

# **Program Announcement**

**for the**

**Defense Health Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

## **Tuberous Sclerosis Research Program**

### **Pilot Clinical Trial Award**

**Funding Opportunity Number: W81XWH-13-TSCR-PCTA**

**Catalog of Federal Domestic Assistance Number: 12.420**

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

- **Pre-Application Submission Deadline: 5:00 p.m. Eastern time (ET), June 27, 2013**
- **Application Submission Deadline: 11:59 p.m. ET, July 11, 2013**
- **Peer Review: August 2013**
- **Programmatic Review: November 2013**

*This Program Announcement 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 2013 (FY13) 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 first funded 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 FY12 totaled \$41 million (M). The FY13 appropriation is \$6M.

### B. FY13 TSCRCP Mission and Focus Areas

The mission of the TSCRCP is to encourage innovative research aimed at understanding the pathogenesis and manifestations of TSC to improve the lives of individuals with TSC. Within this context, the FY13 TSCRCP encourages applications that address one or more of these vital program Focus Areas:

- Genetic, epigenetic, and non-genetic modifiers of TSC.
- Preclinical models and therapeutic strategies (e.g., cytotoxic agents, combination therapies).
- Biomarkers for early detection, prognosis, and prediction of treatment outcomes (such as serum markers, imaging, electrophysiology, prenatal testing, and pharmacogenetics).
- Impact of TSC manifestations in adults (e.g., care management, age-specific pathogenesis, epidemiology, renal, reproductive issues, and lymphangioleiomyomatosis [LAM]).
- Long-term benefits and effects of mTOR inhibitors or other agents.
- Novel strategies for diagnosis, treatment, and prevention of TSC manifestations including those geared toward early identification and intervention.
- Cellular and molecular mechanisms of TSC and LAM pathogenesis.
- Causes and treatment of epilepsy in TSC.
- Causes and treatment of TSC-associated neurocognitive disorders including cognitive impairment, and psychiatric, behavioral, and sleep disorders.

**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 pilot clinical trial. For more guidance on data sharing, refer to the General Application Instructions, Appendix 4, Section K.

## C. Award Information

The TSCRP Pilot Clinical Trial Award mechanism is being offered for the first time in FY13.

The TSCRP Pilot Clinical Trial Award mechanism supports studies of interventions (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) with the potential to have a major impact on the treatment or management of TSC. ***Funding from this award mechanism must support a pilot study aimed at obtaining preliminary data to support the rationale and design of subsequent clinical trials.*** Examples of research topics ***include but are not limited to the following:***

- Studies to identify an appropriate population.
- Studies to identify the dosage, duration, and/or delivery strategy of the intervention.
- Studies to evaluate the feasibility of the intervention in TSC.
- Studies to better understand efficacy and safety.

Pilot clinical trials may include exploratory studies involving limited human exposure that produce diagnostic or therapeutic information (e.g., screening studies, microdose studies), toxicity studies of an intervention, and studies to determine the mechanism of action and side effects of an intervention. The term “human subjects” is used in this Program Announcement/ Funding Opportunity to refer to individuals who will be recruited for or who will participate in the proposed clinical trial. For more information on clinical research and clinical trials, a Human Subject Resource Document is provided at [https://cdmrp.org/Program\\_Announcements\\_and\\_Forms/](https://cdmrp.org/Program_Announcements_and_Forms/).

Principal Investigators (PIs) seeking funding for a preclinical research project should consider one of the other funding opportunities being offered as this mechanism is designed specifically to support clinical studies.

If the pilot clinical trial proposed involves the use of a drug that has not been approved by the U.S. Food and Drug Administration (FDA) for its investigational use, evidence that an Investigational New Drug (IND) exemption application has been submitted or will be submitted **within 60 days of award** is required. If the investigational product is a device, evidence that an Investigational Device Exemption (IDE) has been submitted or will be submitted **within 60 days of award**, or that the device is exempt from an IDE, is required.

***Inclusion of scientific rationale and/or preclinical data relevant to the proposed pilot clinical trial is required.***

**The following are important aspects of submission for the Pilot Clinical Trial Award:**

- The application must demonstrate documented availability of, and access to, the drug/ compound, device, and/or other materials needed, as appropriate.
- The proposed pilot clinical trial must include clearly defined and appropriate endpoints, which may include safety or preliminary efficacy.

**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 5, for more information.

*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 K.*

#### **D. Eligibility Information**

- PIs *at or above* the level of Assistant Professor (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- 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.

