

# Program Announcement

## I. GENERAL INFORMATION

This program announcement is being released prior to the receipt of Federal funds appropriated in a bill for this program; funding of proposals received in response to this program announcement is contingent on the receipt of these funds at the United States Army Medical Research and Materiel Command (USAMRMC).

**A. Title of Award:** *Tuberous Sclerosis Complex Research Program (TSCRCP) Concept Award.*

**B. Program Name:** Department of Defense (DOD) Fiscal Year 2006 (FY06) TSCRCP.

**C. Funding Opportunity Number:** W81XWH-06-TSCRCP-CA.

**D. Agency Name:** USAMRMC, Office of the Congressionally Directed Medical Research Programs (CDMRP), 1077 Patchel Street, Fort Detrick, Maryland 21702-5024.

### E. Agency Contact(s)

**1. Questions related to the program announcement, proposal format, or required documentation:** Applicants should submit questions as early as possible. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079  
Fax: 301-619-7792  
E-mail: [cdmrp.pa@amedd.army.mil](mailto:cdmrp.pa@amedd.army.mil)  
Mail: Commander  
US Army Medical Research and Materiel Command  
ATTN: MCMR-ZB-C (BC06-CA)  
1077 Patchel Street (Building 1077)  
Fort Detrick, MD 21702-5024

**2. Questions related to electronic submission:** A help line for questions relating to proposal submission and the CDMRP eReceipt Online Proposal Submission System is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time at 301-682-5507. Help is also available on the CDMRP website or by e-mail as follows:

Website: <https://cdmrp.org> (User's Guide located in upper right corner of the proposal submission website)  
E-mail: [help@cdmrp.org](mailto:help@cdmrp.org)

**F. Anticipated Instrument Type(s):** The USAMRMC executes its extramural research program predominantly through the award of grants and cooperative agreements. More information on these funding instruments may be obtained by request from:

Fax: 301-619-2937  
E-mail: [qa.baa@amedd.army.mil](mailto:qa.baa@amedd.army.mil)  
Mail: Director  
US Army Medical Research Acquisition Activity  
ATTN: MCMR-AAA-R  
820 Chandler Street  
Fort Detrick, MD 21702-5014

**G. Catalog of Federal Domestic Assistance (CFDA) Number 12.420:** Military Medical Research and Development.

**H. Website to Access Application Package:** Proposals must be submitted at <https://cdmrp.org>. This website contains all the information, forms, documents, and links needed to apply. Applicants experiencing difficulties in downloading documents should contact the CDMRP as indicated in [Subsection I.E.2](#).

**I. Award/Regulatory Approval:** The applicant may not use, employ, or subcontract for the use of any human subjects, human biological substances, cadavers, or laboratory animals until applicable regulatory documents are requested, reviewed, and approved by the USAMRMC. *For Concept Awards, projects involving human subjects or specimens will not be supported unless they are exempt under 32 CFR 219.101(b)(4).<sup>1</sup> Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded.*

## II. FUNDING OPPORTUNITY DESCRIPTION

**A. Program History:** The Concept Award is one of the mechanisms of the Tuberous Sclerosis Complex Research Program (TSCRCP), which was established in FY02 to promote innovative research directed toward improved detection, diagnosis, and/or treatment of tuberous sclerosis complex. Appropriations for the TSCRCP from FY02 through FY05 totaled \$9.2 million (M). During this time, 68 Concept Award proposals were received and 16 were funded. The FY06 appropriation is \$4.3M.

**B. Program Objectives:** The overall goal of the FY06 TSCRCP is to decrease the impact of tuberous sclerosis complex. 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 tuberous sclerosis complex community. Proposals that address the needs of minority, low-

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<sup>1</sup>Title 32, Code of Federal Regulations, Part 219, Section 101(b)(4). Research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, is considered to be exempt under 32 CFR 219.101(b)(4).

income, rural, and other underrepresented and/or medically underserved populations are encouraged and may be submitted from any eligible institutional source.

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 tuberous sclerosis complex 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.

**C. Award Mechanism Description:** The intent of the TSCRP Concept Award is to fund (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 tuberous sclerosis complex. These tools may include, but are not limited to, animal models, antibodies, cell lines, assays, and reagents.

