Program Announcement

Defense Health Program

Department of Defense
Congressionally Directed Medical Research Programs

Tuberous Sclerosis Complex Research Program

Idea Development Award

Funding Opportunity Number: W81XWH-12-TSCRP-IDA
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), May 10, 2012
- **Application Submission Deadline:** 11:59 p.m. ET, May 31, 2012
- **Peer Review:** July 2012
- **Programmatic Review:** September 2012

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications for the Tuberous Sclerosis Complex Research Program (TSCRP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. The TSCRP was established 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 TSCRP from FY02 through FY11 totaled $35.9 million (M). The FY12 appropriation is $5.1M.

FY12 TSCRP Mission and Focus Areas

The mission of the TSCRP is to encourage innovative research aimed at understanding the pathogenesis of TSC and to translate these findings to the care of individuals with TSC. Within this context, the FY12 TSCRP encourages applications that address these vital program focus areas:

- Studies of the pathogenesis, disease severity prediction, and diversity of TSC symptoms affecting cognition, behavior, sleep, renal and pulmonary functions, as well as manifestations of TSC including epilepsy and autism.
- Impact of TSC manifestations over the lifespan (e.g., care management, age-specific pathogenesis, emerging adulthood issues, comorbidities, epidemiology).
- Identification of novel strategies for treatment and prevention of TSC manifestations (e.g., cytotoxic drugs, epilepsy treatments, psychotropic agents) as well as early therapeutic approaches.
- Long-term benefits and effects of mTOR inhibitors or other agents.
- Understanding the cellular and molecular mechanisms of TSC developmental stages in mammalian and non-mammalian systems (including but not limited to studies involving cell origin, cell-type specificity).
- Genetic, epigenetic, and non-genetic modifiers of TSC.
- Identifying biomarkers for early detection, prognosis, and prediction of treatment outcomes (including but not limited to imaging, electrophysiology, prenatal testing, pharmacogenetics).

TSCRP Research Resources Initiative: Resources developed through TSCRP 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 project. For more guidance on data sharing, refer to the General Application Instructions, Appendix 4.

B. Award Information

The TSCRP Idea Development Award mechanism was first offered in FY02. Since then, 187 Idea Development Award applications have been received, and 43 have been recommended for funding.

The FY12 TSCRP Idea Development Award supports high-impact, innovative research that will drive the field of TSC research forward. Preclinical studies are encouraged, but clinical trials are not allowed.

Applications must include preliminary data that is relevant to TSC and the proposed project.

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.D., Funding. The TSCRP reserves the right to fund an application at a lower level if the optional feature does not meet the eligibility criteria or intent of the mechanism.

Optional Qualified Collaborator: The FY12 TSCRP strongly supports collaborative research between basic scientists and clinical researchers, and between academic scientists and biotechnology/pharmaceutical industry 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 Principal Investigator (PI) must submit a 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) and a letter of collaboration (see Section II.C.2) describing his/her involvement in the proposed work. It should be clear that the success of the project depends on the complementary skills and contributions of both the PI and collaborator.

- The collaborator must significantly contribute to the project such that the proposed work could not be accomplished without his/her involvement.
    - A proposed 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) and a biographical sketch (see Section II.C.3). Additionally, the trainee must submit a training statement (see Section II.C.2) 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.

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 eReceipt System at https://cdmrp.org/Program_Announcements_and_Forms/. PIs wishing to apply for funding for a clinical trial should utilize the FY12 TSCRP Clinical Trial Award mechanism (Funding Opportunity Number: W81XWH-12-TSCRP-CTA).

The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated by CDMRP-funded research activities 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.

C. Eligibility Information

The following investigators are eligible:

- Independent investigators with a documented faculty appointment (or equivalent).
- 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.
- The Optional Qualified Collaborators must be ***at or above*** the level of Assistant Professor (or equivalent).
- 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 application submission deadline.
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. 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.
- Applications requesting the higher level of funding that do not include an Optional Qualified Collaborator **or** Optional Nested Postdoctoral Traineeship will have their budget reduced as appropriate.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget. In addition, for this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Research-related subject costs
- 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

The CDMRP expects to allot approximately $2.28M of the $5.1M FY12 TSCRP appropriation to fund approximately 3 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 multi-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 the same research project to different funding opportunities within the same program and fiscal year is prohibited. The Government will reject duplicative applications.

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-12-TSCRP-IDA.

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 application should be the same as those identified in the pre-application. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at 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**

  FY12 TSCRP 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 (1-301-682-5507).

- **Required Files – Tab 4**

  Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted and indicate the TSCRP Focus Area(s). 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 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 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."

     Describe the proposed project in detail using the outline below.

