Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Tuberous Sclerosis Complex Research Program (TSCRP)

Career Transition Award

Funding Opportunity Number: W81XWH-08-TSCRP-CARTA

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I. HELPFUL INFORMATION

A. Contacts

1. Program announcement, proposal format, or required documentation: To view all funding opportunities offered by the Congressionally Directed Medical Research Programs (CDMRP), perform a Grants.gov basic search using the CFDA Number 12.420. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

> Phone: 301-619-7079
>
> Fax: 301-619-7792
>
> Email: cdmrp.pa@amedd.army.mil

2. eReceipt system: Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time.

> Phone: 301-682-5507
>
> Website: https://cdmrp.org
>
> Email: help@cdmrp.org

3. Grants.gov contacts: Questions related to submitting applications through the Grants.gov (http://www.grants.gov/) portal should be directed to Grants.gov help desk. Deadlines for proposal submission are 11:59 p.m. Eastern time on the deadline date. Therefore, there is an approximate 3-hour period during which the Grants.gov help desk will NOT be available. Please plan ahead accordingly, as the CDMRP help desk is not able to answer questions about Grants.gov submissions.

> Phone: 800-518-4726, Monday to Friday, 7:00 a.m. to 9:00 p.m. Eastern time
>
> Email: support@grants.gov

Grants.gov will notify Principal Investigators (PIs) of changes made to this Program Announcement and/or Application Package ONLY if the PI clicks on the "send me change notification emails" link and subscribes to the mailing list on the Opportunity Synopsis Page for this announcement. If the PI does not subscribe and the Application Package is updated or changed, the original version of the Application Package may not be accepted.

B. National Technical Information Service

The technical reference facilities of the National Technical Information Service (www.ntis.gov) are available for the purpose of surveying existing knowledge and avoiding needless duplication

of scientific and engineering effort and the expenditure thereby represented. All other sources also should be consulted to the extent practical for the same purpose.

C. Commonly Made Mistakes

- Not obtaining or confirming the organization's DUNS number well before the proposal submission deadline.

- Not obtaining or confirming the organization's registration with the Central Contractor Registry (CCR) well before the proposal submission deadline.

- Failing to request "send me change notification emails" from Grants.gov.

- Not contacting HELP DESKS until just before or after deadlines.

- Not completing the pre-application submission before the mandatory pre-application deadline (pre-application remains in draft status).

- Using an incorrect Grants.gov application package to submit a proposal through Grants.gov. Each Program Announcement/Funding Opportunity requires a specific application package.

- Uploading attachments into incorrect Grants.gov forms.

- Attaching files in the wrong location on Grants.gov forms.

- Submitting attachments that are not PDF documents, except for the R&R Subaward Budget Attachment(s) Form.

- Exceeding page limitations.

- Failing to submit a proposal 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package.

- Failing to submit proposal by submission deadline.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History and Objectives

The Tuberous Sclerosis Complex Research Program (TSCRP) was established in Fiscal Year 2002 (FY02) to promote innovative research focused on eradicating tuberous sclerosis complex (TSC). Appropriations for the TSCRP from FY02 through FY06 totaled $13.5 million (M). The FY08 appropriation is $4M.

The overall goal of the FY08 TSCRP is to lessen the impact of TSC. Within this context, the encouragement of established scientists in the field and the attraction of new scientific expertise from other fields are essential to the TSC community. Proposals that address the needs of minority, low-income, rural, and other under-represented and/or medically underserved populations are encouraged and may be submitted from any eligible institution.

The TSCRP challenges the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators to the field of TSC

research. Scientific ventures that represent underinvestigated avenues of research or novel applications of existing technologies are highly sought. The TSCRP encourages risk-taking research, although such projects must demonstrate solid scientific judgment and rationale.

B. Award Description

The Career Transition Award (CRA) mechanism is being offered for the first time in FY08.

The Tuberous Sclerosis Complex Research Program (TSCRP) Career Transition Award supports TSC researchers during the transition from postdoctoral training to an independent position. This award will cover up to two years of postdoctoral training followed by up to two years of a faculty-level position. *For the purposes of this award, the postdoctoral candidate is considered the Principal Investigator (PI).*

Important aspects of the Career Transition Award are as follows:

1. The award covers the last two years of a postdoctoral fellowship and the first two years of an independent faculty position.

2. All proposals must include preliminary data relevant to TSC research and the proposed project.

3. Career transition and development plans must be clearly articulated.

4. A named mentor who will support and guide the PI during the postdoctoral period of the award.

It is the responsibility of the PI to clearly and explicitly articulate the project's innovation and the impact it may have on the field of TSC research.

Clinical trials are not acceptable under this mechanism.

C. Eligibility

Postdoctoral investigators within 2-3 years of completing their postdoctoral work are eligible to submit proposals. Refer to Application Instructions, Appendix 1, for general eligibility information.

D. Funding

Funding for a Career Transition Award can be requested for up to $338,000 for direct costs for up to a 4-year performance period, plus indirect costs as appropriate. This includes up to $69,000 per year, for up to two years, for each postdoctoral year in direct costs and up to $100,000 per year, for up to two years, for faculty-level position years in direct costs, plus indirect costs as appropriate.