Presentation of preliminary data is not consistent with the intent of this award mechanism. These awards provide investigators with the opportunity to pursue serendipitous observations and/or develop new research tools for use by the applicant's laboratory and the tuberous sclerosis complex research community. It is expected that research completed through a Concept Award will provide sufficient preliminary data to enable the investigator to prepare a hypothesis-based proposal for future research or result in the development of a new tool or resource for hypothesis-driven research. Proposals must describe how the new concept or theory will enhance existing knowledge of tuberous sclerosis complex or create an entirely new avenue for investigation, and/or how the new resource or tool will advance tuberous sclerosis complex research.

Submissions from complementary areas of science such as chemistry, biophysics, mathematics, engineering, etc. are encouraged as are research proposals involving consumer-scientist collaborations.

***Because these awards are designed for preliminary investigations, projects involving human subjects or human biological substances will not be supported through this mechanism unless they are exempt under 32 CFR 219.101(b)(4). Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded.***

### **III. AWARD INFORMATION**

Funding for Concept Awards may be requested for a maximum of \$67,000 for direct costs over a 1-year performance period, plus indirect costs as appropriate. Proposals for projects requiring lower levels of funding also may be submitted. These funds can cover salary, research supplies, and travel to scientific/technical meetings.

*The CDMRP expects to allot approximately \$0.86 M of the \$4.3M FY06 TSCRIP appropriation to fund approximately 8–9 Concept Awards, depending on the quality and number of proposals received.*

#### IV. ELIGIBILITY INFORMATION

**A. Applicants:** Investigators at all academic levels (or equivalent) are eligible to submit proposals.

All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution as defined in [Subsection IV.B](#), “Institutions” below.

To protect the public interest, the Federal Government ensures the integrity of Federal programs by conducting business only with responsible recipients. The USAMRMC uses the Excluded Parties List System (EPLS) to exclude recipients ineligible to receive Federal awards. The EPLS is online at <http://epls.arnet.gov>. (Reference Department of Defense Grant and Agreement Regulations (DODGAR) 25.110.)

**B. Institutions:** Eligible institutions include for-profit, nonprofit, public, and private organizations, such as universities, colleges, hospitals, laboratories, and companies. The USAMRMC is especially interested in receiving applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI).

A DOD goal is to allocate funds for the CDMRP peer reviewed research to fund proposals from HBCU/MI. This provision is based on guidance from Executive Orders.<sup>2</sup> Proposals are assigned HBCU/MI status when the submitting institution is so designated by the Department of Education on the date the program announcement is released. The most current Department of Education list is posted on the CDMRP website at <http://cdmrp.army.mil/spp> under “Minority Institutions.”

Local, state, and Federal Government agencies are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies are expected to explain how their proposals do not overlap with their intramural programs.

Proposals from Federal agencies *must* provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

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<sup>2</sup>Executive Orders 12876, 12900, and 13021

**C. Duplicate Submissions:** Submission of the same research project to the FY06 TSCRP under different award mechanisms or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

## V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

**A. Proposal Components Summary:** This subsection is a summary of submission requirements. Details, URLs, and other links are provided in the appropriate subsections of this program announcement. Proposals will be evaluated according to peer and programmatic review criteria in [Section VI](#). Reviewers will be blinded to the identity of the applicant and applicant’s institution.

**1. Applicant Responsibility:** The applicant is responsible for entering and/or uploading the following information into the CDMRP eReceipt Online Proposal Submission System at <https://cdmrp.org>:

Item	Tab	Format	Action
Letter of Intent (LOI)	Proposal Information	N/A	None. Not required.
Proposal Information	Proposal Information	Typed	Enter the appropriate information in data fields.
Proposal Contacts	Proposal Contacts	Typed	Enter contact information for the applicant and the Contract Representative.
Collaborators and Conflicts of Interest (COI)	Collaborator/COI	N/A	None. Not required.
Proposal Abstracts, Impact Statement, and Statement of Work (SOW)	Abstract/Impact/SOW	Typed or Cut and Paste	Technical Abstract, Public Abstract, Impact Statement are not required; type N/A into the data fields. Enter the SOW in a separate data field.
Proposal Main Body	Required Files	PDF	Upload as a PDF file.
Supporting Documentation	Required Files	PDF	Upload as a PDF file.
Budget Information	Required Files	PDF	Upload as a PDF file.
Regulatory Documents	Required Files	PDF	Upload the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance forms.

