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CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

# **INSTRUCTIONS FOR APPLICANTS**

**Clinical Trials Network Award  
RFA R-21.2-CTNA**

**FY 2021**

Fiscal Year Award Period

September 1, 2020-August 31, 2021

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## **VERSION HISTORY**

Rev 09/16/20

Instructions for Applicants document posted

## 1. INTRODUCTION

The Cancer Prevention & Research Institute of Texas (CPRIT) Application Receipt System (CARS) (<https://cpritgrants.org>) provides a means for the research community (ie, Principal Investigators [PIs] 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 to submit an application in response to CPRIT's Request for Applications (RFA) for Clinical Trials Network Award (RFA R-21.2-CTNA). Applications may be submitted from September 16, 2020, through January 27, 2021.

**Important note:** An entity may only submit 1 application as the Lead Institution (LI) under this mechanism. Network Affiliates may be listed on 1 application submitted under this mechanism.

## 2. SUMMARY INSTRUCTIONS

- **Technical Support:** Applicants are strongly advised to carefully read this document in its entirety before starting an application. The Helpdesk ([section 19.1](#)) 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 *Version History*.
- **Document Format for Uploaded Files:** Use Portable Document Format (PDF) only.
  - Do NOT password protect documents.
  - 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 provided for biographical sketches (biosketches) and current and pending support. NIH-style biographical sketches can be used if desired.
- **Submission Process:**
  - The applicant completes/finalizes all sections and forwards it to the organization's ASO for review and final submission to CPRIT. The ASO is an individual authorized to submit an application for the organization.
  - The application must be submitted by the ASO on or before January 27, 2021, 4 PM central time.

- **Note:** CARS will be unavailable the third Thursday of each month between 7 PM and 9 PM central time for routine system maintenance.
- **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 PI.
- **Adding an ORCID iD to Applicant Profile (optional step):**
  - All applicants who are currently registered with ORCID are encouraged to associate their iDs with CARS as described below in [section 6](#). Applicants who are not registered with ORCID can do so using the link provided above or within CARS as described in [section 6](#).
- **Application Submission Deadline**
  - The application must be submitted on or before **January 27, 2021, 4 PM central time.**

### 3. APPLICATION PREPARATION AND SUBMISSION PROCESS

- The applicant completes/finalizes a series of numbered tabs of the application.
- Finalized tabs can be reset by the ASO.
- Once all tabs are finalized, the ASO reviews, approves, and submits the application to CPRIT.

### 4. APPLICATION/AUTHORIZED SIGNING OFFICIAL (ASO)

The ASO is an individual authorized to submit an application on behalf of an organization. An ASO is required on the application and must be identified by the PI. As the organization’s representative, the ASO is required to review the tabs finalized by the PI and subsequently submit the application. Only the ASO is authorized to officially submit the application to CPRIT. The ASO can reset PI-finalized tabs to draft at the request of the PI.

## 5. GRANTS CONTRACT/OFFICE OF SPONSORED PROJECTS OFFICIAL

The Grants Contract/Office of Sponsored Projects Official is the individual who will manage the grant if an award is made. This individual must be identified for the application. The PI or the ASO can assign this individual to this role.

## 6. USER REGISTRATION AND/OR LOGIN

Applicants begin the application process by registering or logging into CARS (<https://cpritgrants.org>). On successful login into the system, applicants will be presented with the *My Applications* page. All prior submitted applications by that user 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 of this screen.