Within the guidelines provided in the Application Instructions, funds can cover:

- Salary
- Research supplies
- Equipment
- Clinical costs
- Travel to scientific/technical meetings
- Travel between collaborating institutions

The CDMRP expects to allot approximately $0.5M of the $4.0M FY08 TSCRP appropriation to fund approximately 1 Career Transition Award proposals, depending on the quality and number of proposals received. Funding of proposals received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

E. Award Administration

This award is intended to support the submitting PI's career transition. Funding beyond the second year is contingent upon proof that the PI has secured a faculty-level position. A transfer of the award to another institution is expected if the PI obtains a faculty position at a different institution. Changes in PI will not be allowed.

Refer to the Application Instructions (Appendix 5) for general award administration information.

III. TIMELINE FOR SUBMISSION AND REVIEW

Proposal submission is a two-step process consisting of (1) pre-application submission and (2) proposal submission. ***Pre-application submission is a required first step***.

- **Pre-application Submission Deadline:**   **5:00 p.m. Eastern time, May 22, 2008**
- **Proposal Submission Deadline:**   **11:59 p.m. Eastern time, June 12, 2008**
- **Peer Review:**   **July 2008**
- **Programmatic Review:**   **September 2008**

Awards will be made approximately 4 to 6 months after receiving the funding notification letter, but no later than September 30, 2009.

IV. SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the CDMRP eReceipt system (https://cdmrp.org/) and (2) a proposal submission through Grants.gov (http://www.grants.gov/).

Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

A. Step 1: Pre-Application Components and Submission

The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the CDMRP eReceipt system by *5:00 p.m. Eastern time on the deadline*. Refer to the Application Instructions for detailed information.

- Proposal Information
- Proposal Contacts
- Collaborators and Conflicts of Interest (COI)
- Letter of Intent (LOI) Narrative

B. Step 2: Proposal Components and Submission

Proposal submission will not be accepted unless a pre-application was submitted by the pre-application deadline. Proposals must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov). No paper copies will be accepted.

Each proposal submission must include the completed Grants.gov application package of forms and attachments identified in www.grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) program announcement. In addition to the specific instructions below, please refer to the Application Instructions for detailed requirements of each component.

The package includes:

1. **SF-424 (R&R) Application for Federal Assistance Form**

2. **Attachments Form**

   - Attachment 1: Project Narrative **(10-page limit.)**

     Describe the proposed project in detail using the outline below. *Proposals must include preliminary data relevant to the proposed project.*

       Background: Present the ideas and reasoning behind the proposed work. Cite relevant literature.

       Hypothesis or Objective: State the hypothesis to be tested or the objective to be reached.

       Specific Aims: Concisely explain the projects' specific aims to be funded by this proposal.

       Research Strategy: Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. A detailed plan for the recruitment of subjects or the acquisition of samples must be included. *This award may not be used to conduct clinical trials.*

- Attachment 2: Supporting Documentation
  - References Cited
  - Acronyms and Symbol Definitions
  - Facilities & Other Resources
  - Description of Existing Equipment
  - Publications and/or Patent Abstracts **(Five-document limit.)**
  - Letters of Institutional Support **(Two-page limit.)**

    The letter(s) should indicate the level of institutional commitment to fostering the PI's research and career goals. The letter must demonstrate the willingness of the institution to transfer the award should the faculty level position be obtained outside the PIs current institution.

  - Mentor's Letter of Support **(Two-page limit.)**

    Provide a signed letter from the mentor, which demonstrates his/her background, qualifications, and training experience, and how the mentor will support the PIs research during the postdoctoral stage and assist him or her with the transition to independent investigator status.

  - PI's Career Transition Plan Letter **(Two-page limit.)**

    The PI must clearly articulate his or her plans for transitioning from a postdoctoral position into a faculty level position. This plan must include his/her career goals relative to TSC and outline the timeline for the transition.

  - Intellectual and Material Property Plan (if applicable)
- Attachment 3: Technical and Public Abstracts **(One-page limit for each abstract.)**
  - Both the training program and the research project should be emphasized.
- Attachment 4: Statement of Work (SOW) **(Two-page limit.)**
- Attachment 5: Impact Statement **(One-page limit.)**

Describe the impact of this study on TSC research or patient care. Describe how the expected results of the proposal will contribute to the goals of eradicating the disease and advancing methods, concepts, diagnosis, or treatment of TSC or quality of life for patients.

Attachment 6: Innovation Statement **(One-page limit.)**

Summarize how the proposal is innovative. The following examples of ways in which proposals may be innovative, ***although not all-inclusive***, are intended to help PIs frame the innovative features of their proposals:

- 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.

- ○ 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.

  Investigating the next logical step or incremental advancement on published data is not considered innovative.