#### **E. Funding**

- The maximum period of performance is **2** years.
- The maximum allowable direct costs for the entire period of performance are **\$200,000** 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 **2** 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.

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.*

In addition, for this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary
- Research-related subject costs
- Clinical research costs
- Research supplies
- Equipment
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

Shall not be requested for:

- Preclinical research studies

*The CDMRP expects to allot approximately \$0.64M of the \$6.00M FY13 TSCRP appropriation to fund approximately 2 Pilot Clinical Trial 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 CDMRP eReceipt System (<https://cdmrp.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

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-13-TSCRP-PCTA.

### **B. Pre-Application Submission Content and Form**

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (<https://cdmrp.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@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System 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**
- **Collaborators and Conflicts of Interest – Tab 3**

FY13 TSCRP Integration Panel (IP) members (<http://cdmrp.army.mil/tscrp/panels/panels13.shtml>) 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@cdmrp.org](mailto:help@cdmrp.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. *Note: At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.*

- **Submit Pre-Application – Tab 5**

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

- **Other Documents Tab**

No additional documents are required.

### C. Application Submission Content and Form

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/>).

**Grants.gov application package components:** For the Pilot Clinical Trial 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 pilot clinical trial in detail using the outline below. ***The Project Narrative must include scientific rationale and/or preclinical data relevant to TSC and the proposed pilot clinical trial.***

- **Background:** Describe in detail the intervention and rationale for the proposed pilot clinical trial and include a literature review, preliminary studies, and/or preclinical data that led to the development of the proposed pilot clinical trial. Include a discussion of any current clinical use of the intervention under investigation and/or details of its study in clinical trials for other indications (as applicable). The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or study hypotheses. This section should establish the relevance of the proposed pilot clinical trial and explain the applicability of the proposed findings.
  - **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the proposed pilot clinical trial with detailed specific aims and/or study questions/hypotheses.
  - **Research Strategy and Feasibility:** Describe the type of proposed pilot clinical trial to be performed and outline the proposed methodology in sufficient detail to show a clear course of action.
    - Define the variables and projected outcomes and describe how they will be measured. Include a description of appropriate controls, if applicable, and the endpoints to be tested.
    - Describe the method that will be used to recruit human subjects from the accessible population, including the inclusion and exclusion criteria.
    - Describe the data or statistical analyses that will be performed. Include randomization, sample size projections, and power analyses as appropriate for the proposed pilot clinical trial.
    - Describe methods used for sample and data collection.
  - **Ethical Considerations:** Describe the process for seeking informed consent and clearly identify all study risks and describe safety measures to minimize risks to human subjects and study personnel.
- **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 pilot clinical trial 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 proposed pilot clinical trial.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed pilot clinical trial.
- 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. Identify any 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: Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan (if applicable): Describe how data and resources generated during the performance of the proposed pilot clinical trial will be shared with the research community. Refer to the General Application Instructions, Appendix 4, Section K for more information about the

CDMRP expectations for making data and research resources publicly available.

- **Attachment 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 proposed pilot clinical trial’s key aspects.

- Background: Present the ideas and reasoning behind the proposed pilot clinical trial.
- 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 pilot clinical trial.
- Study Design: Briefly describe the study design including appropriate controls and endpoints.
- Clinical Impact: Briefly describe how the proposed pilot clinical trial will have an impact on TSC research 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 pilot clinical trial.
  - Do not duplicate the technical abstract.
- Describe the ultimate applicability and impact of the research.
  - What types of patients will it help, and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - What are the likely contributions of this proposed pilot clinical trial to advancing the field of TSC research 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., for detailed information, including guidance on appropriate SOW formats.

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

- Identify the FY13 TSCRP Focus Area(s) that this application addresses, if applicable.
- Describe the short- and long-term impact the proposed pilot clinical trial will have on TSC research or patient care.
- Describe any relevant controversies or treatment issues that will be addressed by the proposed pilot clinical trial and any potential issues that may limit its impact.

