

Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Tuberous Sclerosis Complex Research Program

Postdoctoral Development Award

Funding Opportunity Number: W81XWH-16-TSCR-PDA

**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 1, 2016
- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, July 21, 2016
- **Application Submission Deadline:** 11:59 p.m. ET, July 18, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, July 21, 2016
- **Peer Review:** September 2016
- **Programmatic Review:** November 2016

This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2016 (FY16) Tuberous Sclerosis Complex Research Program (TSCRCP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA RDA Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing agent for this Program Announcement/Funding Opportunity 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 FY15 totaled \$59 million (M). The FY16 appropriation is \$6M.

B. FY16 TSCRCP Mission and Focus Areas

The mission of the FY16 TSCRCP is to encourage innovative research aimed at understanding the pathogenesis, and preventing and treating the manifestations of TSC. Within this context, the FY16 TSCRCP encourages applications to address one or more of the following Focus Areas:

- Understanding phenotypic heterogeneity in TSC
- Gaining a deeper knowledge of TSC signaling pathways and the cellular consequences of TSC deficiency
- Improving TSC disease models
- Developing clinical biomarkers for TSC
- Facilitating therapeutics and clinical trials research

If the proposed research project does not address one or more of the FY16 Focus Areas, justification that the proposed research project addresses an important problem or unmet need related to TSC research and/or patient care should be provided.

TSC Research Resources Initiative: Resources developed through TSCRCP funding are available to the scientific community and can be found at <http://cdmrp.army.mil/tscrp/resources/tscresources>; investigators are urged to leverage these resources. Investigators are expected to share data and resources developed through TSCRCP funding via the Research Resources. A Data and Resource Sharing Plan (Attachment 9) describing how data and resources generated during the performance of the proposed research project will be made available to the scientific community should be included in the application. For additional guidance on sharing data and research resources information, refer to the General Application Instructions, Appendix 4, Section K.

C. Award Information

The TSCRP Postdoctoral Development Award mechanism is being offered for the first time in FY16. The Postdoctoral Development Award supports recent doctoral or medical graduates to conduct impactful research with the mentorship of an experienced TSC researcher (i.e., Mentor). This opportunity allows for junior investigators to develop and investigate a TSC research project and further their intellectual development as a TSC researcher of the future. Under this award mechanism, the junior investigator is considered the Principal Investigator (PI), and the application should focus on the PI's research and TSC career development. It should be clear that the proposed research is intellectually designed by the PI with assistance from the Mentor. Applicants for this award must exhibit a strong desire to develop and pursue a career in TSC research, with clear evidence for a researcher development plan that will lead to a successful independent career in TSC. Applicants must also demonstrate that the proposed research has high potential to lead to or make breakthroughs in TSC. **Inclusion of preliminary data is not required. However, logical reasoning and a sound scientific rationale for the proposed research must be demonstrated. *Clinical trials will not be supported by this mechanism.***

Key elements of the award are as follows:

- **Principal Investigator:** The PI must be a postdoctoral fellow with 3 years or less of postdoctoral research experience (excluding clinical residency, clinical fellowship training, or family medical leave) and working in the Mentor's laboratory at the time of the application submission deadline. While the PI is not required to have previous experience in TSC research, the proposed project must focus on TSC. Applications must emphasize the PI's high potential for success in becoming an independent TSC researcher based on his/her qualifications, achievements (including first-author publications), and letters of recommendation.
- **Mentor:** The Mentor must be an experienced TSC researcher as demonstrated by a strong record of active peer reviewed funding and recent publications in the TSC field. In addition, the Mentor must demonstrate a commitment to advancing the PI's career in TSC research. The Mentor's record of accomplishments (such as publications, patents, presentations, etc.) should include documentation of significant contribution to the TSC field.
- **Research Approach:** The scientific rationale and experimental methodology should demonstrate in-depth analysis of the research problem presented. The feasibility of the research design and methods should be well defined, and a clear plan should be articulated as to how the proposed goals of the project can be achieved. Additionally, resources necessary for the proposed research should be identified and their availability should be supported through documentation. Identification of potential problems and pitfalls are strongly encouraged with alternate approaches addressed. A statistical analysis of the proposed research should be included, if applicable, as well as a power analysis to support the design and sample size.
- **Researcher Development Plan:** A researcher development plan is required and should be prepared with appropriate guidance from the Mentor. The application should include a clearly articulated strategy for acquiring the necessary skills, competence, and expertise to successfully complete the proposed TSC research.

