Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Tuberous Sclerosis Complex Research Program (TSCRP)

Concept Award

Funding Opportunity Number: W81XWH-08-TSCRP-CA

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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 TSCRP Concept Award was created in FY04. Since then, 187 Concept Award proposals have been received and 25 have been recommended for funding.

The Tuberous Sclerosis Complex Research Program (TSCRP) Concept Award supports (1) the exploration of an initial concept or theory that could give rise to a testable hypothesis, and/or (2) the development of novel preclinical tools needed to advance research in TSC. These tools may include, but are not limited to, animal models, antibodies, cell lines, assays, and reagents.

Important aspects of the Concept Award are as follows:

1. Preliminary data are not required and are not consistent with the intent of this mechanism.

2. Submissions from complementary areas of science are encouraged as are research proposals involving consumer-scientist collaborations.

3. The Concept Award is blinded during review to the PIs identity and his/her institutional affiliation.

Because these awards are designed for preliminary investigations, projects involving human subjects or specimens will not be supported unless they are exempt under 32 CFR 219.101(b) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110). Studies that do not qualify for exempt or expedited status during review at any level will be administratively withdrawn and will not be funded.

It is the responsibility of the Principal Investigator (PI) to clearly and explicitly articulate how the proposed research is innovative and how the concept is novel.

Clinical trials are not acceptable under this mechanism.

C. Eligibility

PIs at all levels are eligible to submit proposals. Refer to Application Instructions, Appendix 1, for general eligibility information.

D. Funding

Funding for a Concept Award can be requested for up to $75,000 for direct costs for up to a 1-year performance period, 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 $0.45M of the $4.0M FY08 TSCRP appropriation to fund approximately 4 Concept 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

No changes in the institution will be allowed once the proposal has been awarded. 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, April 18, 2008**
- **Proposal Submission Deadline:**   **11:59 p.m. Eastern time, May 14, 2008**
- **Peer Review:**   **June 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 **(Three-page limit.)**

   Describe the proposed project in detail using the outline below. *Preliminary data are not required and are not consistent with the intent of this mechanism.*

   Background: Present the ideas and reasoning behind the proposed research, to include relevant literature citations. Describe previous experience most pertinent to this proposal.

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

   Specific Aims: Concisely explain the project's specific aims. If this proposal is part of a larger study, present only tasks that the DOD award would fund.

   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.

> *Reviewers will be blinded to the identity of the PI and the PI's institution. Due to the blinded nature of the review process, references to the PI or the institution in the project narrative are prohibited and will result in administrative withdrawal of the proposal. In addition, the use of "I," "our," "this institution," or similar phrases that make it possible to identify the PI and/or institution through the references listed will result in administrative withdrawal of the proposal.*

- Attachment 2: Supporting Documentation
  - References Cited
  - Acronyms and Symbol Definitions
- Attachment 3: Statement of Work (SOW) **(Two-page limit.)**
- Attachment 4: Federal Agency Financial Plan (if applicable)

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

- PI Biographical Sketch
  - Although requested, the Biographical Sketch will not be forwarded for review due to the blinded nature of this award. The biographical sketch will be used for administrative purposes only.

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.

B. Review Criteria

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

- **Innovation**
  - How the proposed concept or resource is innovative.
  - That the concept or resource is untested or in the initial stage of development.
  - How the concept will give rise to a testable hypothesis if successful, or how the resource will offer the potential to advance TSC research.
- **Impact**
  - How the study addresses a problem critical to TSC research.
  - How the project will lead to an original and important contribution to advancing basic, clinical, and translational research that will improve outcomes for TSC.
  - What impact this study will have on the concepts or methods that drive the field.
- **Research Strategy and Feasibility**
  - How the scientific rationale and logical reasoning support the project and its feasibility.
  - *For proposals involving the development of novel preclinical tools*: How the methodology proposed is appropriate to developing the resource. Examples include, but are not limited to, animal models, antibodies, cell lines, assays, and reagents.

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 be 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.
- PI's name or institution is included in the Project Narrative.
- 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.
- Use of "I," "our," "this institution," or similar phrases that make it possible to identify the PI and/or institution through the references listed.
- FY08 Integration Panel (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 an investigation and provide those findings to the Grants Officer for a determination of the final disposition of the application.