**2. Contract Representative’s Responsibility:** The Contract Representative (CR) or institutional official responsible for sponsored program administration (or equivalent) at the applicant’s institution is responsible for the following:

Item	Tab	Format	Action
Contract Representative’s Contact Information Profile	My Profile for the CR	Typed	Complete before electronic approval of all submission components.
USAMRAA <sup>a</sup> -Required Documents	My Profile for the CR	PDF	Upload the Rate Agreement, Certifications and Assurances for Assistance Agreements, and Representations for Assistance Agreements.
Approval	CR Approval	Click Approval Button	Click the button to approve the Proposal Information, Proposal Contacts, Abstracts/Impact Statement/SOW, and Required Files <i>before</i> the submission deadline of 5:00 p.m. Eastern time, April 25, 2006.

<sup>a</sup>US Army Medical Research Acquisition Activity

**B. Proposal Format:** Proposals must be uploaded under the “Required Files” tab of the CDMRP eReceipt system at <https://cdmrp.org>. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire and learn to use the appropriate software well in advance of the submission deadline. The instructions in this subsection must be followed carefully to prepare proposals for PDF submission.

The main body of the proposal must be clear and legible and conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ between the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on the computer screen and submitted via the CDMRP eReceipt Online Proposal Submission System.

- **Font Size:** 12 point or larger.
- **Font Type:** Times New Roman is strongly recommended.
- **Spacing:** No more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- **Margins:** Must be at least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (approximately 19.05 cm x 25.40 cm).

- **Color, High Resolution, and Multimedia Objects:** Not allowed for Concept Award submissions.
- **Internet URLs:** URLs directing reviewers to websites containing significant additional information about the proposed research are not allowed in the proposal or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. Links to publications referenced in the proposal are allowed.
- **Language:** English.

Please note that headers should not be included, as the proposal log number will be electronically captured on each page of the proposal after receipt.

**C. Administrative Compliance Issues:** Compliance guidelines have been designed to ensure the presentation of all proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format for each proposal. *Failure to adhere to format requirements makes proposals difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in proposal rejection.*

The following will result in administrative rejection of the entire proposal before it reaches peer review:

- Proposal body exceeds page limit.
- Proposal body is missing.
- Cost Estimate and Budget Justification form is missing.
- Proposal is incomplete after the deadline.
- Applicant and/or institution names are included in the proposal body.

For any other sections of a proposal with a defined page limit, any pages exceeding the specified limit will be removed from the proposal 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.

The electronic PDF file uploaded in the CDMRP eReceipt Online Proposal Submission System is the official proposal submission file. After conversion of word processing documents to PDF files and before electronic submission, applicants should review their files to ensure that the proposal complies with the preparation guidelines outlined in this program announcement.

**D. Proposal Information:** Applicants are required to submit the Proposal Information as described in <https://cdmrp.org> before uploading the proposal, supporting documentation, and budget information.

- **Letter of Intent:** A Letter of Intent is not required for this award mechanism.

- **Title/Referral Page:** The Title/Referral Page is not applicable for this award mechanism.

**E. Proposal Contacts:** The Proposal Contacts *must* include the e-mail address of a Contract Representative authorized to negotiate on behalf of the applicant’s institution. The Proposal Contacts must be approved by the Contract Representative.

**F. Collaborators and Conflicts of Interest:** Not applicable to this award as reviewers are blinded to the identity of the applicant and applicant’s institution.

**G. Proposal Abstracts:** Abstracts are not required at the time of proposal submission. The data fields must be completed by typing “N/A” into both the technical and public abstract data fields.

**H. Impact Statement:** An Impact Statement is not required for this award mechanism. The data field must be completed by typing “N/A.”

**I. Statement of Work – 11,400-character limit, including spaces (approximately two pages):** The SOW is captured as a data field under the “Abstract/Impact/SOW” tab in the CDMRP eReceipt system. Applicants can type the SOW into the data field or “cut and paste” it from a word processing application. *Spell out all Greek letters, other non-English letters, and symbols.* Sample SOWs can be found at <https://cdmrp.org/samples.cfm>. The SOW will be used only during award negotiations.

The SOW is a concise restatement of the research proposal that outlines, step by step, how each of the major goals or objectives of the proposed research/services will be accomplished during the period for which the USAMRMC will provide financial support.

