

Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Tuberous Sclerosis Complex Research Program

Idea Development Award

Funding Opportunity Number: W81XWH-15-TSCR-IDA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), July 10, 2015
- **Application Submission Deadline:** 11:59 p.m. ET, July 27, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, July 30, 2015
- **Peer Review:** September 2015
- **Programmatic Review:** November 2015

The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.

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 2015 (FY15) 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, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The executing 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 FY14 totaled \$53 million (M). The FY15 appropriation is \$6M.

B. FY15 TSCRCP Mission and Focus Areas

The mission of the FY15 TSCRCP is to encourage innovative research aimed at understanding the pathogenesis and preventing and treating the manifestations of TSC. Within this context, the FY15 TSCRCP encourages applications to address one or more of the following Focus Areas:

- Mechanisms Underlying Clinical Manifestations
 - Epilepsy
 - Neurocognition and behavior
 - Tumor development and progression
 - Cell and animal models
 - Genetics and disease modifiers
- Novel Therapeutic Strategies
 - Dose, timing, and duration of mTOR inhibitors and other therapeutics
 - New targets and combination therapies
 - Preclinical and clinical studies
 - Biomarkers
 - Preventative therapies

If the proposed research project does not address one of the FY15 Focus Areas, justification that the proposed research project addresses an important problem related to TSC research and/or patient care should be provided.

TSCRCP Research Resources Initiative: Resources developed through TSCRCP funding that are available to the scientific community can be found at <http://cdmrp.army.mil/tscrp/resources/tscresources.shtml>. Investigators are urged to leverage and contribute to these resources and

include a sharing and distribution plan in the application for data and resources generated during the performance of the proposed research project. For more guidance on data sharing, refer to the General Application Instructions, Appendix 3, Section L.

C. Award Information

The TSCRP Idea Development Award (IDA) mechanism was first offered in FY02. Since then, 263 IDA applications have been received, and 51 have been recommended for funding.

The IDA promotes new ideas that are in the early stages of development and have the potential to yield high-impact findings and new avenues of investigation. This award mechanism supports conceptually innovative, high-risk/potentially high-reward 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 scientific rationale.

The following are important aspects of the Idea Development Award:

- 1. 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.
- 2. 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.
- 3. 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, should be included.

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 (<http://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 X, 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 http://www.elsevier.com/data/promis_misc/622936arrive_guidelines.pdf.

Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this 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.htm>. PIs wishing to apply for funding for a clinical trial should utilize the FY15 TSCRP Pilot Clinical Trial Award mechanism (Funding Opportunity Number: W81XWH-15-TSCRP-PCTA).

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), in addition to the local Institutional Review Board (IRB) of record. Local IRB 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. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 5, 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 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. 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 regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 5, for additional information.

Optional Features: The Idea Development Award mechanism allows for the inclusion of *an Optional Qualified Collaborator*, which would allow the applicant to request additional funds, as described in [Section I.E., Funding](#). The Government reserves the right to fund an application at the lower funding level if the optional feature does not meet the eligibility criteria or intent of the mechanism.

Optional Qualified Collaborator: The FY15 TSCRP strongly supports collaborative research between basic scientists and clinical researchers, and between academic and biotech scientists. **Collaborations that bring new perspectives from other disciplines or bring new investigators into the TSC field are also strongly encouraged.** Although more than one collaborator may participate in the application, only one can be named for this option.

The PI must submit a Statement of Collaboration (see [Section II.C.2, Attachment 9: Statement of Collaboration](#)) that clearly identifies the collaborating investigator and addresses how each of the criteria below are met. Additionally, the collaborator must provide a biographical sketch (see

[Section II.C.3., Research & Related Senior/Key Person Profile](#)) and a letter of collaboration (see [Section II.C.2., Letters of Collaboration](#)) describing his/her involvement in the proposed research project. It should be clear that the success of the proposed research project depends on the complementary skills and contributions of both the PI and collaborator.

- The collaborator must significantly contribute to the proposed research project such that it could not be accomplished without his/her involvement.
 - A proposed research project in which the collaborator merely supplies tissue samples or access to patients will not meet the intent of the Qualified Collaborator option and will not be qualified for the higher level of funding.
 - At least a 10% level of effort is required of the collaborator. Contribution of the collaborator should be reflected in the application's budget.
- The collaborator must be at or above the level of Assistant Professor (or equivalent).