- Attachment 7: Federal Agency Financial Plan (if applicable)

3. **Research & Related Senior/Key Person Profile (Expanded Form)**

- PI Biographical Sketch (**Four-page limit.**)
- PI Current/Pending Support
- Key Personnel Biographical Sketches (**Four-page limit each.**)
  - ○ A Biographical Sketch of the PI's mentor is required.
- Key Personnel Current/Pending Support
  - ○ Current/Pending Support for the PI's mentor is required.

4. **Research & Related Budget Form**

- Budget Justification

5. **Research & Related Project/Performance Site Location(s) Form**

6. **R&R Subaward Budget Attachment(s) Form (if applicable)**

V. INFORMATION FOR PROPOSAL REVIEW

A. Proposal Review and Selection Overview

All proposals are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of proposals against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit and overall goals of the program. Additional information about the two-tier review process used by the CDMRP may be found at http://cdmrp.army.mil/fundingprocess.htm.

The peer review and program review processes are conducted confidentially and anonymously to maintain the integrity of the merit-based selection process. Each tier review requires panelists to sign a non-disclosure statement attesting that proposal 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 correcting actions. Correspondingly, institutional personnel and PIs are prohibited from contacting persons involved in the proposal review process to gain protected evaluation information or to influence the evaluation process. Violations of this prohibition will result in the administrative withdrawal of the institution's proposal. Violations by panelists or PIs that compromise the confidentiality or anonymity of the peer review and

program review processes may also result in suspension or debarment of their employing institutions from Federal awards.

The Government reserves the right to review all proposals based on one or more of the required attachments or supporting documentation (e.g., Impact Statement, Innovation Statement, etc.).

B. Review Criteria

1. Peer Review: All proposals will be evaluated according to the following criteria, which are listed in order of decreasing importance:

- **Principal Investigator**
  - How the PI's training, research experience, and publication record indicate promising achievements to date.
  - How the PI is appropriately trained and well-suited to carry out the proposed research.
  - How the PI has demonstrated a personal commitment to pursuing an independent career in TSC research, including an appropriate level of effort on this proposal.

- **Transition Plan**
  - How the PI's (postdoctoral trainee) mentor has the background, qualifications, training experience, and time to supervise the postdoctoral trainee (PI) and assist him or her with the transition to independent investigator status.
  - Whether there is a commitment from the mentor and institution to allow the PI to take his or her research project to a new position.
  - How well the PI's Career Transition Plan Letter indicates his/her career goals relative to TSC and outlines the timeline for the transition, including when the PI plans to obtain the faculty-level position.

- **Research Strategy and Feasibility (preliminary data are required)**
  - How the conceptual framework, hypotheses, design, methods, and analyses of the research are adequately developed and well-integrated for the PI's research program.
  - How a sound scientific rationale has been presented through a critical review and analysis of the literature, logical reasoning, and/or the use of preliminary data.
  - How the PI acknowledges potential problem areas and considers alternative methods/tactics.
  - How the research will offer a valuable opportunity to further develop research experience to advance and develop the PI's independent TSC research career.

- **Innovation**
  - How 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, and clinical interventions.

- How the project proposes new paradigms or challenges existing paradigms.
- How the proposed research represents more than an incremental advance upon published data.
- How the potential gain warrants the perceived risk.

- **Impact**
  - How the project addresses a critical problem in TSC research or patient care.
  - How the project makes an original and important contribution to advancing basic, clinical, and translational research that will improve outcomes for TSC.
  - The difference the proposed project will make on TSC research or patient care, if successful.
  - How the project will facilitate the transition of the PI from a postdoctoral trainee to an independent investigator.

- **Budget**
  - How the budget is appropriate for the proposed research and training.

2. Programmatic Review: Criteria used by the Integration Panel (IP) members to make funding recommendations that maintain the program's broad portfolio include:

- Ratings and evaluations of the peer reviewers,
- Programmatic relevance,
- Relative innovation and impact,
- Program portfolio balance, and
- Adherence to the intent of the award mechanism.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by Integration Panel members and recommended for funding to the Commanding General, USAMRMC.

VI. COMPLIANCE GUIDELINES

Compliance guidelines have been designed to ensure the presentation of all pre-applications and proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format. Failure to adhere to formatting guidelines makes documents difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in pre-application or proposal rejection. **Pre-applications or proposals missing required components as specified in the Program Announcement/Funding Opportunity may be administratively rejected.**

The following will result in administrative rejection of the entire proposal:

- Project Narrative exceeds page limit.

- Project Narrative is missing.

- Margins are less than specified in the formatting guidelines.

- Print Area exceeds that specified in the formatting guidelines.

- Spacing is less than specified in the formatting guidelines.

- Budget and/or budget justification are missing.

- FY08 IP members are included in any capacity in the pre-application process, the proposal, budgets, and any supporting document. A list of the FY08 IP members may be found at http://cdmrp.army.mil.

For any other sections of the pre-application or proposal with a defined page limit, pages exceeding the specified limit will be removed and not forwarded for peer review.

Material submitted after the submission deadline, unless specifically requested by the Government, will not be forwarded for peer review.

Proposals that appear to involve any allegation of research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to perform the investigation and provide those findings to the Grants Officer for a determination of the final disposition of the application.