     - **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature. Describe previous experience most pertinent to the project. Include relevant preliminary data.
     - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
     - **Specific Aims:** Concisely explain the project's specific aims to be funded by this application. If this proposed work is part of a larger study, present only tasks that this award would fund.
     - **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for scientific peer review. Address potential problem areas and present alternative methods and approaches. Describe the statistical plan if appropriate for the research proposed. 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 component unless otherwise noted. Include only those components described below; inclusion of items not requested may result in administrative rejection 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 if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present 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 they must be included. 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, reflecting 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 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 PI's transcripts from all graduate institutions attended. All foreign-language transcripts must be accompanied by a certified English translation. The Government reserves the right to request official transcripts during award negotiations.
- Data and Research Resources Sharing Plan (if applicable): Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about the 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.

  - Background: Present the ideas and reasoning behind the proposed work.
  - 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 study.
- Study Design: Briefly describe the study design including appropriate controls.
- Innovation: Briefly describe how the proposed project is innovative.
- Impact: Briefly describe how the proposed project will have an impact on TSC research or patient care.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as "LayAbs.pdf."

  Public 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 work.
    - 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 this study to advancing the field of TSC research of 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.

- **Attachment 6: Impact Statement (one-page limit):** Upload as "Impact.pdf." Explain how the expected results of the study will make an original and important contribution to the goal of advancing TSC research and its impact on patient care. Describe the potential clinical applications, benefits, and risks.

- **Attachment 7: Innovation Statement (one-page limit):** Upload as "Innovation.pdf." Summarize how the proposed work is innovative. Investigating the next logical step or incremental advancement on published data is not considered innovative.

  Although not all-inclusive, the following examples are ways in which the proposed work may be innovative and are intended to help PIs frame the innovative features:

  - Study concept: Investigation of a novel idea and/or research question.
  - Research method or technology: Use of novel research methods or new technologies, including technology development, to address a research question.
  - Novel method or technology: Development of a novel method or technology for preventing, detecting, diagnosing, or treatment.

- Existing methods or technologies: Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.

- **Attachment 8: 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 project such that the proposed work could not be accomplished without his/her involvement.
  - It should be clear that the success of the project depends on the complementary skills and contributions of both the PI and collaborator.

- **Attachment 9: 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., for detailed information.
   - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
   - PI 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 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. Organizations are required to provide a Data Universal Numbering System (DUNS) number and register with the Central Contractor Registry (CCR) 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 compares applications to each other and makes recommendations for funding to the Commanding General, U.S. Army Medical Research and Materiel Command, based on technical merit, the relevance to the mission of the Department of Defense (DoD) and the TSCRP 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. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs 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 panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations 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 listed in decreasing order of importance:

   - **Research Strategy and Feasibility**
     - How well the preliminary data and rationale support the research project.
     - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
     - How well the PI identifies potential problems and addresses alternative approaches.
     - If the application includes the Optional Qualified Collaborator, how well the nature of the collaboration supports the research project.

   - **Impact**
     - How well the project addresses a critical problem in TSC research or patient care.
     - How the project will, if successful, make an original and important contribution to the goal of advancing research on the treatment of TSC, or on the quality of life of those living with the disease.

   - **Innovation**
     - To what extent the proposed research is innovative in one or more of the following ways: Concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
     - How well the proposed research represents more than an incremental advance upon published data.

   - **Personnel**
     - The appropriateness of the levels of effort by the PI and other key personnel to ensure success of the project.
     - How well the PI's record of accomplishment demonstrates his/her ability to accomplish the proposed work.
     - Optional Qualified Collaborator (if applicable)
       - The degree to which the collaborator's experience, expertise, and involvement in the study significantly contribute to the project such that the proposed work 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 (i.e., the collaborator is at or above the level of Assistant Professor [or equivalent]; the collaborator is contributing at least 10% level of effort).

- Optional Nested Postdoctoral Traineeship applicants (if applicable):
  - How well the qualifications of the Nested Postdoctoral Trainee will add to the project.
  - How the Nested Postdoctoral Trainee will benefit from participation in this 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.
  - 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.

- **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 influenced the review.

2. **Programmatic Review:** To determine the application's relevance to the mission of the DoD and the TSCRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

- Adherence to the intent of the award mechanism
- Program portfolio composition, with consideration of the FY12 Focus Areas
- Programmatic relevance
- Ratings and evaluations of the peer reviewers
- Relative impact and/or innovation

C. Recipient Qualification

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

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 scientific 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 is 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 FY12 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 FY12 TSCRP IP members can be found at http://cdmrp.army.mil/tscrp/panels/panel12.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.
- 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 U.S. Army Medical Research Acquisition Activity (USAMRAA) Contracting/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, 2013. 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.

D. 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 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: 1-301-682-5507

Email: 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: 1-800-518-4726

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. 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 Innovation Statement (Innovation.pdf) as Attachment 7.	
	Upload Statement of Collaboration (Collaboration.pdf) as Attachment 8 (if applicable).	
	Upload Statement of Traineeship (Traineeship.pdf) as Attachment 9 (if applicable).	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI 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 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.	