finalized before Tab 5 (Budget). Other tabs may be completed in any order. Applicants must successfully complete/finalize all tabs to obtain ASO approval before the preliminary application can be successfully submitted by the ASO. Detailed instructions for completing each tab can be found beginning in section 10.

7.2. Starting a New Full Application

- **NOTE:** An invitation following review of the preliminary application is required to start a full application. Please see the appropriate RFA document for details on the preliminary application peer review process.
- New full applications can be started from the *My Applications* page by clicking the *Start Full Application* link that will be enabled and associated with a preliminary application once a full application has been invited.
- Upon starting a full application, applicants may revise the title (prepopulated from the previous submission; 160-character limit) and select the submitter role. Do NOT use symbols or special characters (eg, Greek letters, bullets)—these will not be transmitted correctly. Once this step is completed, applicants will be directed to the summary page.
 NOTE: Only the title of the previously submitted preliminary application is prepopulated for a full application. All other information, including that for a co-applicant, collaborators, and all required documents, must be submitted de novo.

Carefully read the information on the summary page before moving on to the numbered tabs.

- Tab 1 (Contacts) **must** be completed/finalized before Tab 3 (Project Personnel & Collaborators).
- Tab 2 (Application Information) must be completed/finalized before Tab 5 (Budget).

Other tabs may be completed in any order. Applicants must successfully complete/finalize all tabs to obtain ASO approval before the full application can be successfully submitted by the ASO. Detailed instructions for completing each tab can be found beginning in section 10.

7.3. Starting a Resubmission Application

- Resubmissions of applications previously submitted to the FY 2023 or FY 2024 Product Development Research program and not recommended for funding can be started from the *My Applications* page by clicking the *Start Resubmission Application* link of a previously not recommended preliminary or full application. Upon clicking the link to start a resubmission application, the system will generate a preliminary application, regardless of whether the previous application was a preliminary or full application.
- An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the applicant or company representative for a project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. A change in the type of RFA such as changing from a Texas Therapeutic Company application to a SEED application may constitute a resubmission depending on the number and degree of changes from one application to the other. In such cases, the applicant should contact the program office prior to initiating the subsequent application. In addition, the application is a resubmission only if the previous application was finalized and submitted; the application is not a resubmission if the previous application was left as a draft or withdrawn by CPRIT without review.
- If an applicant wishes to resubmit an application that was submitted to CPRIT prior to FY 2023, the applicant should start a new preliminary application and provide a Resubmission Summary outlining how the application has been improved in response to the previous critiques as described in section 7.5 of the RFA.
- Upon starting a resubmission application, applicants may revise the title of the application (prepopulated from the previous submission; 160-character limit) and select the submitter role. Do NOT use symbols or special characters (eg, Greek letters, bullets)—these will not be transmitted correctly. Once this step is completed, applicants will be directed to the summary page. **NOTE:** Only the title of the previously submitted

application is prepopulated for a resubmission application. All other information, including that for a co-applicant, collaborators, and all required documents, must be submitted de novo.

Carefully read the information on the summary page before moving on to the numbered tabs.

- Tab 1 (Contacts) **must** be completed/finalized before Tab 3 (Project Personnel & Collaborators).
- Tab 2 (Application Information) **must** be completed/finalized before Tab 5 (Budget) [full applications only].

Other tabs may be completed in any order. Applicants must successfully complete/finalize all tabs to obtain ASO approval before the application can be successfully submitted by the ASO. Detailed instructions for completing each tab can be found beginning in section 10.

8. STATUS DISPLAY

8.1. Tab Status

The status of each tab is displayed under the row of numbered tabs. The figure below is an example of the status of Tab 1.



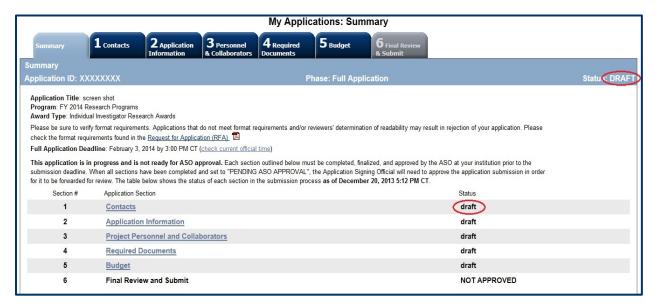
Status	Status Definition		
DRAFT	The tab is being prepared by the applicant.		
PENDING ASO APPROVAL	The tab has been finalized by the applicant. When all tabs are finalized and reflect this status, the ASO will receive email notification stating that the application can be reviewed/submitted. The applicant is included on this notification.		
ASO APPROVED AND SUBMITTED	The ASO has reviewed, approved, and submitted the application to CPRIT. Once the application has been submitted by the ASO, the PI is notified via email.		

8.2. Application Status

The status displayed under the row of numbered tabs on the *Summary* tab indicates the status of the entire application (as indicated in the figure below in <u>section 9</u>—see Status: DRAFT circled in red).

