

# **I OVERVIEW OF THE FUNDING OPPORTUNITY**

**Program Announcement for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Tuberous Sclerosis Complex Research Program**

**Idea Development Award**

**Announcement Type: Modified**

**Funding Opportunity Number: W81XWH-21-TSCR-IDA**

**Catalog of Federal Domestic Assistance Number: 12.420 Military Medical  
Research and Development**

## **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), July 8, 2021
- **Application Submission Deadline:** 11:59 p.m. ET, July 29, 2021
- **End of Application Verification Period:** 5:00 p.m. ET, August 5, 2021
- **Peer Review:** September 2021
- **Programmatic Review:** December 2021

*This program announcement must be read in conjunction with the General Application Instructions, version 603. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”*

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## **II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY**

### **II.A. Program Description**

Applications to the Fiscal Year 2021 (FY21) Tuberous Sclerosis Complex Research Program (TSCRCP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP). The TSCRCP was initiated in 2002 to provide support for research of exceptional scientific merit and to promote innovative research focused on decreasing the clinical impact of tuberous sclerosis complex (TSC). Appropriations for the TSCRCP from FY02 through FY20 totaled \$89 million (M). The FY21 appropriation is \$8M.

#### **II.A.1. TSCRCP Strategic Plan**

The TSCRCP has prepared a Strategic Plan that describes the TSCRCP's background and overview, the research and funding environment, and strategic direction for the program. Applicants are strongly urged to read and consider the TSCRCP Strategic Plan, especially the Strategic Goals and Range of Research Areas, before preparing their application. The TSCRCP Strategic Plan may be found at <https://cdmrp.army.mil/tscrp/pdfs/TSCRCP%20Strategic%20Plan.pdf>.

#### **II.A.2. FY21 TSCRCP Idea Development Award Focus Areas**

The mission of the FY21 TSCRCP is to support innovative and high-impact research that promotes discoveries in TSC, from mechanistic insights to clinical application across all ages, by fostering new ideas and investigators for the benefit of Service Members, their beneficiaries, and the American public. Within this context, the FY21 TSCRCP encourages applications in mechanistic studies, animal model development, biomarkers, therapeutics, and patient-centered studies that address one or more of the following Idea Development Award Focus Areas:

- Eradicating tumors associated with TSC and TSC-associated lymphangioliomyomatosis (LAM), including gaining a deeper mechanistic understanding of TSC signaling pathways
- Preventing epilepsy, improving treatment, and mitigating neurodevelopmental outcomes associated with TSC-related seizures
- Understanding the features of TSC-Associated Neuropsychiatric Disorders (TAND) and reducing their impact, including pharmacological and behavioral interventions

If the proposed research project does not address one or more of the FY21 TSCRCP Idea Development Award Focus Areas, justification that the proposed research project addresses

another important problem or unmet need related to TSC research and/or patient care should be provided.

### **II.A.3. Award History**

The TSCRP Idea Development Award mechanism was first offered in FY02. Since then, 411 Idea Development Award applications have been received, and 82 have been recommended for funding.

### **II.B. Award Information**

The Idea Development Award promotes ideas that have the potential to yield high-impact findings and new avenues of investigation. This award mechanism supports conceptually innovative research that could ultimately lead to critical discoveries in TSC research and/or improvements in patient care. Research projects should include a well-formulated, testable hypothesis based on strong preliminary data and scientific rationale.

#### **The following are important aspects of the Idea Development Award:**

- **Impact:** Applications should articulate both the short- and long-term impact of the proposed research. High-impact research will, if successful, significantly advance TSC research and/or patient care.
- **Innovation:** Innovative research may introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities that may include high-risk/potentially high-gain approaches to TSC research. Research that is merely an incremental advance (the next logical step) is not considered innovative.
- **Preliminary Data:** Unpublished results from the laboratory of the Principal Investigator (PI) or collaborators named on this application, and/or data from the published literature that are relevant to TSC and the proposed research project, **are expected.**

**New Investigator Option:** The FY21 TSCRP Idea Development Award mechanism encourages applications from investigators in the early stages of their TSC research career. *The New Investigator Option is designed to support the continued development of promising independent investigators that are early in their faculty appointments **and/or** the transition of established investigators from other research fields into a career in the field of TSC research.* Applications from New Investigators and Established Investigators will be peer and programmatically reviewed in separate groups. PIs applying under the New Investigator category are strongly encouraged to strengthen their applications through collaboration with investigators experienced in TSC research and/or possessing other relevant expertise as demonstrated by a record of funding and publications.