- **Impact:** The proposed research should have the potential for a major impact and accelerate progress toward advancing TSC research and/or patient care. The impact may be short-term or long-term, but must be significant and move beyond an incremental advancement.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All Department of Defense (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 Materiel Command (USAMRMC) 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. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 6, and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this Program Announcement/Funding Opportunity. For more information on clinical trials and clinical research overall, a Human Subject Resource Document is provided on the CDMRP electronic Biomedical Research Application Portal (eBRAP) system at <https://ebrap.org/eBRAP/public/Program> PIs wishing to apply for funding for a clinical trial should utilize the FY16 TSCRCP Pilot Clinical Trial Award mechanism (Funding Opportunity Number: W81XWH-16-TSCRCP-PCTA).

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC 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. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” ***Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 6, for additional information.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

D. Eligibility Information

- **As of the application deadline, the PI must:**
 - Have successfully completed the requirements for a doctoral and/or medical degree,
 - Be a postdoctoral fellow in the Mentor's laboratory, *and*
 - Have a total of 3 years or less of postdoctoral research experience (excluding clinical residency, clinical fellowship training, or family medical leave).
- **Mentor**
 - Must hold a position at or above the level of an Assistant Professor (or equivalent),
 - Must be an experienced TSC researcher with a strong record of accomplishments, active peer reviewed funding, and recent publications in the TSC field.
- ***The PI and the Mentor must be at the same organization.***
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Submissions from intramural (DoD) organizations are allowed and encouraged for this Program Announcement/Funding Opportunity. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. ***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.***
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **2** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$150,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$150,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.

- The Postdoctoral Development Award is not intended to support general laboratory expenses for the Mentor.

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

- PI salary
- Research workshops
- Research supplies
- Clinical research costs (no clinical trials allowed)
- Travel costs for up to one investigator to travel to one scientific/technical meeting per year

Shall not be requested for:

- Mentor salary
- Any salary other than the PI's
- Clinical trial costs

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural (DoD) agencies and other Federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or DD Form 1144 Support Agreement). Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4., 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 Section II.C.4. of the General Application Instructions.***

The CDMRP expects to allot approximately \$0.72M of the \$6M FY16 TSCRP appropriation to fund approximately three Postdoctoral Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. 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).

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>). Refer to the General Application Instructions, Section II.A., for registration and submission requirements for eBRAP and Grants.gov.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

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. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit 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 or 301-682-5507 prior to the application deadline.

Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the [application verification period](#). After the end of the application verification period, the full application cannot be modified.

A. Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-16-TSCR-PDA in Grants.gov (<http://www.grants.gov/>).

B. Pre-Application Submission Content

The pre-application process should be started early to avoid missing deadlines. There are no grace periods. During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the application process on Grants.gov.

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

PIs, Mentors, and organizations 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 PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

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**
- **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 (R&R) Form). The Business Official must either be 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 (R&R) Form), and click on “*Add Organizations to this Pre-application.*” The organization(s) must either be selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.
 - It is recommended that PIs 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.
 - Include the name of the Mentor.
 - Include the names of the individuals providing letters of recommendation.
 - [FY16 TSCRP Programmatic Panel](#) members should not be involved in any preapplication or application. For questions related to Programmatic Panel members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.
 - 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 application preparation, research, or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and

deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.

- **Tab 4 – Conflicts of Interest**

- List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). Refer to Appendix 1, Section C, of the General Application Instructions for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. If applicable, include the Focus Area(s) under which the application will be submitted. 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.

List of Individuals Providing Confidential Letters of Recommendation: Enter contact information for three individuals who will provide letters of recommendation. One of the three individuals must be the Mentor. Each individual will receive an email generated from eBRAP containing specific instructions on how to upload his/her letter.

- **Tab 6 – Submit Pre-Application**

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

C. Full Application Submission Content

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of the applicant's organization's Entity registration in the SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the General Application Instructions, Section II, for additional information.

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. See Section II.C. of the General Application Instructions for details on compatible Adobe software.

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 Grants.gov application package for this Program Announcement/Funding Opportunity. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>). For the Postdoctoral Development Award, additional application components are also required and should be submitted as directed below.

Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline.

If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form 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 **prior to the application submission deadline.**

Grants.gov application package components: For the Postdoctoral Development Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section II.C., for detailed information.

2. Attachments Form

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (six-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, etc.) 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.

Describe the proposed project in detail using the outline below.

- **Principal Investigator:** Describe the PI’s potential for a career at the forefront of TSC research, including qualifications and achievements that make the PI an ideal candidate for this award. Describe the PI’s career goals as a TSC researcher. Describe the record of accomplishments (including but not limited to awards, publications, etc.) that may demonstrate how the PI will succeed in a future career in TSC research.
- **Mentor:** Describe the qualifications of the Mentor including record of research accomplishments, publications, patents, and funding in TSC research. Describe the Mentor’s track record for training junior investigators.
- **TSCR P Focus Area(s):** State the FY16 Focus Area(s) that the proposed research project will address. If the proposed research project does not address

one or more of the FY16 Focus Areas, provide justification that the proposed research project addresses an important problem or unmet need related to TSC research and/or patient care should be provided.

- **Research Project:**
 - Background: Describe the ideas and rationale behind the proposed research project. *The inclusion of preliminary data is not required.* If applicable, provide sufficient preliminary data to support the feasibility of work proposed. Regardless of whether preliminary data are available, the PI must demonstrate logical reasoning and provide a sound scientific rationale for the proposed project as established through a critical review and analysis of published literature.
 - Hypothesis or Objective: State the hypothesis to be tested or the objective to be reached.
 - Specific Aims: State the project’s specific aims. If this application is part of a larger study, present only tasks that this award would fund.
 - Strategy: Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for scientific review and evaluation. Address potential problem areas and present alternative methods and approaches. A statistical analysis of the proposed research should be included, if applicable, as well as a power analysis to support the design and sample size.
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested 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 publications 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/Funding Opportunity, 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.
- Transcripts: Include a copy of the PI's transcripts from all graduate institutions attended. All foreign-language transcripts must be accompanied by a certified English translation. The Government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts.

If an institution does not provide academic transcripts (i.e., a record of courses completed, grades and credit hours earned, and indication of completion of degree), complete and include the Academic Statement (available for download on the Full Announcement page in Grants.gov) in place of the transcript.

- Intellectual Property
 - Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
 - Clearly identify all such property;
 - Identify the cost to the Federal government for use or license of such property, if applicable; or
 - Provide a statement that no property meeting this definition will be used on this project.
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** 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.

The technical abstract is used by all reviewers. 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.

Describe the proposed research project including the following points:

- **Personnel:** Describe the PI's potential for a career at the forefront of TSC research. Describe the Mentor's background and experience in TSC research.
- **Researcher Development Plan:** Describe the strategy for acquiring the necessary skills, competence, and expertise to successfully contribute to TSC research and/or patient care.
- **Research**
 - Background: Present the ideas and rationale behind the proposed project.
 - Objective/Hypothesis: State the hypothesis to be tested or the objective to be reached. Provide evidence or rationale that supports the objective/hypothesis
 - Specific Aims: State the specific aims of this study.
 - Study Design: Briefly describe the study design including appropriate controls.
- **Impact:** Summarize how the proposed research project will have a short- and long-term impact on TSC research and/or patient care. Identify the FY16 TSCRP Focus Area(s) addressed. If the proposed research project does not address one or more of the FY16 Focus Areas, describe the important problem or unmet need that the proposed research project addresses to advance 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.*** 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 should be written using the outline below. ***Do not duplicate the technical abstract.*** Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer community.

