

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Tuberous Sclerosis Complex Research Program

Career Transition Award

Funding Opportunity Number: W81XWH-09-TSCR-CARTA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Objectives

The Tuberous Sclerosis Complex Research Program (TSCRP) was established in fiscal year 2002 (FY02) to promote innovative research focused on decreasing the clinical impact of tuberous sclerosis complex (TSC). Appropriations for the TSCRP from FY02 through FY08 totaled \$17.5 million (M). The FY09 appropriation is \$6M.

FY09 TSCRP Mission and Goals: 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 TSCRP encourages applications to the FY09 program that address these vital program goals:

- To better understand the molecular mechanisms underlying TSC.
- To better characterize the manifestations of TSC in individual organ systems, including brain, lung, kidney, skin, and heart.
- To promote the translation of new research findings for the diagnosis and treatment of those with TSC.
- To encourage the development of new researchers in TSC and collaborations with other related fields.

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/tscresources.htm>. Investigators are urged to leverage and contribute to these resources. For more guidance on data sharing, refer to Application Instructions and General Information, Appendix 5.

B. Award Description

The TSCRP Career Transition Award mechanism was first offered in FY08. One Career Transition Award application was received and 1 was recommended for funding.

The 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. Under this award mechanism, the postdoctoral candidate is considered the Principal Investigator (PI).

Important aspects of the Career Transition Award are as follows:

- The award covers the last two years of a postdoctoral fellowship and the first two years of an independent faculty position.
- Career transition and development plans must be clearly articulated.

- A named mentor who will support and guide the PI during the postdoctoral period of the award.
- All applications must include preliminary data relevant to TSC research and the proposed project.

Clinical Trials are not allowed under this award mechanism. PIs wishing to apply for funding for a clinical trial should utilize the Clinical and Translational Research Award mechanism.

C. Eligibility

Postdoctoral Investigators with at least two years of postdoctoral experience are eligible to submit applications. Refer to Application Instructions and General Information, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is 4 years.
- The maximum allowable funding for the entire period of performance is **\$338,000** in direct costs.
 - Maximum funding of **\$69,000 per year** in direct costs for each postdoctoral year.
 - Maximum funding of **\$100,000 per year** in direct costs for each faculty-level position year.
- In addition to the direct costs, indirect costs may be proposed in accordance with your current institution's negotiated rate agreement.

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

- Salary
- Research supplies
- Equipment
- Clinical costs (no clinical trials allowed)
- Travel between collaborating institutions
- Travel to scientific/technical meetings

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$0.5M of the \$6M FY09 TSCRAP appropriation to fund approximately 1 Career Transition Award application, depending on the quality and number received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent on 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 level position at a different institution. Changes in PI will not be allowed. Refer to the Application and General Information, Appendix 5, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

Proposal submission is a two-step process consisting of (1) pre-application submission and (2) application submission.

Pre-application Submission Deadline:	March 24, 2009
Application Submission Deadline:	April 14, 2009
Scientific Peer Review:	Summer, 2009
Programmatic Review:	Late Summer/Early Fall, 2009

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2010.

III. SUBMISSION PROCESS

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

PIs and organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or organization after submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507.

The Government reserves the right to reject duplicative applications submitted to different award mechanisms within the same program or to other CDMRP programs.

A. Step 1 – Pre-Application Components and Submission

Pre-application submission is the required first step. The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the [CDMRP eReceipt system](https://cdmrp.org/) by **5:00 p.m. Eastern time (ET) on the deadline date.** Refer to the Application Instructions and General Information for detailed information.

- Proposal Information
- Proposal Contacts

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

B. Step 2 – Application Components and Submission

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline. Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov).

Each application submission must include the completed application package of forms and attachments identified in www.grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information 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. ***The project narrative must include preliminary data originating from the PI, research team, or collaborator that is relevant to TSC research and 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 project's specific aims to be funded by this application. If the proposed work 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. Describe the statistical plan if appropriate for the research proposed. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples and statistical plan. ***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 per letter.)
 - 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 PI's 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 PI's research during the postdoctoral stage and assist him/her with the transition to independent investigator status.
- PI's Career Transition Plan Letter (Two-page limit.)
 - The PI must clearly articulate his/her plans for transitioning from a postdoctoral position into a faculty-level position. This plan must include his/her career goals in TSC and outline a timeline for transition.
- Letters of Collaboration (if applicable; two-page limit per letter.)
- Intellectual and Material Property Plan (if applicable)
- Attachment 3: Technical Abstract (One-page limit.)
 - Both the training program and research project should be emphasized.
- Attachment 4: Public Abstract (One-page limit)
 - Both the training program and research project should be emphasized.
- Attachment 5: Statement of Work (SOW, three-page limit.)
- Attachment 6: Detailed Budget and Justification
- Attachment 7: Impact Statement (One-page limit.)