***The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.***

The types of awards made under the program announcement will be assistance agreements. An assistance agreement is appropriate when the federal government transfers a “thing of value” to a “state, local government,” or “other recipient” to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the Department of Defense (DOD) during project performance is the key factor in determining whether to award a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The anticipated direct costs budgeted for the entire period of performance for an FY21 TSCRP Idea Development Award will not exceed **\$500,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2022. For additional information refer to [Section II.F.1, Federal Award Notices](#).

*The CDMRP expects to allot approximately \$3.2M to fund approximately two Established Investigator and two New Investigator Idea Development Award applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY21 funding opportunity will be funded with FY21 funds, which will expire for use on September 30, 2027.*

**Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers:** All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. *Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.* Refer to the General Application Instructions, Appendix 1, and the Human Research Protections Office Resources and Overview document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission or

award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

***Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed. A clinical trial is defined*** as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

***Clinical research is defined*** as: (1) patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) epidemiologic and behavioral studies; and (3) outcomes research and health services research. Note: Studies that meet the requirements for IRB Exemption 4 are not considered CDMRP-defined clinical research. IRB Exemption 4 refers to research involving the collection or study of existing de-identified specimens or data, if these sources are publicly available.

**Use of DOD or Department of Veterans Affairs (VA) Resources:** If the proposed research involves access to active-duty military patient populations and/or DOD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

**Research Involving Animals:** All DOD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. ***Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

**Guidelines for Animal Research:** All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 (<https://www.nature.com/nature/journal/v490/n7419/full/nature11556.html>). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Projects that include research on animal models are required to submit [Attachment 10, Animal Research Plan](#), as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at

<https://journals.plos.org/plosone/article/file?type=supplementary&id=info:doi/10.1371/journal.pone.0146533.s001>.

**TSCRCP Research Resources Initiative:** Research resources developed through TSCRCP funding are available to the scientific community and can be found at <https://cdmrp.army.mil/tscrp/resources/tscresources.aspx>; investigators are urged to leverage these resources. Investigators are expected to share data and resources developed through TSCRCP funding via the Research Resources Initiative. A Data and Research Resources Sharing Plan ([Attachment 8](#)) describing how data resources generated during the performance of the proposed research will be made available to the scientific community should be included in the application.

## II.C. Eligibility Information

### II.C.1. Eligible Applicants

**II.C.1.a. Organization:** All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.

**Government Agencies Within the United States:** Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this program announcement may be submitted by extramural and intramural organizations, these terms are defined below.

**Extramural Organization:** An eligible non-DOD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organization other than the DOD, and research institutes.

**Intramural DOD Organization:** A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission: Application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.***

**USAMRAA makes awards to eligible organizations, not to individuals.**

### II.C.1.b. Principal Investigator

***Although a PI may be eligible for both the Established Investigator and New Investigator categories, only one category may be chosen at the time of pre-application submission; the choice of application category is at the PI's discretion.***

- **Established Investigator**

The PI must be an independent investigator at or above the level of Assistant Professor (or equivalent).

- **New Investigator**

- By the application submission deadline, the PI must be either:
  - An independent investigator at or below the level of Assistant Professor (or equivalent); *or*
  - An established independent investigator in an area other than TSC at or above the level of Assistant Professor seeking to transition to a career in TSC thereby bringing their expertise to the field.
- Must not have received more than \$300,000 in total direct costs for previous or concurrent TSC research as a PI of one or more federally funded, non-mentored peer-reviewed grants. (National Institutes of Health [NIH] K Awardees are eligible to apply.)
- Must not have received a New Investigator Award previously from any program within the CDMRP.
- The PI must commit at least 10% of their effort toward the proposed TSC research project.
- Graduate students, postdoctoral fellows, and other “mentored” researchers are not eligible for this award.

