

Program Announcement

for the

Defense Health Program

Defense Medical Research and Development Program

Department of Defense

Congressionally Directed Medical Research Programs

Tuberous Sclerosis Complex Research Program

Idea Development Award

Funding Opportunity Number: W81XWH-14-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, 2014
- **Application Submission Deadline:** 11:59 p.m. ET, July 24, 2014
- **End of Application Verification Period:** 5:00 p.m. ET, July 29, 2014
- **Peer Review:** September 2014
- **Programmatic Review:** November 2014

Change for Fiscal Year 2014: 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 2014 (FY14) Tuberous Sclerosis Complex Research Program (TSCRCP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). 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 FY13 totaled \$47 million (M). The FY14 appropriation is \$6M.

B. FY14 TSCRCP Mission and Focus Areas

The mission of the FY14 TSCRCP is to encourage innovative research to improve the lives of individuals with TSC through understanding the pathogenesis and manifestations of TSC and developing improved diagnostic and treatment approaches. Within this context, the FY14 TSCRCP encourages applications that address one or more of these vital program Focus Areas:

- Clinical Aspects of TSC
 - Infantile spasms and epileptic encephalopathy, including biomarkers for early diagnosis and treatment
 - Neurocognitive, sleep, and behavioral issues, e.g., TAND (TSC-associated neuropsychiatric disorders)
 - Impact of TSC manifestations in adults, including LAM and angiomyolipomas
- Personalization of Care
 - Developmental origin of TSC manifestations
 - Phenotype/genotype studies and genetic modifiers
 - Gene dose and lesional genetics
 - Biomarkers for perinatal/newborn screening
- Optimization of Treatments
 - Pathogenesis-based biomarkers of disease progression and response to treatment
 - Development or validation of clinical endpoints in TSC
 - Identification or development of novel pathogenesis-based treatment targets
 - Continued refinement of cell-based and preclinical models
 - Dose, timing, and duration of treatment with mTORC-1 inhibitors

If the proposed research project does not address one of the FY14 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>. 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 4, Section L*.

C. Award Information

The TSCRCP Idea Development Award mechanism was first offered in FY02. Since then, 230 Idea Development Award applications have been received, and 45 have been recommended for funding.

The FY14 TSCRCP Idea Development Award 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:** 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.

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 Congressionally Directed Medical Research Programs (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 FY14 TSCRCP Pilot Clinical Trial Award mechanism (**Funding Opportunity Number: W81XWH-14-TSCRCP-PCTA**).

Use of Human Subjects and Human Anatomical Substances: All Department of Defense (DoD)-funded research involving new and ongoing research with human subjects and human anatomical substances 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 IRB of record. Local IRB approval at the time of submission is NOT required. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is supported by the DoD. These laws and directives will require information in addition to that supplied to the IRB. Allow a minimum of 2-3 months for regulatory review and approval processes. Refer to the General Application Instructions, Appendix 6, for more information.

Optional Features: The Idea Development Award mechanism allows for the inclusion of *one of the following options*, 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 FY14 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).

Optional Nested Postdoctoral Traineeship: The intent of the Nested Postdoctoral Traineeship is to enable doctoral degree graduates to either extend ongoing research related to TSC or broaden the scope of their research to include work relevant to TSC under the guidance of a designated mentor who is participating in the application. It is expected that the training will provide a valuable opportunity to further develop the experience necessary to advance the trainee's research career in TSC.

A trainee is defined as a postdoctoral fellow with 3 years or less of postdoctoral experience at the application submission deadline. Eligible postdoctoral candidates must have successfully defended a doctoral thesis and completed all academic requirements at the application submission deadline.

The trainee must submit a transcript from all graduate institutions attended (see [Section II.C.2., Transcripts](#)) and a biographical sketch (see [Section II.C.3., Research & Related Senior/Key Person Profile](#)). Additionally, the trainee must submit a statement of traineeship (see [Section II.C.2., Attachment 10: Statement of Traineeship](#)) that will highlight how the mentor's record of accomplishment and the research environment will provide the necessary experience to advance the trainee's research career in TSC.