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 3, Section L.

D. Eligibility Information

- Independent investigators with a documented faculty appointment (or equivalent).
- The Optional Qualified Collaborators must be **at or above** the level of Assistant Professor (or equivalent) and must commit at least a 10% level of effort for each budget period throughout the entirety of the award.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, nonprofit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

The TSCRIP encourages applications for the IDA from new investigators including but not limited to:

- New investigators in TSC who have not received more than \$300,000 in total direct costs for TSC research as a PI of one or more federally funded, non-mentored peer reviewed awards.
- Established independent investigators in an area other than TSC seeking to transition into a career in TSC research.

E. Funding

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$450,000**. Associated indirect costs can be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$450,000** direct costs or using an indirect rate exceeding the organization's negotiated rate. If requesting an Optional Qualified Collaborator, the anticipated direct costs budgeted for the entire period of performance will not exceed **\$600,000**. Collaborating organizations should budget associated indirect costs in accordance with each 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 applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.
- The Government reserves the right to fund an application at a lower level if the Optional Qualified Collaborator does not meet the eligibility criteria or intent of the mechanism.

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

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

- Salary
- Research supplies
- Equipment
- Clinical research costs (No clinical trials allowed)
- Travel between collaborating organizations
- Travel costs to attend scientific/technical meetings

Intramural (DoD), other Federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. 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. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from Federal agencies submit applications, they must submit through Grants.gov. Therefore, 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 Section II.A. of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR] or Funding Authorization Document [FAD] process). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

The CDMRP expects to allot approximately \$3.36M of the \$6.0M FY15 appropriation to fund approximately four Idea 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.

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.

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.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the full application submitted to Grants.gov must match those named in the pre-application in

eBRAP. *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. Any other application component cannot be changed after the end of the application verification period.*

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-15-TSCR-IDA in Grants.gov (<http://www.grants.gov/>).

B. Pre-Application Submission Content

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

PIs 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):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
 - 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 SF-424 Form). The Business Official must either be selected from the eBRAP 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.
- **Collaborators and Key Personnel – Tab 3**
 - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
 - FY15 TSCR-IP Integration Panel (IP) members should not be involved in any pre-application or application. For questions related to IP 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.
- **Conflicts of Interest (COIs) – Tab 4**
 - 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).

- **Pre-Application Files – Tab 5**
 - **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. If applicable, include the focus area 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.
- **Submit Pre-Application – Tab 6**
 - This tab must be completed for the pre-application to be accepted and processed.

C. 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 Grants.gov application package provided in Grants.gov 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/>).

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 Idea 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. **SF-424 (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 (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, 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.

- **Background:** Present the ideas and rationale behind the proposed research project. Cite relevant literature. Describe previous experience most pertinent to the proposed research project. *Include preliminary and/or published data that is relevant to TSC and the proposed research project.*
- **Hypothesis or 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 application. 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. Address potential problem areas and present alternative methods and approaches.
 - Describe how the study (or studies) is designed to achieve reproducible and rigorous results. Include controls, blinding, randomization and a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.
 - Describe how data will be handled, collected, and analyzed in a manner that is consistent with the study objectives.
 - If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. *This award may not be used to conduct clinical trials.*
- **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 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 Patent Abstracts: 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; required for Optional Qualified Collaborator): 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.
- Intellectual Property
 - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.
 - 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.”** 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.

Technical abstracts should be structured to include the following points:

- **Background:** Present the ideas and rationale behind the proposed research project.
 - **Objective/Hypothesis:** State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
 - **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 novel and innovative.
 - **Impact:** Briefly describe how the proposed research project will have an impact on TSC research and/or patient care.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”** 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. Lay abstracts should be written using the outline below:

- Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposed research project.
 - Do not duplicate the technical abstract.
 - 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 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 Idea Development Award mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.3., for detailed guidance on creating the SOW.