9. TAB: SUMMARY

The status of each tab is also displayed on this page. Status definitions are described below.



Status	Status Definition		
DRAFT	The tab is being prepared by the applicant.		
PENDING ASO APPROVAL	The tab has been finalized by the applicant. When all tabs are finalized and reflect this status, the ASO will receive email notification that the application can be reviewed/submitted. The applicant is included on this notification.		
NOT APPROVED	The application has not been approved/submitted by the ASO.		
PENDING	All tabs have been finalized by the applicant and reflect the status "pending ASO approval." At this point, the application is awaiting ASO approval and subsequent submission.		

NOTE: As stated in the preceding section, the status displayed under the row of numbered tabs on this page indicates the status of the entire application.

10. TAB 1: CONTACTS

- **Applicant (PI):** Applicant information is entered automatically; the ASO and GC/OSPO are identified and added by the applicant. Verify information for the applicant; update as necessary.
- Co-Applicant (Co-PI; Optional): If desired, 1 co-applicant may be designated on the application. For the Product Development Research program, a co-applicant is an individual designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. If so designated by the applicant organization, co-applicants share the authority and responsibility with the applicant for leading and directing the project, intellectually and logistically. When 2 applicants are named, each is responsible and accountable for the proper conduct of the project, program, or activity, including the submission of all required reports. The presence of more than 1 applicant on an application or award diminishes neither the responsibility nor the accountability of any individual applicant.

To designate a co-applicant, do the following:

- Click the *Search for Co-Applicant* button.
- Enter information and click the *Search Contacts* button.
- If the individual is listed on the subsequent search results page, that individual may be added to the application via the *Add Contact* link.
- If the individual is not listed, different search criteria may be used; for example, using the last name only as well as spelling variations. Alternatively, invite the individual to register in CARS and be part of the application by clicking the Send Them an *Invitation* link. On the subsequent page, complete the fields, and click the *Send Invitation* button. When this individual joins the application as a co-applicant, his or her information will be listed in the appropriate section of the tab.
- o Change or remove an individual by clicking the appropriate button.
- Alternate Submitter (Optional): If an alternate submitter is to be designated on the application, click the Search for Alternate Submitter button. Follow the search guidelines above.

 Application/Authorized Signing Official: The ASO is an individual authorized to submit an application on behalf of an organization. An ASO is required and must be identified by the applicant. The ASO role may also be filled by the applicant using a separate account.

As the organization's representative, the ASO is required to review the tabs finalized by the applicant and submit the application. Only the ASO is authorized to officially submit the application to CPRIT. The ASO can reset applicant-finalized tabs to draft mode at the request of the applicant.

An ASO <u>must</u> be listed in order to complete/finalize this tab. Click the *Search for Application Signing Official* button. Follow the search guidelines above.

- Alternate Application/Authorized Signing Official (Optional): This individual can be assigned only by the ASO. Follow the search guidelines above.
- Grants Contract/Office of Sponsored Projects Official: The GC/OSPO is the individual who will assist the ASO in managing the grant contract if an award is made. This role may be filled by an individual also serving as the applicant and/or the ASO or by a separate individual. The applicant assigns this individual to this role.

A GC/OSPO <u>must</u> be listed in order to complete/finalize this tab. Follow the search guidelines above.

NOTE: For each individual on this tab, please provide a direct phone number (with extensions, if applicable) and include a cell number as an alternate phone number. Please do not include main phone numbers that require navigation through a directory menu.

After a contact is added to the application, only the assigned contact can update his or her information within the application. When all information is entered, click *Finalize Contacts Section*. Note that this tab cannot be finalized until the 3 required fields of this section—namely, "Applicant," "Application/Authorized Signing Official," and "Grants Contract/Office of Sponsored Projects Official"—have been completed.

11. TAB 2: APPLICATION INFORMATION

11.1. Application Information for Preliminary Applications

• Application Identification

- Award Mechanism: Verify the listed award mechanism. Note that the award mechanism cannot be changed here.
- **Application Type:** Verify the application type (droplist defaults to *New Application* or *Resubmission*, as applicable).
- o **Application Title:** Review the application title and edit if necessary.
- Category of research/project to be supported: Select the appropriate option for whether the proposed project will be directed toward childhood and adolescent cancer. If Yes is selected, provide a brief description of the childhood and adolescent focus.

• Project Information

- Requested Award Duration: Enter requested award duration. Only whole numbers are allowed.
- Award Amount Requested: Provide the anticipated budget request for the project;
 this should reflect only CPRIT-requested funds. Do *not* include other amounts that
 will comprise the total budget for the project, including the use of matching funds.

• Product Development

- Regulatory Filing: Select "Yes" if the proposed project will lead to the development of a product that requires regulatory filing.
- Regulatory Agency Communication: Select "Yes" if the Applicant (PI) has communicated with a regulatory agency.