There are no limitations on the number of applications for which an investigator may be named as a PI within the category selected for application (i.e., either Established Investigator or New Investigator).

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by, or affiliated with, an eligible organization.

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at <https://orcid.org/>.

### **II.C.2. Cost Sharing**

Cost sharing/matching is not an eligibility requirement.

### **II.C.3. Other**

Organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.



For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to [Section II.H.2, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

## **II.D. Application and Submission Information**

*Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).*

### ***Extramural Submission:***

- Pre-application content and forms must be accessed and submitted at [eBRAP.org](http://eBRAP.org).
- Full application packages must be accessed and submitted at Grants.gov.

### ***Intramural DOD Submission:***

- Pre-application content and forms must be accessed and submitted at [eBRAP.org](http://eBRAP.org).
- Full application packages must be accessed and submitted at [eBRAP.org](http://eBRAP.org).

***Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.***

### **II.D.1. Address to Request Application Package**

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in [Section II.G, Federal Awarding Agency Contacts](#).

### **II.D.2. Content and Form of the Application Submission**

Submission is a two-step process requiring both ***pre-application*** (eBRAP.org) and ***full application*** (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to [Table 1, Full Application Guidelines](#)).

***The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the***

*entire pre-application and full application submission process.* Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507 prior to the application submission deadline.

#### **II.D.2.a. Step 1: Pre-Application Submission Content**

*During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required during the full application submission process.*

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507 to request a change in designation.

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>).

The applicant organization and associated PI identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

PIs with an ORCID identifier should enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP.

*When starting the pre-application, PIs should ensure that they have selected the appropriate application category:*

- Idea Development Award –*New Investigator (IDA-NI)*
- Idea Development Award –*Established Investigator (IDA-EI)*

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B, for additional information on pre-application submission):

- **Tab 1 – Application Information**

Submission of application information includes assignment of primary and secondary research classification codes, which may be found at <https://eBRAP.org/eBRAP/public/Program.htm>. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 Research & Related Form), and click on “Add Organizations to this Pre-application.” The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

It is recommended that applicants identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

Enter the name, organization, and role of all collaborators and key personnel associated with the application.

[FY21 TSCRP Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

List all individuals other than collaborators and key personnel who may have a conflict of interest in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Tab 5 – Pre-Application Files**

**Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the [FY21 TSCRP Idea Development Award Focus Area\(s\)](#) or another important problem or unmet need related to TSC research and/or patient care to be addressed. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions. An invitation to submit is *not* required.

- **Tab 6 – Submit Pre-Application**

This tab must be completed for the pre-application to be accepted and processed.

**II.D.2.b. Step 2: Full Application Submission Content**

*The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.*

Each application submission must include the completed full application package for this program announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://www.grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines.

**II.D.2.b.i. Full Application Guidelines**

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the **same version** of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user’s computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

*Do not password protect any files of the application package, including the Project Narrative.*

**Table 1. Full Application Submission Guidelines**

| Extramural Submissions   | Intramural DOD Submissions   |
|--|--|
| <b>Application Package Location</b>  |  |
| Download application package components for W81XWH-21-TSCR-IDA from Grants.gov ( <a href="https://www.grants.gov/">https://www.grants.gov/</a> ) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission. | Download application package components for W81XWH-21-TSCR-IDA from eBRAP ( <a href="https://ebrap.org/">https://ebrap.org/</a> ). |
| <b>Full Application Package Components</b>   |  |
| <b>SF424 Research &amp; Related Application for Federal Assistance Form:</b> Refer to the General  | <b>Tab 1 – Summary:</b> Provide a summary of the application information.  |