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf.”** Explain how the proposed research project addresses one or more of the FY15 TSCRP Focus Areas, or, if the project does not address a Focus Area, provide justification that the proposed research project addresses an important problem in TSC research and/or patient care. Detail the anticipated outcome(s) that will be directly attributed to the results of the proposed research (short-term gains). 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 novel and innovative in the field of TSC. Research deemed innovative may represent a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other highly creative qualities. Innovative research may include high-risk approaches. Research that is an incremental advance upon published data is not considered innovative.

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

- The proposed research project will explore a novel idea and/or research question in TSC.
- The proposed research project will use or develop novel methods or technologies to address a question in TSC.
- The proposed research project will apply or adapt 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 (if applicable): 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 3, Section L, for more information about the CDMRP expectations for making data and research resources publicly available.

- **Attachment 9: Statement of Collaboration (required if requesting an Optional Qualified Collaborator; two-page limit). Upload as “Collaboration.pdf.”**
 - The PI must submit a statement that identifies the Optional Qualified Collaborator and addresses all criteria described above in [Section I.C., Award Information](#).
 - In addition, the Optional Qualified Collaborator must describe how he/she will significantly contribute to the proposed research project such that it could not be accomplished without his/her involvement.
 - It should be clear that the success of the proposed research project depends on the complementary skills and contributions of both the PI and the collaborator.

- **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), including a budget justification, for each Military Facility as instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information. *Note: Some of the items in this attachment may be made available for programmatic review.*
- 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.
 - 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.”
 - Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.5., 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.6., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.7., for detailed information.

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, 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 application rejection.

F. Other Submission Requirements

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

All 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 applicants are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the Office of the Assistant Secretary of Defense for Health Affairs, based on (a) technical merit and (b) the relevance to the mission of the DHP and TSCR, and to the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess.shtml>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a nondisclosure 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:

- **Impact**
 - *Assuming the objectives/goals of the research project are realized*, to what extent the proposed project could (in the short-term and 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 FY15 TSCRP Focus Areas or a critical problem in TSC research and/or patient care.
- **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 is consistent with the study objectives.
 - How well any animal studies proposed 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 PI identifies potential problems and addresses alternative approaches.
- **Innovation**
 - To what extent the proposed research project is innovative to 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, or other ways.
 - To what extent the proposed research project represents more than an incremental advance upon published data and/or may be considered high risk.

- **Personnel**

- To what degree the PI's experience, expertise, and record of accomplishment demonstrate his/her ability to successfully complete the proposed research project.
- To what extent the levels of effort by the PI and other key personnel are appropriate to ensure success of the proposed research project.
- Optional Qualified Collaborator (if applicable)
 - Whether the collaborator's experience, expertise, and involvement represent a significant contribution to the proposed research project such that it could not be accomplished without his/her involvement.
 - Whether the collaborator meets the criteria for an Optional Qualified Collaborator as verified by the Statement of Collaboration.

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 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 equally considered criteria are used by programmatic reviewers:

- a. Ratings and evaluations of the peer reviewers**

- b. Relevance to the mission of the DHP and FY15 TSCRP, as evidenced by the following:**

- Adherence to the intent of the award mechanism
- Program portfolio composition
- Programmatic relevance
- Relative impact and innovation

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 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 application:

- A FY15 TSCRP Integration Panel (IP) 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 FY15 TSCRP IP members can be found at <http://cdmrp.army.mil/tscrp/panels/panels15.shtml>.
- 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).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., 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.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution 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, 2016. Refer to the General Application Instructions, Appendix 3, 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 3 for general information regarding administrative requirements.

C. National Policy Requirements

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

D. Reporting

Refer to the General Application Instructions, Appendix 3, Section I, for general information on reporting requirements.

E. Award Transfers

Changes in PI 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.

Refer to the General Application Instructions, Appendix 3, Section M, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. 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

B. 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

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
SF-424 (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	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	7	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf."	
	8	Data and Research Resources Sharing Plan: Upload as Attachment 8 with file name "ResourceSharing.pdf," if applicable.	
	9	Statement of Collaboration: Upload as Attachment 9 with file name "Collaboration.pdf," if applicable.	
	10	Collaborating DoD Military Facility Budget Form(s): Upload 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.	