• Cancellation of Applications/Awards by Granting Organization (in past 5 years)

- Select whether the applicant is currently eligible to receive federal grant funds. If no,
 please provide the reason in the dropdown text box.
- Select whether the applicant had an application or award terminated for cause within the last 5 years. If yes, then select the category of Application or Award. Select the Granting Organization. Enter the Award Title, Award Number, Award Amount, and

the Reason for Cancellation. Click the *Add Application/Award* link to include additional applications or awards.

Donations

Select whether the applicant or any individual listed on the application has made a donation, gift, or grant to CPRIT, the CPRIT Foundation, the Texas Cancer Coalition, or any nonprofit organization/entity established to benefit CPRIT. If yes, then enter the name of the donor, entity name, donation amount, and date of donation. Click the *Add Donation* link to include additional donations.

• CPRIT Priorities Addressed (from Statute or Texas Cancer Plan)

 Choose the CPRIT priority addressed in the application. More than 1 priority may be selected.

Review the instructions and click the appropriate box (*Save Application Information as Draft* or *Finalize Application Information for ASO Approval*) to save entered application information.

NOTE: Application information saved as a "draft" can be edited at a later time. Application information "finalized for ASO approval" can be edited only after the ASO has reset the section to draft mode at the request of the applicant.

11.2. Application Information for Full Applications

• Application Identification

- Award Mechanism: Verify the listed award mechanism. Note that the award mechanism cannot be changed here.
- Application Type: Verify the application type (droplist defaults to New Application or Resubmission, as applicable)
- o **Application Title:** Review the application title and edit if necessary.
- Category of research/project to be supported: Select the appropriate option for whether the proposed project will be directed toward childhood and adolescent cancer. If Yes is selected, provide a brief description of the childhood and adolescent focus.

• Project Information

 Requested Award Duration: Enter requested award duration. Only whole numbers are allowed. Please provide a list of all projected sources of funding for this project (do not include

CPRIT as a funding source).

o Indicate whether you have received at least 1 round of Professional Institutional

Funding (ie, Series A financing or a substantive equivalent).

Application Fee

For full applications only, all applicants must submit a nonrefundable Product

Development Review Fee. SEED applicants must submit a review fee of \$500, all other

mechanisms must submit a review fee of \$1,000. Payment should be made by check or

money order payable to CPRIT; electronic payments are not accepted at this time. The

application ID and applicant name must be indicated on the payment. Unless a request to

submit a late application fee has been approved by CPRIT, all payments must be

postmarked by the full application submission deadline and mailed as described below.

Checks may be mailed via the US Postal Service to the following address:

Cancer Prevention and Research Institute of Texas

PO Box 12097

Austin, TX 78711

Contact name: Michelle Huddleston

Phone 1-512-305-8420

Mail sent via a delivery service (ie, FedEx, UPS, etc) will need to use this address:

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

• Application Classification

- o Company Focus: Select the research area that best describes the proposed work.
- Detailed Company Focus: To define the company focus more narrowly, select up to
 3 choices from the Detailed Company Focus list.
- o **Program Focus:** Select the focus of the proposed work.
- Cancer Focus Addressed: Select the cancer site(s) that will be addressed during the proposed project.
- Vertebrate Animals: Indicate whether vertebrate animals will be used.
- Biologic/Anatomic Substances: Indicate whether cadavers will be used. In addition, specify the use of human anatomical substances. If human anatomical substances will be used, specify if the substances are traceable to specific donors. Also, select applicable safety provisions.
- **Human Subjects:** Indicate whether human subjects will be used. Specify the sex, age, ethnicity, and race of the study population. Specify the method of data collection. Provide the general demographic focus. Select the type of clinical trial, if applicable.

• State Legislative Districts

- State Senate District: Enter the state Senate district of the applicant's institution.
 Use the link provided to find this information using the applicant's institutional address.
- **State House District:** Enter the state House district of the applicant's institution. Use the link provided to find this information using the applicant's institutional address.
- Applicants not currently based in Texas should enter the state Senate and state House districts of their proposed new location.

• Cancellation of Applications/Awards by Granting Organization (in past 5 years)

- Select whether the applicant is currently eligible to receive federal grant funds. If no, please provide the reason in the dropdown text box.
- Select whether the applicant had an application or award terminated for cause within the last 5 years. If yes, then select the category of Application or Award. Select the Granting Organization. Enter the Award Title, Award Number, Award Amount, and the Reason for Cancellation. Click the *Add Application/Award* link to include additional applications or awards.

Donations

Select whether the applicant or any individual listed on the application has made a donation, gift, or grant to CPRIT, the CPRIT Foundation, the Texas Cancer Coalition, or any nonprofit organization/entity established to benefit CPRIT. If yes, then enter the name of the donor, entity name, donation amount, and date of donation. Click the Add Donation link to include additional donations.

• CPRIT Priorities Addressed (from Statute or Texas Cancer Plan)

 Choose the CPRIT priority addressed in the application. More than 1 priority may be selected.

Review the instructions and click the appropriate box (*Save Application Information as Draft* or *Finalize Application Information for ASO Approval*) to save entered application information.