The screenshot displays the 'My Profile: Account Info' page. At the top, there is a navigation bar with links like 'My Profile', 'My Applications', 'Bridge', 'My Grants', 'Manage Organizations', 'Current Funding Opportunities', 'Feedback', 'Review Grants', 'HelpDesk', and 'Administrative'. Below this is a sub-navigation bar with 'Account Information', 'Contact Information', 'Descriptive Information', and 'Biosketch'. The main content area is titled 'My Profile: Account Info' and contains a form for account information. The form includes fields for 'Role' (with a dropdown menu), 'Salutation' (with a dropdown menu), 'First Name' (with an asterisk indicating it is required), 'Middle Initial' (with an asterisk indicating it is required), 'Last Name' (with an asterisk indicating it is required), 'Suffix' (with a dropdown menu), 'Login/Username', and 'Password'. There are also links for 'Update Password' and 'Update Security Questions'. A red arrow points to a button labeled 'Register or Connect your ORCID ID'. The page also includes a 'Save Changes' button at the bottom. The status bar at the top right indicates 'Logged in as: System Admin' with a link to 'not System Admin click here'.

As directed by the modal window, 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. Users without an ORCID account can initiate one from this window.

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 APPLICATION

New applications can be started in 1 of 2 ways:

1. My Applications (this is the default page after login) → click *Start New Application* → *FY 2021 Academic Research Programs* → select *Clinical Trials Network Award* → click *New Application*, or
2. Current Funding Opportunities → click *FY 2021 Academic Research Programs* → select *Clinical Trials Network Award* → click *Start New Application*.

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

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

All tabs must be completed/finalized by the PI before the ASO can review, approve, and successfully submit the application.

## 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.

The screenshot shows a web interface titled "My Applications: Contacts". Below the title is a row of six numbered tabs: 1 Contacts, 2 Application Information, 3 Personnel & Collaborators, 4 Required Documents, 5 Budget, and 6 Final Review & Submit. The "1 Contacts" tab is highlighted. Below the tabs, the text "Contacts" and "Application ID: XXXXXXXX" are visible on the left. In the center, it says "Phase: Full Application". On the right, there is a "Status" label followed by a red-bordered box containing the word "DRAFT".

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 application (as indicated in the figure below).

## 9. TAB: SUMMARY

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

My Applications: Summary

Summary

1 Contacts

2 Application Information

3 Personnel & Collaborators

4 Required Documents

5 Budget

6 Final Review & Submit

Summary

Application ID: XXXXXXXX

Phase: Full Application

Status: **DRAFT**

Application Title: screen shot  
Program: FY 2014 Research Programs  
Award Type: Individual Investigator Research Awards

Please be sure to verify format requirements. Applications that do not meet format requirements and/or reviewers' determination of readability may result in rejection of your application. Please check the format requirements found in the [Request for Application \(RFA\)](#).

Full Application Deadline: February 3, 2014 by 3:00 PM CT ([check current official time](#))

This application is in progress and is not ready for ASO approval. Each section outlined below must be completed, finalized, and approved by the ASO at your institution prior to the submission deadline. When all sections have been completed and set to "PENDING ASO APPROVAL", the Application Signing Official will need to approve the application submission in order for it to be forwarded for review. The table below shows the status of each section in the submission process as of December 20, 2013 5:12 PM CT.

Section #	Application Section	Status
1	<a href="#">Contacts</a>	<b>draft</b>
2	<a href="#">Application Information</a>	draft
3	<a href="#">Project Personnel and Collaborators</a>	draft
4	<a href="#">Required Documents</a>	draft
5	<a href="#">Budget</a>	draft
6	Final Review and Submit	NOT APPROVED

Section	Status	Status Definition
1-5	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.
6	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

- **Principal Investigator:** Verify information for the PI; update as necessary.
- **Alternate Submitter (Optional):** An alternate submitter may be designated on the application by the PI. Follow the search guidelines above.

- **Application Signing Official (Required):** An ASO must be listed in order to complete/finalize this tab. Click the *Search for Application Signing Official* button. Follow the search guidelines above.
- **Alternate Application Signing Official (Optional):** This individual can be assigned only by the ASO. Follow the search guidelines above.
- **Grants Contract/Office of Sponsored Projects Official (Required):** A Grants Contract/Office of Sponsored Projects Official must be listed in order to complete/finalize this tab. This individual can be assigned by the PI or the ASO. Follow the search guidelines above.