- 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 PI's career goals in TSC research.
 - How will the researcher development plan support the PI in attaining these goals?
 - How will the research plan support the PI in achieving these goals?
 - Describe the ultimate applicability and impact 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 immediate clinical applicability, describe the interim outcomes.
 - What are the likely contributions to advancing the field of TSC research and/or patient care?
- **Attachment 5: Statement of Work (SOW) (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>). For the Postdoctoral Development Award mechanism, use the SOW format example titled “SOW (Statement of Work) for Basic Research (Training Section optional).” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.
The SOW should indicate a feasible plan and timeline to conduct the research and researcher development and should provide clearly defined milestones.
 - **Attachment 6: Researcher Development Plan (one page limit): Upload as “ResearchDev.pdf.”**
 - Clearly articulate a strategy for acquiring the necessary skills, competence, and expertise to successfully contribute to TSC research and/or patient care.
 - Indicate how the individualized researcher development plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in the field of TSC, and further his/her intellectual development as a TSC researcher of the future.
 - Describe how the researcher development plan is supported by the environment and mentorship, including a description of TSC research at the institution. Include information on collaborations with other investigators, seminars, workshops, and other opportunities to interact with leaders in the TSC field. *Do not reference or include members of the FY16 TSCRP Programmatic Panel.*
 - **Attachment 7: Impact Statement (one-page limit):** Upload as “Impact.pdf.” Explain how the proposed research project addresses one or more of the FY16 TSCRP Focus Areas, or, if the project does not address a Focus Area, provide

justification that the proposed research project addresses an important problem or unmet need in TSC research and/or patient care.

Explain in detail why the proposed research project is important, as follows:

- ***Describe the short-term impact:*** Detail the anticipated outcome(s)/product(s) that will be directly attributed to the results of the proposed research.
 - ***Describe the long-term impact:*** Explain the anticipated long-term gains from the proposed research, including the anticipated advantages that the new understanding may contribute to the goal of advancing TSC research and/or patient care.
- **Attachment 8: Eligibility Statement (one-page limit): Upload as “Eligibility.pdf.”** Use the Eligibility Statement template (available for download on the Full Announcement page under this Funding Opportunity on Grants.gov) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met.
 - **Attachment 9: Data and Research Resources Sharing Plan: Upload as “ResourceSharing.pdf.”** Describe how data and resources generated during the performance of the proposed research 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 4, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
 - **Attachment 10: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility (military health system facility, research laboratory, 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 the Collaborating DoD Military Facility Budget Form, 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 and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.
- 3. Research & Related Senior/Key Person Profile (Expanded): Refer to the General Application Instructions, Section II.C.4., 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 five-page National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.

Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch_LastName.pdf.”
 - Include Mentor’s (and co-Mentor’s, if applicable) biographical sketch.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
 - Include Mentor’s (and co-Mentor’s, if applicable) previous/current/pending support.

4. Research & Related Budget: Refer to the General Application Instructions, Section II.C.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.

5. Project/Performance Site Location(s) Form: Refer to the General Application Instructions, Section II.C.5., for detailed information.

6. R & R Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section II.C.6., for detailed information.

Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.Gov R & R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 10, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.

Additional Application Components:

In addition to the complete Grants.gov application package, Postdoctoral Development Award applications also require the following components:

1. Confidential Letters of Recommendations (two pages per letter recommended)

The PI should monitor whether the letters have been received in eBRAP by viewing the status in the “Pre-Application Files” tab of the pre-application; however, the PI will not be able to view these letters.

The confidential letters should include the following:

- **A confidential letter of recommendation from the Mentor:** The PI's Mentor must submit a letter describing the Mentor's commitment to the PI's researcher development, and mentorship in TSC research. The Mentor's letter should address the following:
 - The PI's potential to become a successful and independent TSC researcher;
 - The Mentor's commitment to the career development and mentorship of the PI, including details of his/her proposed interactions with the PI and how he/she intends to support the PI's research endeavors; and
 - The relevance of the proposed research project to the PI's development as a TSC researcher.
- **Two additional confidential letters of recommendation:** The remaining letters should be from independent researchers who have had interactions with the PI. The letters should highlight the PI's potential for success in pursuing a career in TSC research. Specifically, each letter should offer the writer's perspective on:
 - The PI's qualifications, characteristics, and achievements;
 - The PI's potential for productivity and desire for establishing a successful career at the forefront of TSC research;
 - The relevance of the proposed research project to the PI's development as a TSC researcher; and
 - The suitability of the Mentor and researcher development plan for providing the PI with a solid foundation in TSC research.

D. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. ***If either the Project Narrative or the budget fails eBRAP validation or 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 prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

E. Submission Dates and Times

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in submission rejection.

F. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All extramural applications must be submitted through Grants.gov. Applicant organizations and all subrecipient 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. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

III. APPLICATION REVIEW INFORMATION

A. 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 of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and TSCR, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***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 III.B.2., Programmatic Review](#).*** Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement 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 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 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 Title 18 United States Code 1905.