NOTE: Application information saved as a "draft" can be edited at a later time. Application information "finalized for ASO approval" can be edited only after the ASO has reset the section to draft mode at the request of the applicant.

12. TAB 3: PROJECT PERSONNEL & COLLABORATORS

It is your responsibility to enter information for <u>all project personnel</u>, including any collaborators and advisors, paid or unpaid. The list should include all individuals named in the application. The purpose of this section is for reviewers to be able to determine if they have any conflicts of <u>interest with any of the listed individuals</u>, at which point they would be required to recuse themselves from the review of the application. When all information is entered, click *Finalize Project Personnel & Collaborators*.

13. TAB 4: REQUIRED DOCUMENTS

The system will not allow upload of documents that exceed the page limits specified in the RFA for the award mechanism. Do NOT password protect documents.

Applicants are advised to carefully read these instructions and the appropriate RFA.

The following abbreviations are used in the RFA section references below:

 TDDC: Texas Device and Diagnostics Company Awards for Product Development Research

- TNTC: Texas New Technologies Company Awards for Product Development Research
- TTC: Texas Therapeutic Company Awards for Product Development Research
- SEED: SEED Awards for Product Development Research

13.1. Required Documents for Preliminary Applications

13.1.1. Enter Abstract (use text box provided)

- **RFA section reference:** section 7.1 (TDDC, TNTC, TTC, SEED)
- Character limit: 1,500 character maximum, including spaces
- Do NOT use symbols or special characters (eg, Greek letters, bullets)—these will not be transmitted correctly. Save the entered information. Information must be saved before any documents are uploaded or the abstract will be lost when the upload refreshes the Web page.

13.1.2. Upload Executive Summary (PDF Format)

- **RFA section reference:** section 7.2 (TDDC, TNTC, TTC, SEED)
- Page limit: 2-page maximum-
- CPRIT encourages applicants to provide concise responses in bulleted format.

13.1.3. Upload the Slide Presentation (PDF Format)

- **RFA section reference**: Section 7.3 (TDDC, TNTC, TTC, SEED)
- Page limit: 16-page maximum
- The presentation should be submitted in PDF format, with 1 slide filling each landscapeorientated page. The slides should succinctly capture all essential elements of the application and should stand alone as a visual representation of the application.

13.1.4. Upload Proposed Project Aims and Budget (PDF format)

- **RFA section reference:** Section 7.4 (TDDC, TNTC, TTC, SEED)
- **Page limit:** 1-page maximum
- Succinctly describe the aims of the proposed project, and provide an anticipated budget request for the project, linking the aims to expected budget amounts. The budget request

should be limited to the amount to be requested from CPRIT and should not include other sources of funding, including matching funds.

13.1.5. Resubmission Summary (PDF format)

- **RFA section reference:** Section 7.5 (TDDC, TNTC, TTC, SEED)
- Page limit: 1-page maximum
- If the project was submitted as a preliminary or full application to CPRIT in previous fiscal years, upload a summary of the revised approach, including a summary of the applicant's response to specific feedback.

13.2. Required Documents for Full Applications

13.2.1. Enter Abstract and Significance (use text box provided)

- **RFA section reference:** Section 8.1 (TDDC, TNTC, TTC, SEED)
- Character limit: 5,000-character maximum, including spaces
- Do NOT use symbols or special characters (eg, Greek letters, bullets)—these will not be transmitted correctly. Save the entered information. Information must be saved before any documents are uploaded or the abstract will be lost when the upload refreshes the Web page.

13.2.2. Enter the Layperson's Summary (use text box provided)

- **RFA section reference:** Section 8.2 (TDDC, TNTC, TTC, SEED)
- Character limit: 1,500-character maximum, including spaces
- Do NOT use symbols or special characters (eg, Greek letters, bullets)—these will not be transmitted correctly. Save the entered information. Information must be saved before any documents are uploaded or the abstract will be lost when the upload refreshes the Web page.

13.2.3. Enter Goals and Objectives (use text box provided)

- **RFA section reference:** Section 8.3 (TDDC, TNTC, TTC, SEED)
- Funding will be tranched and tied to the achievement of contract-specified milestones.

 The contract-specific milestones are the Goals & Objectives (G&Os) submitted by the

- applicant within the proposal. The progress-based release of funds will be dependent on the completion of the applicant's proposed G&Os for each project year.
- List specific G&Os for each year of the project. These G&Os will also be used during the submission and evaluation of progress reports and assessment of project success if the award is made. Identify time-specific references as follows: Year 1, Quarter 1 (Y1Q1), Y1Q2, etc. Do not specify actual calendar dates as this can be confusing when dates change.
- Character limit: 1,200-character maximum for each goal and each objective, <u>including</u> spaces
- G&Os will be reviewed during the evaluation of annual progress reports. Do NOT use symbols or special characters (eg, Greek letters, bullets)—these will not be transmitted correctly. Save the entered information. Information must be saved before any documents are uploaded or the abstract will be lost when the upload refreshes the Web page.
- At least 1 goal and 1 objective are required. At least 1 objective is required per goal. Up to 5 goals and 5 objectives per goal may be entered.
- Click the *Add Objective* link to add an additional objective to a goal.
- Click the *Add Goal* link to add an additional goal.