| Extramural Submissions  | Intramural DOD Submissions  |
|---|---|
| Application Instructions, Section III.A.1, for detailed information.  | <b>Tab 2 – Application Contacts:</b> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.   |
| <p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">Research &amp; Related Subaward Budget Attachment(s) Form</a></li> </ul>  | <p><b>Tab 3 – Full Application Files:</b> Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Key Personnel</a></li> <li>• <a href="#">Budget</a></li> <li>• <a href="#">Performance Sites</a></li> </ul> <p><b>Tab 4 – Application and Budget Data:</b> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>  |
| <b>Application Package Submission</b>   |   |
| <p><b>Create a Grants.gov Workspace.</b><br/>Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p><b>Submit a Grants.gov Workspace Package.</b><br/>An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package <b>at least 24-48 hours prior to the close date</b> to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p><i>Note:</i> If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p> | <p><b>Submit package components to eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</b></p> <p><b>Tab 5 – Submit/Request Approval Full Application:</b> After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p> |

| Extramural Submissions  | Intramural DOD Submissions   |
|---|--|
| <u><a href="#">Application Verification Period</a></u>  |  |
| <p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research &amp; Related Budget Form</i>.</p>   | <p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research &amp; Related Budget Form</i>. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p> |
| <b>Further Information</b>  |  |
| <p><b>Tracking a Grants.gov Workspace Package.</b><br/>After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p> | <p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>  |

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

#### II.D.2.b.ii. Full Application Submission Components

- **Extramural Applications Only**

**SF424 Research & Related Application for Federal Assistance Form:** Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications**

**Attachments:**

*Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.*

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB, and the file size for the entire full application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (10-page limit): Upload as “ProjectNarrative.pdf”.** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.
  - **Background/Rationale:** Present the ideas and rationale behind the proposed research project, including a clear mechanistic underpinning. Include relevant literature citations. Describe previous experience most pertinent to the proposed research project. *Include preliminary and/or published data that are relevant to TSC and the proposed research project.*
  - **Hypothesis/Objective:** State the hypothesis to be tested or the objective to be reached.
  - **Specific Aims:** Concisely explain the proposed research project’s specific aims to be funded by this award. If this research project is part of a larger study, present only tasks that this award would fund.
  - **Research Strategy**
    - Describe the experimental design and methods, including appropriate randomization, blinding, and controls, in sufficient detail for scientific peer review. If any biological material will be used, the name, definition, pathological classification, and source of the material must be provided.
    - Describe how data will be collected, handled, and analyzed in a manner that is consistent with the study objectives. Describe the statistical analysis plan appropriate for the proposed research project. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.
    - If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. For clinical research, describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. *This award may not be used to conduct clinical trials.*

- Address potential problem areas and present alternative methods and approaches.
- **New Investigators:** Collaboration with investigators experienced in TSC research and/or possessing other relevant expertise is encouraged. If applicable, describe the specific contributions of the collaborator(s) to the research project. The application should describe how the collaboration(s) will augment the PI’s expertise to best address the research question. All New Investigator applicants must meet specific eligibility criteria as described in [Section II.C.1.b, Principal Investigator](#).
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

*There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.*

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- **Letters of Organizational Support:** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.



- **Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.
- **Intellectual Property:** Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), “Intangible Property.”
  - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.
- **Use of VA Resources (if applicable):** Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **Inclusion Enrollment Report (if applicable):** Provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment Report format is a one-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Of particular importance, programmatic reviewers may not have access to the full application and therefore rely on the technical abstract for appropriate description of the project’s key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

The technical abstract should be structured to include the following points:

- **Background/Rationale:** State the [FY21 TSCRP Idea Development Award Focus Area\(s\)](#) or another important problem or unmet need in TSC research and/or patient care to be addressed. Present the ideas and rationale behind the proposed research project.
  - **Hypothesis/Objective:** State the hypothesis to be tested or the objective to be reached. Provide evidence or rationale that supports the hypothesis/objective.
  - **Specific Aims:** State the specific aims of the proposed research project.
  - **Study Design:** Briefly describe the study design including appropriate controls.
  - **Innovation:** Briefly describe how the proposed research project is innovative in the field of TSC.
  - **Impact:** Briefly describe how the proposed research project will have a short- and long-term impact on TSC research and/or patient care.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. *Do not include proprietary or confidential information. Do not duplicate the technical abstract.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The lay abstract is an important component of the application review process because it addresses issues of particular interest to the advocate community. Minimize use of acronyms and abbreviations, where appropriate.