When all information is entered, click the *Finalize Contacts Section* button. Note that this tab cannot be finalized until the 3 required fields of this section, namely, “Principal Investigator,” “Application Signing Official,” and “Grants Contract/Office of Sponsored Projects Official” have been completed. PI information is entered automatically; an ASO must be identified and added by the PI. The Grants Contract/Office of Sponsored Projects Official may be identified and added by the PI or the ASO.

## 11. TAB 2: APPLICATION INFORMATION

- **Application Identification:**
  - **Award Mechanism:** Verify the listed award mechanism. Note that the award mechanism cannot be changed here.
  - **Application Type:** Verify application type (drop list defaults to New Application).
  - **Application Title:** The application title is stated. Edit if necessary.
- **Project Information:**
  - **Contract Start Date (mm/dd/yyyy):** The contract start date of 8/31/2021 is prepopulated.
  - **Proposed End Date (mm/dd/yyyy):** Enter the proposed end date of the project. The maximum duration is 4 years (48 months) for Clinical Trials Network Award applications.
- **Application Classification:**
  - **Research Area:** Select the research area that best describes the proposed work. Please refer to [Appendix 1](#) for a detailed description of each research area.

- **Program Focus:** Select the focus of the proposed work. Please refer to [Appendix 2](#) for definition of cancer research types.
- **Cancer Site Addressed:** Select the most relevant cancer site(s) addressed, up to a maximum of 3. If the focus of the project is not on specific cancer site(s), select All Cancers (eg, Research Training Award). The selection of cancer sites in this section assists CPRIT with reporting on cancer research that is being performed.
- **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 gender, age, and ethnicity 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 your institution. Use the link provided to find this information using the applicant's institutional address.
  - **State House District:** Enter the State Senate District of your institution. Use the link provided to find this information using the applicant's institutional address.
- **Cancellation of Applications/Awards by Granting Organization (in past 5 years):**
  - Select whether the PI is currently eligible to receive federal grant funds. If "No" is selected, provide a reason.
  - Select whether the PI 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 add additional applications or awards.
- **Donations:**
  - Select whether the PI 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 add 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. If choice 5 is selected, then enter the name of the research sponsor and the sponsor’s priority that the application addresses.

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

**NOTE:** Application information saved “as draft” can be edited at a later time. Application information “finalized for ASO approval” can be edited only after the ASO has reset the application to draft mode at the request of the PI.

## 12. TAB 3: PROJECT PERSONNEL AND COLLABORATORS

- **Investigators and Submitters**
  - **Please note that the biosketch for the Lead PI and Network Affiliate Physician Leader must be uploaded under the *Required Documents* Tab (see [section 13](#)). Biosketches previously uploaded in *My Profile* will not be included in the application.**
- **Project Personnel and Collaborators**
  - It is your responsibility to enter information for all project personnel, paid or unpaid, including any collaborators. A collaborator is an individual who contributes to the scientific or business development or execution of the project but is not responsible for leadership or accountability for managing the project. A collaborator can be paid or unpaid. 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. Select the appropriate *Role for Application* from the drop list. Click the *Save as Draft* button to save additions.

When all information is entered, click the *Finalize Project Personnel & Collaborators* button.

Note that this tab can be finalized only after Tab 1 (*Contacts*) has been finalized.

### 13. TAB 4: REQUIRED DOCUMENTS

**NOTE:** All documents must be uploaded in PDF format only. The system will not allow upload of documents in other formats or of documents that exceed the page limits specified in the individual RFAs. Do NOT password protect documents. Do NOT submit documents that are bound together in a single PDF package.