13.2.4. Upload Executive Summary (PDF format)

- **RFA section reference:** Section 8.4 (TDDC, TNTC, TTC, SEED)
- Page limit: 2-page maximum
- CPRIT encourages applicants to provide concise responses in bulleted format.

13.2.5. Upload Timeline (PDF format)

- **RFA section reference:** Section 8.5 (TDDC, TNTC, TTC, SEED)
- Page limit: 1-page maximum
- Timelines will be reviewed during the evaluation of annual progress reports.

13.2.6. Upload the Slide Presentation (PDF format)

- **RFA section reference:** Section 8.6 (TDDC, TNTC, TTC, SEED)
- **Page limit:** 10-page maximum (full application)

• The presentation should be submitted in PDF format, with 1 slide filling each landscapeorientated page. The slides should succinctly capture all essential elements of the application and should stand alone as a visual representation of the application.

13.2.7. Upload the Resubmission Summary (for Resubmissions only; PDF format)

- **RFA section reference:** Section 8.7 (TDDC, TNTC, TTC, SEED)
- Page limit: 2-pages maximum
- When submitting a new application, an upload box for a resubmission summary will be present but will be optional. See relevant RFA section for further information.

13.2.8. Upload the Integrated Product Development Plan/Development Plan (PDF format)

- **RFA section reference:** Section 8.8 (TDDC, TNTC, TTC, SEED)
- Page limit: 12-page maximum
- Applicants are advised to read the relevant RFA section carefully, a portion of which is copied here for emphasis: The development plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by the highly qualified group of reviewers. To the extent possible, the development plan should be driven by data. In the past, applications that have been scored poorly have been criticized for assuming that assertions could be taken on faith. Convincing data are much preferred. References should be uploaded as a separate document, see below.

13.2.9. Upload References (PDF format)

- **RFA section reference:** Section 8.8.1 (TDDC, TNTC, TTC); Section 8.8 (SEED)
- Page limit: None
- Provide references for the development plan in a separate document. In the interest of brevity include only the most pertinent and current literature. While references will not count toward the development plan section page limit, it is essential to be concise and to select only those references relevant to the development plan. Do not use the references to circumvent development plan section page limits by including data, analysis, or other nonbibliographic material.

13.2.10. Upload the Regulatory Correspondence Documentation (PDF format) (optional)

- **RFA section reference:** Section 8.8.6 (TDDC, TNTC); Section 8.8.10 (TTC); Section 8.8 (SEED)
- Page limit: None
- Upload all meeting minutes, communications between the company and regulatory agencies, and summaries of interactions with regulatory authorities (such as 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 application review process. If the applicant receives meeting minutes or other communications after submitting the application but before CPRIT has made a final decision on the application, the applicant should contact the CPRIT Helpdesk (see section 18.1) for assistance on filing the additional information.

13.2.11. Upload the Business Rationale (PDF format)

- **RFA section reference:** Section 8.9.1 (TDDC, TNTC, TTC, SEED)
- Page limit: 2-page maximum (TDDC, TNTC, TTC); 1-page maximum (SEED)
- Provide an overview that explains why this project is an appropriate investment of CPRIT and private funds.
- Throughout the Business Plan, applicants are advised to read the relevant RFA section carefully. Successful applicants will make thoughtful, careful, and economical use of the limited space to address all of the required topics.

13.2.12. Upload Product and Market (PDF format)

- **RFA section reference:** Section 8.9.2 (TDDC, TNTC, TTC, SEED)
- Page limit: 1-page maximum
- Provide an overview of the envisioned product and the target market.

13.2.13. Upload Competition and Value Proposition (PDF format)

- **RFA section reference:** Section 8.9.3 (TDDC, TNTC, TTC, SEED)
- Page limit: 1-page maximum

• Provide an overview of the competitive environment and how the envisioned product will compete in the marketplace.

13.2.14. Upload Clinical and Regulatory Plans (PDF format)

- **RFA section reference:** Section 8.9.4 (TDDC, TNTC, TTC, SEED)
- **Page limit:** 1-page maximum
- Provide an overview of plans for clinical activities and the regulatory pathway for major markets.

13.2.15. Upload Pricing and Reimbursement (PDF format)

- **RFA section reference:** Section 8.9.5 (TDDC, TNTC, TTC)
- Page limit: 1-page maximum
- Provide an overview of the projected product cost and anticipated revenue.

13.2.16. Upload Commercial Strategy (PDF format)

- **RFA section reference:** Section 8.9.6 (TDDC, TNTC, TTC), Section 8.9.5 (SEED)
- Page limit: 1-page maximum
- Provide an overview of financial projections and how the company plans to generate a return on this investment.