B. Application Review Process

1. Peer Review: To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

- **Principal Investigator**
 - To what degree the PI's qualifications and achievements demonstrate the PI's potential for a successful career in TSC.
 - To what extent the PI's stated career goals demonstrate a strong personal commitment to pursuing an independent career as a leader in TSC research.
 - To what extent the letters of recommendation support the PI's potential for a successful career as a TSC researcher.
 - Whether the PI's proposed level of effort, if not 100%, is appropriate for successful development as a TSC researcher and completion of the proposed work.
- **Mentor(s)**
 - To what degree the Mentor's record of research accomplishments, publications, patents, and funding demonstrate a strong commitment and high level of expertise in TSC research.
 - Whether the Mentor has successfully trained junior investigators in TSC.
 - Whether the Mentor's letter of recommendation indicates a high level of commitment to the PI's development as a TSC researcher.
 - Whether the quality of the application suggests that the Mentor provided appropriate guidance in its preparation.
- **Research Strategy and Feasibility**
 - How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, logical reasoning, and preliminary data, if applicable.
 - Whether the experimental design and the statistical plan, if applicable, are appropriate for the research proposed.
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
 - To what degree the research project is appropriate for the PI's development as a TSC researcher.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
- **Researcher Development Plan and Environment**
 - Whether the plan articulates a strategy for the PI to acquire the necessary skills, competence, and expertise to successfully contribute to TSC research and/or patient care.

- How well the individualized researcher development plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in the field of TSC and further his/her intellectual development as a TSC researcher of the future.
- To what extent the researcher development plan is supported by the environment and mentorship including a description of ongoing TSC research at the institution.
- To what extent unique features of the research environment are integrated into the researcher development plan.
- **Impact**
 - *Assuming the objectives/goals of the research project are realized*, to what extent the proposed project could, whether in the short term or long term, make a significant impact on TSC research and/or patient care.
 - How well the proposed research project addresses one or more of the FY16 Focus Areas or an important problem or unmet need in TSC research and/or patient care.

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

- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influence the review.

2. **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:
 - a. **Ratings and evaluations of the peer reviewers**
 - b. **Relevance to the mission of the DHP and FY16 TSCRP, as evidenced by the following:**
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Relative impact

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D. Application Review Dates

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

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.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

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.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.

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.

C. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- An FY16 TSCRP 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 FY16 TSCRP Programmatic Panel members can be found at <http://cdmrp.army.mil/tscrp/panels/panels16>.*
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.

- 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 FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- If a clinical trial is proposed, the application will be withdrawn.
- An application submitted by a PI who does not meet the eligibility criteria will be withdrawn.
- An application submitted with a Mentor who does not meet the eligibility criteria will be withdrawn.

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.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2017. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

B. Administrative Requirements

Refer to the General Application Instructions, Appendix 4 for general information regarding administrative requirements.

C. National Policy Requirements

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

D. Reporting

Refer to the General Application Instructions, Appendix 4, Section H, for general information on reporting requirements.

Annual progress reports should include a comprehensive description of progress toward the tasks related to the researcher development and mentoring plans as well as the research underway.

E. Award Transfers

Changes in PI are not allowed.

Changes in Mentor or institution are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer. 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 4, Section L, for general information on organization or PI changes.

VI. VERSION CODES AND AGENCY CONTACTS

A. Program Announcement/Funding Opportunity and General Application Instructions Version

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code 20160210i. The Program Announcement/Funding Opportunity numeric version code will match the General Applications Instructions version code 20160210.

B. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application 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

C. Grants.gov Contact Center

Questions related to 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

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity 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.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Completed
SF424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Researcher Development Plan: Upload as Attachment 6 with file name "ResearchDev.pdf."	
	7	Impact Statement: Upload as Attachment 7 with file name "Impact.pdf."	
	8	Eligibility Statement: Upload as Attachment 8 with file name "Eligibility.pdf."	
	9	Data and Research Resources Sharing Plan: Upload as Attachment 9 with file name "ResourceSharing.pdf."	
	10	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 10 with file name "MFBudget.pdf," if applicable.	
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		Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form		Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.	
Additional Application Components	Upload Order	Action	Completed
Confidential Letters of Recommendation		Confirm upload to eBRAP.	