The lay abstract should be written using the outline below.

- Explain how the proposed research addresses one or more of the [FY21 TSCRP Idea Development Award Focus Areas](#) or another important problem or unmet need in TSC research and/or patient care. Describe the scientific objective and rationale for the proposed project in a manner that will be readily understood by readers without a background in science or medicine.
- Describe the ultimate applicability of the research.
  - What types of patients will it help, and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected time it may take to achieve a patient-related outcome?

- If the research is too basic for clinical applicability, describe the interim outcomes.
- What are the likely contributions of the proposed research project to improving the diagnosis, prognosis, or treatment of TSC?
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>.

For the Idea Development Award mechanism, refer to the “*Suggested SOW Strategy Generic Research*” document for guidance on preparing the SOW and use the blank SOW format titled “*Suggested SOW Format*”. The SOW must be in PDF format prior to attaching.

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf”.**

Explain why the proposed research is important and the impact it will have on one or more of the [FY21 TSCRP Idea Development Award Focus Areas](#). If the project does not address an FY21 TSCRP Idea Development Award Focus Area, provide justification that the proposed research project addresses another important problem or unmet need in TSC research and/or patient care.

**Short-term impact:** Detail the anticipated outcome(s) that will be directly attributed to the results of the proposed research.

**Long-term impact:** Explain the anticipated long-term gains from the proposed research project, including how the new understanding may ultimately contribute to the goal of advancing TSC research and/or patient care

- **Attachment 7: Innovation Statement (one-page limit): Upload as “Innovation.pdf”.**

- Describe how the proposed research project is innovative in the field of TSC.
- Describe how the proposed research project introduces a new paradigm, challenges existing paradigms, or looks at existing problems or issues from a new perspective.
- Describe how the research represents more than an incremental advance on published data or current work in the applicant’s laboratory.

**Although not all-inclusive,** the following examples are ways in which the proposed research project may be innovative:

- Explores a novel idea and/or research question in TSC research and/or patient care.

- Uses or develops novel methods or technologies to address a question in TSC research and/or patient care.
  - Applies or adapts existing methods or technologies for novel TSC research or clinical purposes that differ fundamentally from those originally intended.
- **Attachment 8: Data and Research Resources Sharing Plan: Upload as “ResourceSharing.pdf”.** Describe how data and resources generated during the performance of the project will be shared with the research community. Specifically describe a plan to make animal models, tissue samples, and other resources developed as part of the proposed research project available to the scientific community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
  - **Attachment 9: (New Investigators Only) Eligibility Statement (one-page limit): Upload as “Eligibility.pdf”.** Provide a letter, signed by the PI and the Department Chair, Dean, or equivalent official, verifying that the eligibility requirements will be met by the application submission deadline. The letter should verify that the PI is an independent investigator at or above the level of Assistant Professor (or equivalent) or an established independent investigator in an area other than TSC at or above the level of Assistant Professor seeking to transition to a career in TSC thereby bringing their expertise to the field; that the PI has not received more than \$300,000 in total direct costs for previous or concurrent TSC research as a PI of one or more federally funded, non-mentored peer-reviewed grants; and that the PI has not received a New Investigator Award previously from any program within the CDMRP (Refer to [Section II.C.1.b, Principal Investigator](#), for eligibility information).
  - **Attachment 10: Animal Research Plan (three-page limit) (required if proposed research project involves animals): Upload as “AnimalPlan.pdf”.** For research projects involving animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:
    - Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study’s relevance to human biology.
    - Summarize the procedures to be conducted. Describe how the study will be controlled.
    - Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.

- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.

Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint

- **Attachment 11: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- **Attachment 12: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using “Suggested Collaborating DOD Military Facility Budget Format”, available for download on the eBRAP “Funding Opportunities & Forms” web page <https://ebrap.org/eBRAP/public/Program.htm>, including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681(a) et seq.), the DOD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

**Research & Related Personal Data:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

**Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch\_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

- PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.
  - For extramural submissions, refer to the General Application Instructions, Section III.A.4 for detailed information.
  - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch\_LastName.pdf”.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.