The SOW should:

- Describe the work to be accomplished as tasks (tasks may relate to specific aims);
- Identify the timeline and milestones for the work over the period of the proposed effort;
- Indicate the number of animal subjects projected or required for each task;
- Identify methods; and
- Identify outcomes, products, and deliverables for each phase of the project.

**J. Proposal Main Body: Three-page limit inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the proposal.**

Clearly explain how the proposed research is innovative and what impact it will have on tuberous sclerosis complex. Presentation of preliminary data is not required. However, for the proposal to be competitive, investigators must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature.



***Due to the blinded nature of the review process (see [Subsection VI.A](#)), references to the applicant or the applicant's institution in the proposal body are prohibited and will be cause for administrative withdrawal of the proposal.***

The proposal main body is uploaded as a PDF file under the “Required Files” tab of the CDMRP eReceipt system.

Describe the proposed project using the following outline:

- 1. Background:** Present the ideas and reasoning behind the proposed work. Describe experience most pertinent to this project.
- 2. Specific Aims:** Concisely state the project's specific aims.
- 3. Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls. As applicable, describe the resource to be developed and possible uses for this resource.
- 4. Innovation:** State concisely how the proposed research uses innovation to advance the detection, diagnosis, and/or treatment of tuberous sclerosis complex. Demonstrate how the proposed research represents more than an extension or incremental advance to published data.
- 5. Impact:** The rationale should clearly reflect that the research is focused on results that will have a significant impact on the concepts or methods that drive the field and that it will make an original and important contribution to the goal of advancing research on the detection, diagnosis, and treatment of tuberous sclerosis complex. As applicable, describe how the proposed resource addresses an unmet need in the fight against tuberous sclerosis complex.

**K. Supporting Documentation:** Submit only material specifically requested in this section of the program announcement. ***This section is not intended for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other information needed to judge the proposal.*** Submitting material that was not requested may be construed as an attempt to gain a competitive advantage and such material will be removed; submitting such material may be grounds for administrative rejection of the proposal.

Supporting documentation must be uploaded as a single PDF file under the “Required Files” tab of the CDMRP eReceipt system.

***A maximum of 10 references*** may be included in this section. List up to 10 relevant references 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).

**L. Budget Information:** Applicants must complete the [Concept Award Cost Estimate and Budget Justification form](#) and upload it as a PDF file under the “Required Files” tab of the CDMRP eReceipt system.

**1. Funding Restrictions:** Funding for Concept Awards can be requested for a maximum of \$67,000 for direct costs over a 1-year performance period, plus indirect costs as appropriate. These funds can cover salary, expenses including research supplies, and travel to scientific/technical meetings.

The travel allotment is \$1,800 per year for travel to scientific/technical meetings.

**2. Concept Award Cost Estimate and Budget Justification Form Instructions:** Budget is an important consideration in both peer review and programmatic review, and applicants are cautioned to use discretion in budget requests. Budgets also will be reviewed during award negotiations. *Organizations must provide sufficient detail so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research.* All costs must be entered in U.S. dollars.

The [Concept Award Cost Estimate and Budget Justification form](#) must be uploaded as a PDF file under the “Required Files” tab in the CDMRP eReceipt system.

The USAMRMC encourages in-kind contributions and cost-sharing for CDMRP-supported research. In-kind contributions may include support of services (e.g., laboratory services and salaries of personnel), real property and equipment, and/or supplies (e.g., drugs, devices, reagents) directly benefiting and specifically identifiable to the research project.

Costs proposed must conform to the following regulations and principles:

- **Commercial Firms:** Federal Acquisition Regulations (FAR) Part 31 and Defense FAR Supplement Part 31 (<http://farsite.hill.af.mil>), Contract Cost Principles and Procedures.
- **Educational Institutions:** Office of Management and Budget (OMB) Circular A-21, Cost Principles for Educational Institutions ([http://www.whitehouse.gov/omb/grants/grants\\_circulars.html](http://www.whitehouse.gov/omb/grants/grants_circulars.html)).
- **Nonprofit Organizations:** OMB Circular A-122, Cost Principles for Nonprofit Organizations. OMB Circular A-133, Audits of Institutions of Higher Education and Other Nonprofit Organizations ([http://www.whitehouse.gov/omb/grants/grants\\_circulars.html](http://www.whitehouse.gov/omb/grants/grants_circulars.html)).
- **State, Local, and Tribal Governments:** OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments ([http://www.whitehouse.gov/omb/grants/grants\\_circulars.html](http://www.whitehouse.gov/omb/grants/grants_circulars.html)).