The Congressionally Directed Medical Research Programs (CDMRP) intends that 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 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 meets at least a 10% level of effort on the proposed research project.
- The Optional Nested Postdoctoral Trainee must have successfully defended a doctoral thesis and completed all academic requirements and have 3 years or less of postdoctoral experience at the time of the application submission deadline.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

The TSCRP encourages applications for the Idea Development Award 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 maximum allowable direct costs for the entire period of performance are **\$425,000** plus indirect costs. If requesting an Optional Qualified Collaborator *or* Optional Nested Postdoctoral Traineeship, the maximum allowable direct costs for the entire period of performance are **\$575,000** plus indirect costs.
- 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.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.
- The Government reserves the right to fund an application at the lower level if the Optional Qualified Collaborator or Optional Nested Postdoctoral Traineeship does not meet the eligibility criteria or intent of the mechanism.

Refer to the General Application Instructions, Section II.C.4., 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.4. 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 of up to \$1,800 per year 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 Appendix 3 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 will be executed through 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.4. Research & Related Budget, for additional information on budget considerations for applications involving federal agencies.

The CDMRP expects to allot approximately \$2.96M of the \$6.0M FY14 TSCRP appropriation to fund approximately 4 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 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/>).

New for FY14: *The CDMRP has replaced its eReceipt System with eBRAP.* Submission remains a two-step process requiring both pre-application and application submission.

PIs must be registered in eBRAP in order to submit a pre-application and receive notification of the status of a pre-application or application. A key feature of eBRAP is that an organization's representatives and PIs are able to view and modify the Grants.gov application submissions associated with them, but only if the organization, Business Officials, and PIs are registered and affiliated to the organization in eBRAP (see *eBRAP User Guide* at <https://ebrap.org/eBRAP/public/UserGuide.pdf>). Upon completion of an organization's registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization's business officials and PIs as they register.

Note: Submission of either the pre-application to eBRAP or application to Grants.gov does not require registering an organization and affiliating its Business Officials and PIs in eBRAP; however, the ability to view and modify the Grants.gov application in eBRAP is contingent upon the registration and affiliation. ***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.*** If verification is not completed

by the end of the application verification period, the application will be reviewed as submitted through Grants.gov or may be subject to administrative rejection (see [Section IV.A., Rejection](#)).

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.

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-14-TSCR-IDA.

B. Pre-Application Submission and Content Form

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**

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

- **Collaborators and Conflicts of Interest – Tab 3**

FY14 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 at help@eBRAP.org or 301-682-5507.

- **Required Files – Tab 4**

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. 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 5**

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

C. Application Submission Content and Forms

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

New for FY14: Applications submitted through and validated by Grants.gov will be retrieved and processed by eBRAP to allow for review, modification, and verification. The PI and organizational representatives will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing files (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the verification period.

Note: Changes to either the Project Narrative or Budget are not allowed in eBRAP; if such changes are required, the entire application package must be submitted through Grants.gov as a “Changed/Corrected Application” with the Previous Grants.gov Tracking ID *prior to the application submission deadline (which occurs earlier than the end of the application verification period).*

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**
 - **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 will result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning 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. Address potential problem areas and present alternative methods and approaches.
 - Describe how data will be handled, collected, and analyzed in a manner that is consistent with the study objectives. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.
 - If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples.
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 may result in the removal of those items or 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 (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must 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 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 in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. 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.
- Transcripts (required for Optional Nested Postdoctoral Traineeship): Include a copy of the Trainee’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.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”

Technical abstracts should be written using the outline below. The technical abstract is used by all reviewers. Of particular importance, programmatic reviewers do not have access to the full application and therefore rely on the technical abstract for appropriate description of the project’s key aspects.

 - Background: Present the ideas and reasoning 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.”

Lay abstracts should be written using the outline below. The lay abstract is used by consumer reviewers along with other components of the application package.

 - 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.” Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Program Announcement and 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.