13.2.17. Upload Risk Analysis (PDF format)

- **RFA section reference:** Section 8.9.7 (TDDC, TNTC, TTC), Section 8.9.6 (SEED)
- **Page limit:** 1-page maximum
- Describe the risks inherent to the product plan and how they would be mitigated.

13.2.18. Upload Funding to Date (PDF format)

- RFA section reference: Section 8.9.8 (TDDC, TNTC, TTC), Section 8.9.7 (SEED)
- Page limit: May exceed a 1-page limit as necessary to fully capture all funding sources
- Provide an overview of funding received by the company, including a list of funding sources and a comprehensive capitalization table. CPRIT provides a template named "Product Development Research Programs Capitalization Table" located in the

My Applications: Summary tab that the applicant <u>must</u> use when completing the capitalization table of the application.

13.2.19. Upload Company Financial Overview (PDF format)

- **RFA section reference:** Section 8.9.9 (TDDC, TNTC, TTC), Section 8.9.8 (SEED)
- Page limit: 1-page maximum
- Provide a description of the company's overall financial condition.

13.2.20. Upload Intellectual Property (IP)/Freedom to Operate (PDF format)

- **RFA section reference:** Section 8.9.10 (TDDC, TNTC, TTC), Section 8.9.9 (SEED)
- Page limit: 1-page maximum
- Provide a discussion of the IP considerations related to the project and list any relevant issued patents, patent applications, and licensing agreements.

13.2.21. Upload Management Team and Key Personnel (PDF format)

- **RFA section reference:** Section 8.9.11 (TDDC, TNTC, TTC), Section 8.9.10 (SEED)
- Page limit: 1-page maximum
- Provide an overview of the management team members and other key personnel substantively contributing to the development or execution of the project.

13.2.22. Upload the Biographical Sketches of Key Scientific Personnel (PDF format)

- **RFA section reference:** Section 8.10 (TDDC, TNTC, TTC, SEED)
- Page limit: 8-page maximum
- The template named "Product Development Research Programs: Biographical Sketches," located in the *My Applications: Summary* tab or the NIH biographical sketch format must be used. Up to 4 biographical sketches (up to 2 pages each) of key scientific personnel should be included as a combined PDF document of up to 8 pages total. Biosketches must not exceed 2 pages for any individual. If multiple biosketches are being provided, these must be combined into a single file and submitted as a single PDF document. For example, 2 key personnel would submit a single 4-page document consisting of two 2-page biosketches.

- Key personnel are the PI/Project Director as well as other individuals who contribute to the development or the execution of the project in a substantive, measurable way.

 Substantive means they have a critical role in the overall success of the project and that their absence from the project would have a significant impact on executing the approved scope of the project.

 Measurable means that they devote a specified percentage of time to the project. The indicated time is an obligatory commitment, regardless of whether or not they request salaries or compensation. "Zero percent effort" or "TBD" or "as needed" are not acceptable levels of involvement for those designated as Key Personnel. While all participants that meet these criteria should be identified as "key," it is expected that the number of key personnel will be kept to a minimum.
- The following are examples of key scientific personnel: Chief medical officer, senior scientist, and scientific advisor. If the president and/or chief executive officer have significant involvement with the scientific direction of the company, it may be appropriate to include them as key scientific personnel.
- The following examples are NOT key scientific personnel: Chief operating officer, chief financial officer, regulatory specialist, project manager, and intellectual property consultant. Biographical sketches for such individuals should not be included in this upload. Instead, the qualifications of key, nonscientific personnel are to be described in the Key Personnel section of the business plan.

13.2.23. Upload the Commitment to Texas (PDF format)

- **RFA section reference:** Section 8.11 (TDDC, TNTC, TTC, SEED)
- **Page limit:** 1-page maximum
- Describe the company's commitment to locating in Texas and maintaining its business
 presence in the state. Identify the criteria specified in section 4.1 of the RFA, "Award
 Recipients Must be Texas Based," that the company will fulfill if it receives a CPRIT
 award.
- If the company is not currently Texas-based, provide a timetable with key dates indicating the applicant's plan and commitment to relocate the company to Texas. In addition, describe which personnel and management will be headquartered in Texas.

13.2.24. Verify and Finalize Required Documents for ASO Approval and Submission

When all information is entered, click the *Finalize Required Documents* button.

14. TAB 5: BUDGET (FULL APPLICATIONS ONLY)

This tab should include only the amount requested from CPRIT; do NOT include the amount of the match.

The Budget section is composed of 4 subtabs that must be completed:

- 1. Budget for All Project Personnel
- 2. Detailed Budget for Year 1
- 3. Budget for Entire Proposed Period of Performance
- 4. Budget Justification

Each award mechanism allows for up to a 3-year funding program. CPRIT has limited funds for company investment in this cycle, and all non-SEED company award budget requests are capped at \$5 million maximum. SEED award funding requests are capped at a maximum budget of \$3 million. Financial support will be awarded based upon the breadth and nature of the program proposed. Requested funds must be well justified. Funding will be tranched and milestone driven.