**Research & Related Budget:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

**Budget Justification (no page limit): Upload as “BudgetJustification.pdf”.** The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

**Project/Performance Site Location(s) Form:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

**Research & Related Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- **Intramural DOD Collaborator(s):** Complete the “Suggested Collaborating DOD Military Facility Budget Format” and upload to Grants.gov attachment form as [Attachment 12](#). (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

### **II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)**

Applicant organizations and all sub-recipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Verify the status of the applicant organization’s Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the federal awarding agency is ready to make a federal award, the federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that determination as a basis for making a federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

***Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI):*** Through April 2022, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

### **II.D.4. Submission Dates and Times**

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

### **Applicant Verification of Full Application Submission in eBRAP**

***For Both Extramural and Intramural Applicants:*** eBRAP allows an organization’s representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in an email to the PI and in the “Full Application Files” tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

**Extramural Submission:** The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, *with the exception of the Project Narrative and Budget Form*, may be modified.

**Intramural DOD Submission:** After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, *with the exception of the Project Narrative and Budget Form*, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

**For All Submissions:** Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

#### **II.D.5. Funding Restrictions**

The maximum period of performance is **3** years.

The anticipated direct costs budgeted for the entire period of performance will not exceed **\$500,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the government exceeding **\$500,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Support for multidisciplinary collaborations, including travel
- Travel costs for one investigator to travel to one scientific/technical meeting per year to present project information or disseminate project results from the FY21 TSCRIP Idea Development Award

Must not be requested for:

- Clinical trial costs

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DOD or other federal agency is not allowed except under very



limited circumstances. Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. *For federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.5.*

## **II.D.6. Other Submission Requirements**

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

## **II.E. Application Review Information**

### **II.E.1. Criteria**

#### **II.E.1.a. Peer Review**

To determine technical merit, all applications will be evaluated according to the following **scored criteria**, where **Impact** is ranked as most important, **Innovation** is ranked as **second most important**, and the other scored criteria are of equal importance:

- **Impact**
  - How well the proposed research project addresses one or more of the [FY21 TSCRP Idea Development Award Focus Areas](#) or another important problem or unmet need in TSC research and/or patient care.
  - *Assuming the objectives/goals of the proposed research project are realized:*
    - To what extent the anticipated short-term outcomes will make an important contribution toward advancing TSC research.
    - To what extent the anticipated long-term outcomes will make an important contribution toward the goal of advancing TSC research and/or patient care.
    - To what extent the data and resources generated during the performance of the project will be shared with the research community.
- **Innovation**
  - To what extent the proposed research project is innovative in the field of TSC in one or more of the following ways: research concept or question, development of novel research methods or technologies, adaptations of existing methods or technologies.

- To what extent the proposed research project represents more than an incremental advance upon published data or current research being performed in the laboratory of the PI or collaborators named on the application.

- **Rationale**

- How well the scientific rationale, including a well-formulated, testable hypothesis and clear mechanistic underpinning, supports the proposed research project.
- To what extent the provided preliminary data support the proposed research project.

- **Research Strategy and Feasibility**

- How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and power analysis.
- How well the handling, collection, and analysis of data are consistent with the study objectives.
- If applicable, how well the proposed animal studies are designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used.
- To what extent the proposed research project is feasible as described.
- How well the application identifies potential problems and addresses alternative approaches.
- If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.

- **Personnel**

- To what extent the levels of effort by the PI and other key personnel are appropriate to ensure success of the proposed research project.
- To what degree the PI and research team's experience, expertise, and record of accomplishment demonstrate their ability to successfully complete the proposed research project.
- *In addition, for New Investigators:*
  - *(If applicable)* To what extent the specific contributions of the collaborator(s) will augment the PI's expertise to best address the research question.