- **Application Abstracts: Abstract and Significance and Layperson’s Summary:** Enter the Abstract and Significance (5,000 characters) and Layperson’s Summary (2,000 characters) of the proposed work. Character limits include letters, spaces, and punctuations. Do NOT use symbols or special characters (eg, Greek letters)—these will not be transmitted correctly. Save the entered information by clicking the *Save Application Abstracts as Draft* button. Information must be saved before any documents are uploaded below or the Abstract and Significance and/or Layperson’s Summary will be lost when the upload refreshes the Web page.
- **Goals and Objectives:** Enter your goals and objectives as plain text (1,200 characters per goal and per objective). Goals and objectives will be reviewed during the evaluation of annual progress reports. HTML formatting, tables, charts, and diagrams are not supported. Goals and objectives may be saved as a DRAFT at any time by clicking the *Save Goals and Objectives as Draft* button. Any unsaved goals and objectives will be lost.
  - 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 additional objective to a goal.
  - Click the *Add Goal* link to add additional goal.
- **Timeline (1 page):** Upload Timeline PDF document. Include Stage 1 and Stage 2 development and execution in the Timeline. The Timeline will be reviewed during the evaluation of annual progress reports.
- **Network Description (up to 10 pages):** Upload the Network Description PDF document (see RFA for details).
- **Institutional Review Board agreement:** Upload the documentation requested in the RFA as a PDF document (see RFA for details).

- **Publications/References:** Upload the Publications/References PDF document. Complete journal articles are not allowed in this section.
- **PI Biosketch (up to 5 pages):** Upload a PDF biosketch for the PI. NIH biosketches may be used.
- **Network Affiliate Lead Biosketch (up to 5 pages each):** Upload a PDF biosketch for each Network Affiliate Lead (see RFA for details). NIH biosketches may be used.
- **Biographical sketches for additional collaborators (up to 5 pages each):** If desired, upload a PDF biosketch for key collaborators or advisors (see RFA for details). NIH biosketches may be used.
- **Current and Pending Support:** For all personnel who have included a biographical sketch with the application, upload their current and pending support (use the template posted under the *Summary* tab) and see the RFA for additional details. Multiple documents must be combined and submitted as a single PDF document.
- **Institutional/Collaborator Support and/or Other Certification (up to 4 pages):** If desired, upload letters of institutional and/or collaborator support and other certification documents. Multiple letters/files must be combined and submitted as a single PDF document. A maximum of 2 letters may be present on a page. Applicants are strongly advised NOT to submit “appendix material,” such as publications, figures, and/or data.
- **Budget Justification:** Upload the Budget Justification PDF document. Provide a detailed justification of the budget for each component of the CTNA over the entire proposed period of support for all charge categories: personnel (salaries and fringe benefits), travel, equipment, supplies, consultant charges, contractual (subaward/consortium) charges, research-related subject charges, other expenses (including animal care charges), and indirect charges (see RFA for details). Each subaward must itemize project charges for all charge categories. (see also [section 14.4](#))

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

## 14. TAB 5: BUDGET

**This tab should include only the amount requested from CPRIT; do NOT include the amount of the matching funds.**

The Budget section is composed of 4 subtabs:

1. Budget for All Project Personnel
2. Detailed Budget for Year 1
3. Budget for Entire Proposed Period of Performance—Include budget for proposed Stage 2.
4. Budget Justification—Include detailed justification for Stage 1 and Stage 2 costs in alignment with required timeline document. Note: CPRIT approval is required to expend Stage 2 funds.

All 4 subtabs must be completed to finalize this section. A detailed budget for the first year of the project is required. For Clinical Trials Network Award awards, applicants may request a maximum of \$600,000 annually for Stage 1 and a maximum of \$900,000 annually for Stage 2 over 48 months, inclusive of both direct and indirect charges.

**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.

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 be 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 for both the Lead Institution and each Network Affiliate, for both Stage 1 and Stage 2. (use Web form provided)**

Complete the requested information.

**First Name and Last Name:** The PI's name is prepopulated. Enter names of other individuals, as necessary. Additional rows will autoappear once text is entered into the existing last row.

**Role on Project:** The PI's role is prepopulated. Enter roles of other individuals, as necessary.

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

**Annual Base Salary:** For each individual listed, enter his or her institutional base salary. The salary cap for CPRIT awards for FY 2021 (September 1, 2020, through August 31, 2021) is \$200,000; see [section 14.5](#) Salary Cap.