- **Attachment 6: Impact Statement (one-page limit):** Upload as “Impact.pdf.” Explain how the proposed research project addresses one or more of the FY14 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 4, 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 provide a letter describing 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: Statement of Traineeship (required if requesting an Optional Nested Postdoctoral Traineeship; three-page limit). Upload as “Traineeship.pdf.”** Identify the mentor. Describe the research training plan including a timeline, laboratory techniques, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Describe how the research being performed under the mentor’s direction is relevant to TSC. Describe the mentor’s history of training other postdoctoral fellows. Specify how the mentor will assist in training the postdoctoral fellow for a career in TSC research. Describe the laboratory’s resources to demonstrate the adequacy of support for the trainee’s project.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.3., for detailed information. *Note: Some of the items in this attachment may be made available for programmatic review.*
- PI Biographical Sketch (four-page limit): Upload as “Biosketch_LastName.pdf.”
 - PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
 - Key Personnel Biographical Sketches (four-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.4., for detailed information.
 - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
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.

D. Verification of Grants.gov Application in eBRAP

For FY14, a new process has been initiated whereby organizational representatives and PIs can view their applications as submitted through Grants.gov and prior to peer review of the application. This will enable applicants to make modifications prior to scientific and programmatic evaluation of applications, provided the modifications are made by either the end of the application verification period or, for changes to the Project Narrative or Budget, by the application submission deadline.

After application submission to Grants.gov, eBRAP will retrieve and validate the application submission. eBRAP will notify the organizational representatives and PI via email and instruct them to log into eBRAP to review, modify, and verify the application. Files that fail eBRAP validation will be noted in both the email and in the Full Application Files tab. eBRAP does not validate the accuracy or completeness of content in the files. PIs are strongly encouraged to review all application components. If either the Project Narrative or the Budget fail eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov prior to the application submission deadline, which occurs earlier than the end of the application verification period. *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.*

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, Appendix 3, for information on Grants.gov 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 Commanding General, U.S. Army Medical Research and Materiel Command (USAMRMC), based on (a) technical merit and (b) the relevance to the mission of the DHP and TSCRCP and to the specific intent of the award mechanism. The highestscoring 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>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a non-disclosure 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 listed in decreasing order of importance:
 - **Research Strategy and Feasibility**
 - How well the preliminary data and rationale support the research project.
 - To what extent the experimental design and methods, including randomization, blinding, and controls, are appropriate for the proposed research project
 - To what extent the manner in which the data will be handled, collected, and analyzed is consistent with the study objectives.
 - To what extent the power analysis demonstrates that the sample size is appropriate to meet the objectives of the study.
 - To what extent the proposed research project is feasible as described.
 - How well potential problems are identified and addressed, and alternative approaches are proposed.

- **Impact**
 - Assuming the objectives/goals of the research project are realized, how the proposed project could (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 FY14 TSCRP Focus Areas or a critical problem in TSC research and/or patient care.
- **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**
 - How well the PI's experience, expertise, and record of accomplishment demonstrates 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.
 - Optional Nested Postdoctoral Traineeship applicants (if applicable):
 - How well the qualifications of the Nested Postdoctoral Trainee will add to the proposed research project.
 - How the Nested Postdoctoral Trainee will benefit from participation in the proposed research project.

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 project 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, 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 FY14 TSCR, 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.
- Following application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing documents (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the application verification period; otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- A FY14 TSCRP 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 FY14 TSCRP IP members can be found at <http://cdmrp.army.mil/tscrp/panels/panels14>.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- 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.
- The proposed research is, or requests funding for, a clinical trial.
- The PI does not meet the eligibility criteria.

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, 2015. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

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 J, 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 4, 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 application package. If the 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	Action	Completed
SF-424 (R&R) Application for Federal Assistance	Complete form as instructed.	
Attachments Form	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf."	
	Data and Research Resources Sharing Plan: Upload as Attachment 8 with file name "ResourceSharing.pdf," if applicable.	
	Statement of Collaboration: Upload as Attachment 9 with file name "Collaboration.pdf," if applicable.	
	Statement of Traineeship: Upload as Attachment 10 with file name "Traineeship.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.	