Follow the instructions below when providing the information requested in the Concept Award Cost Estimate and Budget Justification form.

**a. Personnel**

**i. Name:** Beginning with the applicant, list all participants who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff. *The applicant must be identified as the Principal Investigator of the proposal.*

**ii. Role on Project:** Identify the role of each participant listed.

**iii. Type of Appointment (Months):** List the number of months per year reflected in an individual's contractual appointment with the applicant organization. The Government assumes that appointments at the applicant organization are full time for each individual unless otherwise noted. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.

**iv. Annual Base Salary:** Enter the annual institutional base salary for each individual listed for the project.

**v. Percentage of Effort on Project:** The applicant's qualifications and the amount of time that he or she and other professional personnel will devote to the research are important factors in selecting research proposals for funding. List the percentage of each appointment to be spent on this project for each key staff member identified on the budget form. Include the percentage of effort of all unpaid collaborators and consultants.

**vi. Salaries Requested:** Enter the salaries in whole U.S. dollar figures for each position for which funds are requested. The salary requested is calculated by multiplying an individual's institutional base salary by the percentage of effort on the project.

**vii. Fringe Benefits:** Fringe benefits may be requested in accordance with institutional guidelines for each position, provided the costs are treated consistently for all sponsors by the applicant's organization. Documentation to support the fringe benefits should be provided.

**viii. Totals:** Calculate the totals for each position and enter these as subtotals in the columns indicated.

**b. Consultant Costs:** Provide the names and organizational affiliations of all consultants whether or not funds are requested.

**c. Major Equipment:** Funding for this award cannot be used for the purchase of equipment.

**d. Materials, Supplies, and Consumables:** A general description and total estimated cost of expendable equipment and supplies are required. Itemize supplies in separate categories (e.g., glassware, chemicals, radioisotopes). Categories in amounts less than \$1,000 do not need to be itemized. If animals are to be purchased, state the species, strain (if applicable), and the number to be used. If human cell lines (which must be exempt under 32 CFR 219.101(b)(4)) are to be purchased, state the source and the description.

**e. Travel Costs:** The travel allotment is \$1,800 per year for travel to scientific/technical meetings.

Travel costs associated with the execution of the proposed work should be entered in this section. If applicable, reasonable costs for travel between collaborating institutions should be included and are not subject to the yearly \$1,800 limitation on travel to meetings. Justification for these travel costs should be provided. Travel outside the U.S. requires prior approval from the US Army Medical Research Acquisition Activity (USAMRAA).

**f. Other Direct Costs:** Itemize other anticipated direct costs such as publication and report costs, rental for computers and other equipment (provide hours and rates), and communication costs. Unusual or expensive items should be fully explained and justified. Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution.

**g. Subaward Costs:** A description of services or materials to be awarded by subcontract or subgrant is required. For awards totaling \$10,000 or more:

- Identify the type of award to be used (e.g., cost reimbursement, fixed price);
- Identify the proposed subcontractor or subgrantee, if known, and provide an explanation of why and how the subcontractor or subgrantee was selected or will be selected;
- Specify whether the award will be competitive and, if noncompetitive, provide a rationale to justify the absence of competition; and
- Provide the proposed acquisition price.

**h. Indirect Costs (overhead, general and administrative, and other):** The most recent rates, dates of negotiation, base(s), and periods to which the rates apply should be disclosed with a statement identifying whether the proposed rates are provisional or fixed.

**i. Total Costs:** Direct costs, indirect costs, and the total cost for the entire proposed performance period should equal the amount entered in the “Required Files” tab at <https://cdmrp.org>.

**3. Budget Justification (second page of the Concept Award Cost Estimate form):** Each item in the budget must be clearly justified in the Budget Justification section of the Concept Award Cost Estimate form.

**4. Federal Agency Financial Requirement:** Proposals from Federal agencies *must* provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

*Start the plan on a new page at the end of the Budget Information section.* The Federal Agency Financial Plan must be uploaded as part of the budget information prior to the submission deadline of **5:00 p.m. Eastern time, April 25, 2006.**

**M. Regulatory Requirements:** Completed and signed copies of the [Certificate of Environmental Compliance](#) and [Principal Investigator Safety Program Assurance](#) form must be uploaded under the “Required Files” tab of the CDMRP eReceipt system as separate PDF files.