In addition, the following **unscored** criteria will also contribute to the overall evaluation of the application:

- **Environment**
  - To what degree the scientific environment is appropriate for the proposed research project.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - To what degree the quality and extent of institutional support/commitment are appropriate for the proposed research project.
  - If applicable, to what degree the intellectual and material property plan is appropriate.
- **Budget**
  - Whether the direct costs exceed the allowable direct costs as published in the program announcement.
  - Whether the budget is appropriate for the proposed research.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

#### **II.E.1.b. Programmatic Review**

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY21 TSCR, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Relative impact and innovation

#### **II.E.2. Application Review and Selection Process**

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding

General, USAMRDC, on behalf of the DHA and the OASD(HA). *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section II.E.1.b, Programmatic Review](#).* Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.army.mil/about/2tierRevProcess>. An information paper describing the funding recommendations and review process for the award mechanisms for the TSCRIP will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

### **II.E.3. Integrity and Performance Information**

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a federal awarding agency previously entered and is currently available in FAPIIS.

The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

### **II.E.4. Anticipated Announcement and Federal Award Dates**

All application review dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

## **II.F. Federal Award Administration Information**

### **II.F.1. Federal Award Notices**

Awards supported with FY21 funds are anticipated to be made no later than September 30, 2022. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

**Pre-Award Costs:** An institution of higher education, hospital, or other non-profit organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Application Instructions, Section III.A.5.

***Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds.*** No commitment on the part of the government should be inferred from discussions with any other individual. **The award document signed by the Grants Officer is the official authorizing document.**

**Federal Government Organizations:** Funding made to federal government organizations (to include intramural DOD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

#### **II.F.1.a. PI Changes and Award Transfers**

Unless otherwise restricted, changes in PI or organization will be allowed at the discretion of the USAMRAA Grants Officer, provided the intent of the award mechanism is met.

An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

### **II.F.2. Administrative and National Policy Requirements**

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this program announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the latest [DoD R&D General Terms and Conditions](#); the [USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions](#); and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

### **II.F.3. Reporting**

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Annual progress reports as well as a final progress report will be required.

The Award Terms and Conditions will specify if more frequent reporting is required.

**Award Expiration Transition Plan:** An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template “Award Expiration Transition Plan,” available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) under the “Progress Report Formats” section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

**Inclusion Enrollment Reporting Requirement (*only required for clinical research studies*):** Enrollment on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final technical report. The suggested Inclusion Enrollment Report format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP.

Awards resulting from this program announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

## **II.G. Federal Awarding Agency Contacts**

### **II.G.1. CDMRP Help Desk**

Questions related to program announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

### **II.G.2. Grants.gov Contact Center**

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726; International 1-606-545-5035

Email: [support@grants.gov](mailto:support@grants.gov)

Sign up on Grants.gov for “send me change notification emails” by following the link on the “Synopsis” page for the program announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

## **II.H. Other Information**

### **II.H.1. Program Announcement and General Application Instructions Versions**

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 603b. The program announcement numeric version code will match the General Application Instructions version code 603.

### **II.H.2. Administrative Actions**

After receipt of applications, the following administrative actions may occur:

#### **II.H.2.a. Rejection**

The following will result in administrative rejection of the application:

- Pre-application was not submitted.

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

#### **II.H.2.b. Modification**

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

#### **II.H.2.c. Withdrawal**

The following may result in administrative withdrawal of the application:

- An FY21 TSCR P Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the FY21 TSCR P Programmatic Panel members can be found at <https://cdmrp.army.mil/tscrp/panels/panels21>.*
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY21, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.



- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- [Attachment 10, Animal Research Plan](#), is missing (if applicable).
- A clinical trial is proposed.
- The PI does not meet the eligibility criteria.