NOTE: Some or all of the following buttons appear on each subtab:

Previous = Move to the previous subtab

Next = Move to the next subtab

Save Budget as Draft = Save entered information

Finalize Budget for ASO Approval = Finalize section

The *Previous* and *Next* buttons allow the user to move between subtabs while retaining entered information for as long as the user is on the *Budget* tab. Information entered on any subtab is NOT saved until the *Save Budget as Draft* button is clicked. Moving to another tab without

saving will result in loss of any unsaved changes. Amounts should be rounded to the nearest dollar—the budget forms will not accommodate decimals.

Expenses in the proposed budget must be categorized as personnel, fringe benefits, travel, equipment, supplies, contractual, other, and indirect costs. Information on the expenses associated with these budget categories and allowable costs can be found in chapters 9 and 10 of the *CPRIT Policies and Procedures Guide*. The guide's expense classifications in each budget category carry over to the quarterly financial status report that must completed for every funded project and approved by CPRIT. If for any reason an expense is not categorized correctly in the budget of an application that becomes an approved project, that expense will have to be recategorized to conform to CPRIT's requirements and be approved in a quarterly financial status report.

14.1. Budget for All Project Personnel (use Web form provided)

Name: The applicant (PI) name is prepopulated. Provide the name, role, appointment type, percent effort, salary requested, and fringe benefits for all other personnel engaged in this project and funded by CPRIT.

Additional rows will automatically appear once text is entered into the existing last row.

Role on Project: The applicant role is prepopulated. Enter roles of other individuals as necessary.

Type of Appointment (Months): For each individual listed, enter appointment type (eg, 6-month, 9-month, 12-month appointment).

Annual Base Salary: For each individual listed, enter institutional base salary.

Effort on Project: For each individual listed, enter percent effort on the project.

Salary Requested: The individual salary cap for CPRIT Awards is \$200,000; see section 14.5, Salary Cap.

- Click *Calc* to automatically calculate the requested salary.
- A salary of \$0 may be entered for any listed individual. In such cases, the system will display a "warning" to notify the submitter of this amount. The tab can still be finalized with warnings. However, an "error" must be addressed before a tab can be finalized.

Fringe Benefits: For each individual listed, institutional fringe benefits must be calculated based on the individual's direct salary requested.

14.2. Detailed Budget for Year 1 (use text boxes/Web form provided)

Provide the information requested for other direct costs in the first year of the project. <u>This</u> section should only include the amount requested from <u>CPRIT</u>; do NOT include the amount of the matching funds or the budget for the total project.

Travel: Include any costs associated with necessary travel. CPRIT funds may be used to send up to 2 people to CPRIT's annual conference. If out-of-state or overseas travel is anticipated, identify that necessity now. International travel and travel to conferences requires approval prior to the travel occurrence through either the application or the submission of a request after a project is funded.

Equipment (400-character limit): Itemize each piece of equipment having a useful life of more than 1 year and an acquisition charge of \$5,000 or more per unit that is anticipated to be purchased for use in the project. Each piece of equipment must be approved by CPRIT in the application or after the project is funded. If the project is funded, approval may be requested during the period a grant is active and will be considered on a case-by-case basis. However, any proposed equipment purchase in an application removed by a peer review panel will not be reconsidered if the project is funded.

Supplies: (800-character limit) Itemize costs for research materials, consumable office supplies, and tangible equipment with a cost under \$5,000.

Contractual (Subaward/Service Contracts): (400-character limit) Itemize each subaward, consulting service contract, and service contract directly related to the project such as those for contract research organizations or other specialized services. For the purposes of the budget, these are all considered subcontracts. Provide direct contract costs only. Any indirect costs charged on a subcontract must be categorized as an *Indirect Cost* and are calculated in the overall 5% indirect cost limitation. Each subcontract must be itemized in the *Budget Justification* subtab by providing project charges for personnel, travel, equipment, supplies, and other expenses.

Other: (800-character limit) Itemize other project-associated expenses such as the organization's costs for the participation of human subjects in clinicals trials or animal care charges for animal

studies that will not be paid through a contractual arrangement. Funds can be used to pay for any patient care costs outlined in the RFA as well as patient participation incentive gift cards or direct paid transportation services; however, grant funds cannot be used to reimburse a patient or pay for travel expenses or other participation expenses of a patient participating in a clinical trial at this time.

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

14.3. Budget for Entire Proposed Period of Performance (use Web form provided)

This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project. Amounts for *Budget Year 1* will be automatically populated based on the information provided on the previous subtabs; namely, *Budget for All Project Personnel* and *Detailed Budget for Year 1*. Additionally, adjustments of up to a 3% increase in annual salary are permitted for Years 2 and 3 up to the cap of \$200,000. The salary cap (section 14.5) may be revised at CPRIT's discretion.