Do not submit other regulatory documents (for example, documents supporting research exempt under 32 CFR 219.101(b)(4) or Research Involving Animals) with the proposal. The applicant should provide these documents to the USAMRMC only upon request.

**N. USAMRAA-Required Documents:** The most current version of the institution’s negotiated Rate Agreement, the [Certifications and Assurances for Assistance Agreements](#), and the [Representations for Assistance Agreements](#) must be uploaded by the Contract Representative at the applicant’s institution. These documents must be uploaded as separate PDF files under the Contract Representative’s “My Profile” tab of the CDMRP eReceipt system by the proposal submission deadline.

**O. Submission Date and Time:** Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant’s institution by the deadline. Proposals that are incomplete or not approved electronically before the deadline will not be considered for review. The eReceipt system will *not* accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time, April 25, 2006 deadline.

***The timeline for the Concept Award is:***

Online Proposal Information:	Required prior to proposal submission
<b><i>Proposal Submission/Approval Deadline:</i></b>	<b><i>5:00 p.m. Eastern time, April 25, 2006</i></b>
Peer Review (First Tier):	June, 2006
Programmatic Review (Second Tier):	October, 2006
Request for Additional Documents:	As early as 2 weeks after the completion of programmatic review

Notification Letter:	Approximately 4 weeks after the completion of programmatic review
Award Start Date:	Anticipated between December 2006 and April 2007

**P. Electronic Submission Requirements:** Electronic submission is required. Proposals will be accepted only as PDF files submitted through the CDMRP eReceipt system at <https://cdmrp.org>.

Several steps are critical to successful proposal submission:

- The Proposal Information must be “Finalized for CR Approval” before the proposal is submitted. Applicants are encouraged to begin this part of the submission process early.
- Proposal Contacts must be “Finalized for CR Approval” before the proposal is submitted. The e-mail address of a Contract Representative at the applicant’s institution must be included in the Proposal Contacts. Applicants are encouraged to begin this part of the submission process early.
- Applicants are encouraged to coordinate with their Contract Representative early in the application process.
- The Contract Representative authorized to negotiate on behalf of the applicant’s institution is required to provide final approval before the proposal is accepted.
- The eReceipt system will *not* accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time, April 25, 2006 deadline.
- Some items in the proposal including figures, tables, graphs, letters, or publications will need to be scanned electronically. These documents should be scanned at a resolution of 300 dpi or less.
- Applicants are encouraged to retain a date and time-stamped copy of the proposal component files as prepared by word processing software (e.g., Microsoft Word, WordPerfect) as well as the original PDF conversion file.
- The Concept Cost Estimate and Budget Justification form must be uploaded under the “Required Files” tab of the CDMRP eReceipt system.
- The regulatory documents required at submission include a completed and signed Certificate of Environmental Compliance and a completed and signed Principal Investigator Safety Program Assurance form. These forms must be uploaded under the “Required Files” tab of the CDMRP eReceipt system.

## VI. PROPOSAL REVIEW INFORMATION

### A. Proposal Review and Selection Overview

**1. Process:** The CDMRP uses a two-tier review process for proposal evaluation. The two tiers differ fundamentally. The first tier is a scientific peer review of proposals against

established criteria for determining scientific merit. The second tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on scientific merit and overall goals of the program.

***This will be a blinded review process; the applicant and institution names will not be provided during either peer or programmatic review.***

**2. Peer Review:** Peer review is conducted by scientific and consumer reviewers. The primary responsibility of the peer reviewers is to provide unbiased, expert advice on the scientific/technical merit and relevance of proposals based on the review criteria published for each award mechanism.

Scientific reviewers are selected for their subject matter expertise and experience with scientific peer review. Consumer reviewers are nominated by an advocacy or support organization and are selected on the basis of their leadership skills, commitment to advocacy, and interest in science. Consumers augment peer review by bringing the patient perspective to the assessment of science and the relevance of the research.

**3. Programmatic Review:** Programmatic review is conducted by the Integration Panel, which is composed of scientists, clinicians, and consumer advocates. The scientific members of the Integration Panel represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. A function of programmatic review is to structure a broad portfolio of grants across all disciplines. Programmatic review is a comparison-based process in which proposals from multiple research areas compete in a common pool. Integration Panel members base programmatic review on the three-page Concept Award proposal and the peer review evaluations.