#### **II.H.2.d. Withhold**

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

### II.H.3. Application Submission Checklist

| Application Components   | Action   | Completed |
|--|--|-----------|
| SF424 Research & Related Application for Federal Assistance ( <b>extramural submissions only</b> ) | Complete form as instructed  |           |
| Summary (Tab 1) and Application Contacts (Tab 2) ( <b>intramural submissions only</b> )            | Complete tabs as instructed  |           |
| Attachments  | Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"  |           |
|  | Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"  |           |
|  | Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"  |           |
|  | Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"   |           |
|  | Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"   |           |
|  | Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"   |           |
|  | Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf"   |           |
|  | Data and Research Resources Sharing Plan: Upload as Attachment 8 with file name "ResourceSharing.pdf"                            |           |
|  | Eligibility Statement: Upload as Attachment 9 with file name "Eligibility.pdf" if applicable                                     |           |
|  | Animal Research Plan: Upload as Attachment 10 with file name "AnimalPlan.pdf" if applicable                                      |           |
|  | Representations (extramural submissions only): Upload as Attachment 11 with file name "RequiredReps.pdf" if applicable           |           |
|  | Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 12 with file name "MFBudget.pdf" if applicable |           |
| Research & Related Personal Data   | Complete form as instructed  |           |

| Application Components   | Action   | Completed |
|--|--|-----------|
| Research & Related Senior/Key Person Profile (Expanded)              | Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field                            |           |
|  | Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field                 |           |
|  | Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field    |           |
|  | Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field |           |
| Research & Related Budget ( <b>extramural submissions only</b> )     | Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field     |           |
| Budget ( <b>intramural submissions only</b> )                        | Suggested DOD Military Budget Format, including justification  |           |
| Project/Performance Site Location(s) Form                            | Complete form as instructed  |           |
| Research & Related Subaward Budget Attachment(s) Form, if applicable | Complete form as instructed  |           |

## APPENDIX 1: ACRONYM LIST

|          |   |
|----------|---|
| ACOS/R&D | Associate Chief of Staff for Research and Development           |
| ACURO    | Animal Care and Use Review Office                               |
| ARRIVE   | Animal Research: Reporting <i>In Vivo</i> Experiments           |
| CDMRP    | Congressionally Directed Medical Research Programs              |
| CFR      | Code of Federal Regulations                                     |
| DHA      | Defense Health Agency   |
| DHP      | Defense Health Program  |
| DOD      | Department of Defense   |
| DoDGARs  | Department of Defense Grant and Agreement Regulations           |
| DUNS     | Data Universal Numbering System                                 |
| eBRAP    | Electronic Biomedical Research Application Portal               |
| EC       | Ethics Committee  |
| ET       | Eastern Time  |
| FAD      | Funding Authorization Document                                  |
| FAPIIS   | Federal Awardee Performance and Integrity Information System    |
| FY       | Fiscal Year   |
| HRPO     | Human Research Protection Office                                |
| IACUC    | Institutional Animal Care and Use Committee                     |
| IDA      | Idea Development Award  |
| IDA-EI   | Idea Development Award –Established Investigator                |
| IDA-NI   | Idea Development Award –New Investigator                        |
| IRB      | Institutional Review Board                                      |
| LAM      | Lymphangioliomyomatosis   |
| LOI      | Letter of Intent  |
| M        | Million   |
| MIPR     | Military Interdepartmental Purchase Request                     |
| NIH      | National Institutes of Health                                   |
| OASD(HA) | Office of the Assistant Secretary of Defense for Health Affairs |
| ORCID    | Open Researcher and Contributor ID, Inc.                        |
| ORP      | Office of Research Protections                                  |
| PI       | Principal Investigator  |
| RDT&E    | Research, Development, Test, and Evaluation                     |
| SAM      | System for Award Management                                     |
| SOW      | Statement of Work   |
| STEM     | Science, Technology, Engineering, and/or Mathematics            |
| TAND     | TSC-Associated Neuropsychiatric Disorders                       |
| TSC      | Tuberous Sclerosis Complex                                      |
| TSCRCP   | Tuberous Sclerosis Complex Research Program                     |
| UEI      | Unique Entity Identifier  |

|         |  |
|---------|--|
| URL     | Uniform Resource Locator                           |
| USAMRAA | U.S. Army Medical Research Acquisition Activity    |
| USAMRDC | U.S. Army Medical Research and Development Command |
| USC     | United States Code                                 |
| VA      | Department of Veterans Affairs                     |