**Effort on Project:** For each individual listed, enter his or her percent effort on the project. Note that support of up to 20% effort for the LI PI and 10% effort for the Network Affiliate physician leader are required up to a maximum full-time salary of \$200,000/year.

**Salary Requested:** After entering the information in these categories, click "Calc" to autocalculate the requested salary.

**Fringe Benefits:** For each individual listed, his or her institutional fringe benefits must be calculated based on direct *Salary Requested*. Fringe benefits may not exceed 35% of the salary requested (a warning will be displayed).

#### **14.2. Detailed Budget for Year 1**

Provide the information requested for other direct charges in the first year of the project.

**Stage 1: Provide a detailed budget for stage 1 (the development and oversight of a network of 2 cancer care facilities [Network Affiliates])**

**Travel:** CPRIT funds may be used for travel by project personnel between the LI and Network sites. CPRIT funds may also be used to send up to 2 people to CPRIT's biennial conference. CPRIT cannot support patient-related travel charges. Requests for funds to travel to scientific meetings other than CPRIT's biennial conference are not appropriate for this funding mechanism.

**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.

**Construction and Renovation** funds are not an appropriate request for this funding mechanism.

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

**Contractual (Subaward/Services 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 fees for central IRB review, Clinical Trials Management Support System licensing fees that will not be paid through a contractual arrangement. Note that patient care costs associated with the conduct of a clinical trial are not allowable costs for this mechanism. Also, 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).

Total Indirect Charges for Year 1 (line D) should not exceed 5% of the Total Charges for Year 1 (line E). As an example, for a total award of \$100,000, indirect charges may not exceed \$5,000; direct charges would be \$95,000.

Calculate as follows: Total Indirect Charges = (Total Direct Charges/0.95) – Total Direct Charges.

**Note on Subaward contracts:** Subawards may recover up to the maximum of 5% in indirect charges of the total requested subaward amount. However, any indirect charges recovered in a subaward count toward the overall 5% indirect cost limitation of the funded award. Therefore, the primary institution completing the application must ensure that all indirect costs are calculated correctly in the total amount requested. If a project is funded, the primary institution receiving the award must manage the subaward contract costs including the allowable indirect costs. CPRIT recognizes that an LI and/or Network Affiliate may not be considered a public or private institution of higher education or may have an FIDC rate credit that is less than 55%. If that is the case, non-CPRIT funds (eg, federal grants, industry contracts, philanthropic funds, institutional funds, etc) paid to support the clinical trials that are the subject of this award may be used to fulfill the matching funds requirement. CPRIT will also allow the grant recipient to count funds paid for the nonresearch-related patient care costs toward the matching funds requirement. The grant recipient must submit documentation to CPRIT supporting all matching fund expenses.

### **14.3. Budget for Entire Proposed Period of Performance**

Include Stage 2 costs (expansion of network to 2 additional facilities located outside the Lead Institution current catchment area) by Year 2 or 3 of the award. Note, prior approval from CPRIT is required to utilize stage 2 funds. CPRIT approval is based on the grantee's satisfactory demonstration for expansion. **Stage 2 Network Affiliates do not need to be identified until stage 1 networks are in place and functioning and the Lead Institution is ready to initiate Stage 2.**

Amounts for *Budget Year 1* will be autopopulated based on the information provided on the previous subtabs, namely, *Budget for All Project Personnel* and *Detailed Budget for Year 1*. For each additional year of support requested, enter the budget requested for personnel charges (including Network Affiliates) and other applicable direct charges. Fringe benefits may not exceed 35% of the salary (a warning will be displayed). Adjustments of up to a 3% annual increase for salary and other categories are permitted for additional years. A 3% salary increase for each year after year 1 is permitted up to the cap of \$200,000. The salary cap ([section 14.5](#)) may be revised every year at CPRIT's discretion.

Enter the indirect charges for each additional year of support requested. *Total Indirect Charges* (line D) should not exceed 5% of the total requested award amount for that year (sum of lines C and D).