## **B. Review Criteria**

**1. Peer Review:** Concept Award proposals will be evaluated by peer reviewers according to the following criteria. The reviewers will evaluate:

- **Innovation and Novelty of Concept**
  - 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 tuberous sclerosis complex research.
- **Impact**
  - How the study addresses a problem critical to tuberous sclerosis complex research.
  - How the project will lead to an original and important contribution to the detection, diagnosis, and/or treatment of tuberous sclerosis complex.
  - What impact this study will have on the concepts or methods that drive the field.

- **Research Strategy**
  - How the scientific rationale and logical reasoning support the project and its feasibility.
  - *For proposals involving preclinical resource development:* How the methodology proposed is appropriate to developing the resource.

**2. Programmatic Review:** Criteria used by the Integration Panel to make funding recommendations that maintain the TSCRPs' broad portfolio include:

- Ratings and evaluations of the scientific and consumer reviewers,
- Programmatic relevance,
- Relative innovation and impact,
- Program portfolio balance,
- Adherence to the intent of the award mechanism, and
- The three-page Concept Award proposal.

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

## **VII. AWARD ADMINISTRATION INFORMATION**

**A. Award Notices:** Each applicant will receive notification of the award status of his or her proposal. Applicants can expect to receive this notification approximately 4 weeks after programmatic review. Peer review summary statements will not be provided to the applicants.

**B. Administrative Requirements:** Awards are made to organizations, not individuals. An applicant must submit a proposal through, and be employed by or affiliated with, a university, college, nonprofit research institution, commercial firm, or Government agency (including military laboratories) to receive support. A prospective recipient must meet certain minimum standards pertaining to institutional support, financial resources, record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (OMB Circular A-110 and DOD Grant and Agreement Regulations) to be eligible for an award. *Any organization requesting receipt of an award through this announcement must be registered in the Central Contractor Registration (CCR) database. Access to the CCR online registration is through the CCR homepage at <http://www.ccr.gov>.*



Proposals from Federal agencies *must* provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

*For Concept Awards, no changes in the institution or the SOW will be allowed once the proposal has been submitted.*

**C. Award Negotiation:** Award negotiation consists of discussions, reviews, and justifications of critical issues involving the USAMRAA. A Contract Specialist and/or representative from the USAMRAA will contact the Contract Representative authorized to negotiate contracts and grants at the applicant's institution. Additional documentation and justifications related to the proposed SOW and associated budget may be required as part of the negotiation process. Technical and public abstracts will be requested at this time.

The award start date will be determined during the negotiation process.

#### **D. Regulatory Review**

**1. Overview:** Concurrent with the USAMRAA negotiation, the Office of Surety, Safety and Environment will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form submitted with the proposal. The applicable USAMRMC regulatory office will review documents related to research involving animal use, human subjects/anatomical substance use, and cadaver use submitted upon request to ensure that DOD regulations are met.

**2. Certificate of Environmental Compliance:** The [Certificate of Environmental Compliance](#) must be submitted with the proposal. If multiple research sites/institutions are funded in the proposal, then a Certificate of Environmental Compliance for each site will be requested at a later date.

**3. Safety Program Documents:** The [Principal Investigator Safety Program Assurance form](#) must be submitted with the proposal.

A Facility Safety Plan is required; it will be requested at a later date. A Facility Safety Plan from the applicant's institution may have been received previously and approved by the USAMRMC. A list of institutions that have approved Facility Safety Plans can be found on the USAMRMC website at <https://mrmc.detrick.army.mil/crprcqsohdfsplan.asp>. If the applicant's institution is not listed on the website, contact the institution's Facility Safety Director/Manager to initiate completion of the institution-based Facility Safety Plan. Specific requirements for the Facility Safety Plan can be found at <https://mrmc.detrick.army.mil/docs/rcq/FY02FSPAppendix.doc>.

**4. Research Involving Animal Use:** Specific documents relating to the use of animals in the proposed research will be requested by the CDMRP if the proposal is selected for funding

(these documents should not be submitted with the proposal). The Animal Care and Use Review Office (ACURO), a component of USAMRMC Office of Research Protections (formerly Regulatory Compliance and Quality), must review and approve all animal use prior to the start of working with animals. Applicants must complete and submit the animal use appendix titled “Research Involving Animals,” which can be found on the ACURO website <https://mrmc-www.army.mil/rodorpaurd.asp>).