14.4. Budget Justification (Use template provided)

Applicants must use the provided budget justification template, available in CARS <u>here</u>. For projects that involve contract research organizations (CROs) or other third parties providing clinical trial services, include estimates/quotations for the planned services. Combine them with the budget justification and upload as a single PDF document.

Please specify your CPRIT-requested funds <u>and</u> other amounts that will comprise the total budget for the project, including the use of matching funds. Provide a brief and concise justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, and other expenses. <u>Each subaward must itemize project costs</u> for all cost categories.

14.5. Salary Cap

The salary cap for CPRIT Awards in FY 2024 (September 1, 2023, through August 31, 2024) is \$200,000. Note that this is the maximum that can be requested from CPRIT for any one

individual annual salary; however, larger salaries can be paid as long as the difference (amount exceeding \$200,000) comes from matching dollars. Thus, the maximum direct salary support that an individual can request from CPRIT is up to \$200,000 of his or her salary based on percent effort on a project. In other words,

- With 100% effort on the project, individuals with a salary of less than \$200,000 would request the entire salary amount.
- With 100% effort on the project, individuals with a salary of more than \$200,000 would request the salary cap of \$200,000.
- With 50% effort on the project, individuals with a salary of more than \$200,000 would request \$100,000.

The following table outlines the salary cap guidelines. Institutional fringe benefits should be calculated based on the direct salary support requested.

Base institutional salary (full-time calendar appointment)	Effort on project	Maximum direct salary support that would be requested by the applicant
Less than \$200,000	1%-100%	Up to base salary
More than \$200,000 (eg, \$300,000)	100%	\$200,000
More than \$200,000 (eg, \$300,000)	50%	\$100,000

15. FINAL REVIEW AND SUBMISSION

When Tabs 1 through 4 (for preliminary applications) or Tabs 1 through 5 (for full applications) have been completed and finalized by the applicant, the status of the application will be set to "PENDING ASO APPROVAL." The ASO will then receive a notification email to review, approve, and submit the application to CPRIT. Only the ASO is authorized to officially submit the application. The ASO should log in to CARS and click the appropriate application ID number on the *My Applications* page. To submit the application, the ASO must enter his or her password and click the *Approve and Submit Application* button. The ASO will then be asked to click the *Continue* button to submit the application. After the application has been submitted, the status of the application on the *My Applications* page (and also on all tabs of that application)

will be "ASO APPROVED AND SUBMITTED." For preliminary applications, the ASO at the applicant's institution must submit by December 11, 2023, 4 PM central time. For full applications, the ASO at the applicant's institution must submit the application by February 13, 2024, 4 PM central time.

16. TEMPLATES

Four templates are provided (https://cpritgrants.org/Current_Funding_Opportunities). All applicants must use the "Product Development Research Programs Budget Justification" template for the budget justification. The "Product Development Research Programs Biographical Sketches" template or the NIH Biographical Sketch format must be used for the biographical sketches of key scientific personnel. The "Product Development Research Programs Capitalization Table" template must be used for the capitalization table.

17. FORMATTING INSTRUCTIONS

All sections of the application should be written in clear and comprehensible text and must follow the guidelines described below. Applicants are advised to use font sizes, font faces, line spacing, page sizes, and page margins that permit easy readability of the application text. Applications that do not meet these guidelines are subject to administrative withdrawal.

Formatting guidelines for all submitted CPRIT applications are as follows:

• **Document type:** PDF

• Language: English

• Font Type/Size: Arial (11 point), Calibri (11 point), or Times New Roman (12 point), with the exception of reference lists, which may be provided in 8-point font to save space

• Line Spacing: Single

• Page Size: 8.5 x 11 inches

• Margins: 0.75 inch in all directions

• Color and High-Resolution Images: Any images, graphs, figures, and other illustrations must be submitted as part of the appropriate submitted document. It is suggested that

applicants include text to explain illustrations that may be difficult to interpret when printed in black and white. Color may be used in the text as well.

- Scanning Resolution: 100 to 150 dpi
- The CPRIT logo may NOT be used.
- Reference format: 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 as long as the journal information is stated. Include URLs of publications referenced in the application.

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

- Headers and Footers: Do not apply a header. A header in the following format will be applied to the whole application after the various application components are combined:
 [Application ID]/[Company Name]/[Applicant Name]/[Page Number]
- Page Numbering: Add page numbers in the footer for each document that is uploaded as a PDF. Restart the page numbering at 1 for each document.
- Cover Page: A cover page for each application component section is automatically generated; for example, "[Application ID], Business Plan." Therefore, there is no need to use one of the limited number of pages for each section to create an additional cover page.

18. CONTACT INFORMATION

18.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding scientific and commercialization aspects of applications. For Frequently Asked Programmatic Questions, please go here and for Frequently Asked Technical Questions, please go here.

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

Tel: 866-941-7146 (toll free in United States only)

Email: Help@CPRITGrants.org

18.2. Programmatic Questions

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

Tel: 512-305-7676

Email: proddev@cprit.texas.gov

Website: www.cprit.texas.gov