- Compare the proposed intervention to other interventions currently available or standard of care, if applicable.
  - **Attachment 7: Surveys, Questionnaires, and Other Data Collection Instruments, if applicable (no page limit):** Upload as “Surveys.pdf.” The Surveys, Questionnaires, and Other Data Collection Instruments attachment should include a copy of the most recent version of surveys, questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the proposed pilot clinical trial. Describe the psychometrics of each instrument and discuss whether any modifications will be made to the instrument.
  - **Attachment 8: IND/IDE Documentation (if applicable):** If submitting multiple documents, start each document on a new page. Combine and upload as a single file named “IND-IDE.pdf.”
    - Complete the IND/IDE Documentation Form, which is available for download on the Full Announcement page for this Program Announcement/Funding Opportunity on Grants.gov.
    - If an IND or IDE has been submitted, an explanation of the status of the IND or IDE must be provided (e.g., past the critical 30-day period, pending response to questions raised by the Agency, on clinical hold). Inclusion of a copy of the Agency meeting minutes is encouraged but not required. If the IND or IDE application is not yet submitted, provide evidence that an IND or IDE will be submitted within 60 days of award. Examples include a pre-IND or pre-IDE meeting with the FDA, a pre-IND/pre-IDE meeting request to the FDA, or other communication with the FDA. Provide the anticipated date of IND/IDE submission. If an IND or IDE is not required for the proposed pilot clinical trial, provide evidence in the form of communication from the FDA or the IRB of record to that effect.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., 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., 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., for detailed information.

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

#### **D. 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 any one of the deadlines will result in application rejection.

#### **E. 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 Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (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 applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a 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 technical merit, the relevance to the mission of the DHP and TSCR, and 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 review 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 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 Criteria**

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

- **Clinical Impact**

- How well the applicant addresses one or more of the TSCRP Focus Areas, if applicable.
- How relevant the anticipated outcomes of the proposed pilot clinical trial are to individuals with TSC.
- How well the sample population represents the targeted patient population that might benefit from the proposed intervention.
- How the potential outcomes of the proposed clinical trial will significantly provide/improve short-term and long-term benefits for individuals with TSC.
- How well the intervention compares with currently available interventions and/or standards of care.

- **Research Strategy and Feasibility**

- How well the scientific rationale for testing the intervention is supported by the preliminary data, critical review and analysis of the literature, and/or laboratory/preclinical evidence.
- How well the aims, hypotheses or objectives, experimental design, methods, human subjects recruitment including inclusion/exclusion criteria, data collection procedures, and analyses are designed to clearly answer the clinical objective.
- How well the statistical plan is developed and appropriate and meets the needs of the proposed pilot clinical trial.

- **Personnel:**

- The appropriateness of the levels of effort by the PI and other key personnel to ensure success of the proposed pilot clinical trial.
- How well the PI's and other key personnel's background and expertise are appropriate to accomplish the proposed pilot clinical trial (e.g., expertise in the disease and clinical studies).

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

- **Ethical Considerations**

How well the applicant identifies potential study risks and outlines safety steps to protect study subjects and staff.

- **Environment**
  - To what degree the scientific environment, clinical setting, and the accessibility of institutional resources support the pilot clinical trial at each participating center or institution (including collaborative arrangements).
  - Whether there is evidence for appropriate institutional support/commitment from each participating institution.
  - If applicable, how the intellectual and material property plan that is agreed upon by each participating institution is appropriate for the proposed pilot clinical trial.
- **Budget**
  - Whether the budget is appropriate for the proposed pilot clinical trial and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influenced 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 FY13 TSCRP, as evidenced by the following:**
  - Adherence to the intent of the award mechanism
  - Program portfolio composition, with consideration of the FY13 TSCRP Focus Areas
  - Programmatic relevance
  - Relative impact

### **C. Recipient Qualification**

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

### **D. Application Review Dates**

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

### **E. Notification of Application Review Results**

Each PI and organization will receive notification of the funding recommendation. 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 specified limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

### **C. Withdrawal**

The following may result in administrative withdrawal of the application:

- A FY13 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 document. A list of the FY13 TSCRP IP members can be found at <http://cdmrp.army.mil/tscrp/panels/panels13.shtml>.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- 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 project is not 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, 2014. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

#### **B. Administrative and National Policy Requirements**

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

#### **C. Reporting**

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

Quarterly technical progress reports will be required.

#### **D. Award Transfers**

The transfer of an award to another institution is strongly discouraged. A transfer will not be allowed for any institution that includes a study site/clinical trial at its location. Approval of a transfer request from an institution that does not include a study site at its location will be at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 4, Section F, 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 the CDMRP eReceipt System 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@cdmrp.org](mailto:help@cdmrp.org)

### **B. Grants.gov Contact Center**

Questions related to application submission through the 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](mailto:support@grants.gov)

***Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/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 Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact Statement (Impact.pdf) as Attachment 6.	
	Upload Surveys, Questionnaires, and Other Data Collection Instruments (Surveys.pdf) as Attachment 7, if applicable	
	Upload IND/IDE Documentation (IND/IDE.pdf) as Attachment 8, 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 (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.	