#### **14.4. Budget Justification**

Provide a detailed justification of the budget by Stage 1 and Stage 2 for the entire proposed period of support for all budget categories: Personnel (salaries and fringe benefits), travel, equipment, supplies, contractual charges, other expenses, and indirect charges. **Each subaward must itemize project charges for all budget categories.**

**If you uploaded this document under Tab 4 (*Required Documents*) (see [section 13](#)) you can click on the link directing you to your uploaded file. If you have not uploaded this document yet, please click on the link that will direct you to Tab 4 (*Required Documents*) where you can upload this file (see [section 13](#)).**

#### **14.5. Salary Cap**

The salary cap for CPRIT awards in FY 2021 (September 1, 2020, through August 31, 2021) is \$200,000. Thus, the maximum direct salary support an individual can request is up to \$200,000 of his or her institutional salary based on effort on a project. Note: Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs (See RFA for details).

The following table outlines the salary cap guidelines; note that the maximum salary for levels of effort below 100% is proportionate to the allowable direct salary (see the third line in the table as an example). 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. TAB 6: FINAL REVIEW & SUBMIT

When Tabs 1 through 5 have been completed and finalized by the applicant, the status of the application is set to “PENDING ASO APPROVAL.” The ASO will then receive email notification to review, approve, and submit the application to CPRIT. Only the ASO is authorized to officially submit the application. The ASO must log in to the system and click the appropriate application ID number listed under his/her *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 on all tabs of that application) will be “ASO APPROVED AND SUBMITTED.” The ASO at the PI’s institution must submit the application by the submission deadline: **January 27, 2021, 4 PM central time.**

## 16. PROVIDED TEMPLATES

Applicants must use the provided template to prepare and submit the following documents:

- Current and Pending Support (.doc, .PDF)

A template is provided for biographical sketches, but an NIH biographical sketch may be used if desired.

Templates are posted under the *Summary* tab and are available in .doc and .PDF format.

## 17. HUMAN SUBJECTS

LI and Network Affiliates are required to use a common Institutional Review Board (IRB) either provided by the Lead Institution or a central IRB and to share access to a Web-based clinical trials management support system (CTMS). Whenever human subjects are part of a CPRIT-funded project, a copy of the recipient organization's IRB must be provided to CPRIT before funding can be released. For multiyear projects, annual confirmation of IRB approval is required. This information is not required at the time of submission of the application.

## 18. FORMATTING INSTRUCTIONS

All sections of the application should be written in clear and legible 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. Every attempt should be made to keep files sizes to a minimum (see *Scanning Resolution* below). Applications that do not meet these guidelines are subject to administrative withdrawal.

Formatting guidelines for all submitted CPRIT applications are as follows:

- **Language:** English
- **Document Format:** PDF only
- **Font Type/Size:** Arial (11 point), Calibri (11 point), or Times New Roman (12 point)
- **Line Spacing:** Single
- **Page Size:** 8.5 x 11 inches
- **Margins:** 0.75 inch, all directions
- **Color and High-Resolution Images:** Images, graphs, figures, and other illustrations must be submitted as part of the appropriate submitted document. Applicants should include text to explain illustrations that may be difficult to interpret when printed in black and white.
- **Scanning Resolution:** Images and figures must be of lowest reasonable resolution that permits clarity and readability. Unnecessarily large files will NOT be accepted, especially those that include only text.
- **References:** Applicants should use a citation style that includes the full name of the article and that lists at least the first 3 authors. Official journal abbreviations may be used.

An example is included below; however, other citation styles meeting these parameters are also acceptable 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.

- **Internet URLs:** Applicants are encouraged to provide the URLs of publications referenced in the application; however, applicants should not include URLs directing reviewers to websites containing additional information about the proposed research.
- **Headers and Footers:** These should not be used unless they are part of a provided template. Page numbers may be included in the footer (see following point).
- **Page Numbering:** Add page numbers in the footer for each document that is uploaded as a PDF. Restart the page numbering at 1 for each document. Pages should be numbered at the bottom right corner of each page.
- **All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded in PDF format.**

## **19. CONTACT INFORMATION**

### **19.1. Helpdesk**

Helpdesk support is available for technical 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 aspects of applications.