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

- Attachment 8: Innovation Statement (One-page limit)

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 of ways in which the proposed work may be innovative 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 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 9: Federal Agency Financial Plan (if applicable)
- Attachment 10-15: Subaward Detailed Budget and Justification (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 Project/Performance Site Location(s) Form

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications 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, overall goals of the program and the specific intent of the award mechanism. 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 programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier 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 correcting actions. Institutional personnel and PIs are prohibited from contacting persons involved in the application 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 application. Violations by panelists or PIs that compromise the confidentiality of the peer review and programmatic review processes may also result in suspension or debarment of

their employing institutions from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

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

B. Review Criteria

1. Peer Review: All applications will be evaluated according to the following criteria, which are listed in decreasing order of 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 application.
- **Transition Plan**
 - How the mentor's background, qualifications, research program, committed resources, and available time support his/her ability to supervise the PI's training, research project, and transition to independent investigator.
 - Whether there is commitment from the mentor and institution to allow the PI to take his/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 a 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 scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, the presentation of preliminary data, and/or logical reasoning.
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
 - 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 research proposes new paradigms or challenges existing paradigms 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 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 or 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.

The following criteria will not be individually scored, but may impact the overall evaluation of the application:

- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of the award mechanism.
- **Application Presentation**
 - How the writing and components of the application influenced the review.

2. Programmatic Review: Criteria used by programmatic reviewers to make funding recommendations that maintain the program's broad portfolio include:

- Ratings and evaluations of the peer reviewers,
- Program portfolio balance,
- Programmatic relevance,
- Relative innovation and impact,
- 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. The highest scoring applications from the first tier of review are not automatically recommended for funding. All applications are carefully considered to ensure that the

funds available are allocated to those proposals that best fulfill the goals and objectives of the program.

Investigators are urged to view previously TSCRP-funded proposals at <http://cdmrp.army.mil/search.aspx?program=TSCRP> to aid in the development of applications that represent novel areas of research, as portfolio balance is an important consideration at programmatic review to ensure that gaps in the research are adequately addressed.

V. 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:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

B. Modifications

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
- Documents not requested will be removed.
- **NEW for FY09:** Following the application deadline, you may be contacted by email from CDMRP with a request to provide certain missing supporting documents (excluding those listed directly above in Section A, Rejection). The missing documents must be provided within 48 hours of the date and time the email was sent. Otherwise, the application will be peer reviewed without the missing documents.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY09 IP member(s) is found to be involved 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 FY09 IP members may be found at <http://cdmrp.army.mil/research.htm>.
- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.
- The application does not conform to this funding opportunity description to an extent that precludes appropriate scientific peer and programmatic review.

- Direct costs as shown on the detailed budget form exceed the maximum allowed by the award mechanism.
- Inclusion of URLs, with the exception of links to published references.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to provide the findings of the investigation to the USAMRAA Contracting/Grants Officer for a determination of the final disposition of the application.

VI. CONTACT INFORMATION

A. Program Announcement/Funding Opportunity, application format, or required documentation: To view all funding opportunities offered by the 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

B. 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. ET.

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

C. Grants.gov contacts: Questions related to application submission through the [Grants.gov](http://www.grants.gov/) (<http://www.grants.gov/>) portal should be directed to the Grants.gov help desk, which is available Monday through Friday, 7:00 a.m. to 9:00 p.m. ET. Deadlines for application submission are 11:59 p.m. ET on the deadline date. Please note that the CDMRP help desk is unable to answer questions about Grants.gov submissions.

Phone: 800-518-4726
 Email: support@grants.gov

Grants.gov will notify PIs of changes made to this Program Announcement/Funding Opportunity and/or application package ONLY if the PI subscribes to the mailing list by clicking on the “send me change notification emails” link 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.