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

**Tel:** 866-941-7146

**Email:** [Help@CPRITGrants.org](mailto:Help@CPRITGrants.org)

### **19.2. Scientific and Programmatic Questions**

Questions regarding the CPRIT program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Senior Program Manager for Academic Research.

**Tel:** 512-305-8491

**Email:** [Help@CPRITGrants.org](mailto:Help@CPRITGrants.org)

**Website:** [www.cprit.texas.gov](http://www.cprit.texas.gov)

## Appendix 1: DESCRIPTION OF RESEARCH AREAS

In [Tab 2](#) (*Application Information/Application Classification*) the applicant is required to select a research area that best describes the proposed work. Descriptions of research areas are the following:

- **Cancer biology:** Research on the biology of how cancer starts and progresses, as well as normal biology relevant to these processes. Examples include oncogenes and suppressor genes, epigenetics, DNA repair, growth factors, signaling pathways, cancer immunology, microenvironment, and tumor progression and metastasis.
- **Cancer control, survivorship, and outcomes research:** Research in this category covers a broad range of areas, including patient care and pain management, cancer surveillance, cancer disparities research, quality of life for patients with cancer and their families, identification and reduction of late effects of cancer treatment, education and communications that reduce cancer risk, health services research, and attitudes and belief systems that affect cancer control.
- **Childhood and adolescent cancer**
- **Computational biology and analytic methods**
- **Early detection, diagnosis, and prognosis:** Identification and testing cancer markers and imaging methods detecting and/or diagnosing cancer as well as predicting the outcome or chance of recurrence. Examples include discovery of markers and/or technologies for use in cancer detection and diagnosis and/or prognosis, animal trials and clinical human trials, tumor response to therapy, risk assessment, screening methods, informatics and informatics networks, and biostatistics.
- **Etiology:** Research on the causes of cancer—genetic, environmental, and lifestyle factors and their interactions. Examples include environmental chemicals, hormone-disrupting agents, gene-environment interactions, microbial agents, radiation exposure, and genetic polymorphisms that affect carcinogen metabolism.
- **Prevention:** Identification of interventions that reduce cancer risk. Examples include chemoprevention, vaccines to prevent cancer, behavioral modifications that reduce cancer risk, studies on energy balance and dietary factors associated with cancer risk, and identification of cancer risk factors.

- **Scientific model systems:** Development of new animal models, cell culture systems, and computer simulations and their application to other studies across the spectrum of cancer research. Examples include mathematical modeling of cancer processes; development of diverse animal models, including transgenic mice, zebra fish, *Drosophila*, etc; and development of organ and tissue model systems.
- **Treatment:** Identification, development, and testing of treatments for cancer. Examples include drug development, immunotherapy, personalized cancer therapy, methods of drug delivery, antiangiogenic therapy, clinical trials, and treatments to prevent recurrence.

## Appendix 2: PROGRAM FOCUS - Definitions of Cancer Research Types

In [Tab 2](#) (*Application Information/Application Classification*), the applicant is required to select a program focus that best describes the proposed cancer research type. Descriptions of cancer research types are as follows\*:

- **Basic Research** - results in the acquisition of new knowledge and elucidates fundamental mechanisms in biology.
- **Translational Research** - involves the application of discoveries from basic research to practical problems associated with cancer as well as research on how to improve best practices in the community.
- **Clinical Research** - involves studies with human subjects and includes patient-oriented research on mechanisms of disease, therapy, and development of new technologies as well as epidemiologic and behavioral studies and outcomes and health services research.

\*Taken from, Rubio et al, “Defining Translational Research: Implications for Training,” *Academic Medicine*, 85:470-475, 2010.