Questions related to animal use may be directed to ACURO as follows:

Phone: 301-619-6694  
Fax: 301-619-4165  
E-mail: [acuro@amedd.army.mil](mailto:acuro@amedd.army.mil)  
Mail: MCMR-ZB-PA  
504 Scott Street  
Fort Detrick, MD 21702-5012

Specific requirements for research involving animals can be found at <https://mrmc.detrick.army.mil/docs/rcq/FY05AnimalAppendix.doc>.

## 5. Research Involving Human Subjects/Biological Substances/Cadavers

**a. Restrictions:** Projects involving human subjects or specimens will not be supported through this mechanism unless they are exempt under 32 CFR 219.101(b)(4) or involve the use of only commercially available anonymized specimens.

In addition to local Institutional Review Board (IRB) approval or determination of exempt status, a second-level review is required by the DOD for concurrence with the exempt status. This second review is conducted by the USAMRMC Office of Research Protections. Documents supporting the exempt status of the project will be requested at a later date. These documents will include documentation of local IRB determination of exempt status and the completed USAMRMC Office of Research Protections Claim of Exemption Form. For studies using only commercially available specimens, the USAMRMC Office of Research Protections Claim of Exemption Form will be requested.

See [Subsection V.M](#), “Regulatory Requirements,” for information pertaining to the submission of documents related to the use of human biological substances.

Specific requirements for research involving human biological substances can be found at <https://mrmc.detrick.army.mil/rodorphrpo.asp>.

**b. Conditions Regarding DOD Funding of Research on Human Embryonic Stem Cells:** Research involving the derivation and use of human embryonic germ cells from fetal tissue may be conducted with DOD support *only* if the research is in compliance with 45 CFR 46, Subpart B; 42 USC 289g through 289g-2<sup>3</sup>; US Food and Drug

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<sup>3</sup>Title 42 United States Code, Sections 289g through 289-2

Administration regulations; and any other applicable Federal, state, and local laws and regulations.

Research on existing human embryonic stem (hES) cell lines may be conducted with Federal support through the DOD *only* when the cell lines meet the current US Federal criteria as listed on the following National Institutes of Health (NIH) website (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>). A list of the currently approved cell lines can be obtained from the NIH Human Embryonic Stem Cell Registry (<https://stemcells.nih.gov/research/registry>). The NIH code should be used to identify the cell lines in the proposal.

Research involving the derivation of new stem cells from human embryos or the use of hES cells that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal support through the DOD.

Please note this restriction applies to hES cells derived from blastocysts remaining after infertility treatments and donated for research, blastocysts produced from donated gametes (oocytes and sperm) for research purposes, and the products of nuclear transfer. The research is subject to all applicable local, state, and Federal regulatory requirements.

**6. Award/Regulatory Approval:** The applicant may not use, employ, or subcontract for the use of any exempt human anatomical substances or laboratory animals without written approval from the applicable USAMRMC regulatory office once an award is made. The applicable USAMRMC regulatory office will forward applied-for written approvals directly to the applicant.

**E. Reporting Requirements:** The Government requires reports to be submitted for the continuation of the research and funding. The specific reports due to the Government will be described in each award mechanism. (Full USAMRMC reporting requirements can be found at <https://mrmc-www.army.mil>, under “Links and Resources.”) *Failure to submit required reports by the required date may result in a delay in or termination of award funding.*

Reporting requirements include the following:

- 1. Research Progress Reports:** Reporting requirements consist of a final report that details the scientific findings and issues for the entire project. Copies of all scientific publications and patent applications resulting from CDMRP funding should be included in the progress report.
- 2. Fiscal Reports:** Quarterly fiscal report requirements may include the Standard Form Report, SF 272, Federal Cash Transaction, used for grants and cooperative agreements to track the expenditure of funds on the research project.
- 3. Animal Use Reports:** Applicants are required to submit annual animal use information for a report to Congress, verification of annual protocol review, and notification of protocol suspension or revocation. Institutions are required to provide updated US Department of

Agriculture reports and notification of changes to accreditation status as verified by the Association for Assessment and Accreditation of Laboratory Animals and Office of Laboratory Animal Welfare.

## VIII. OTHER INFORMATION

**A. Disclosure of Proprietary Information outside the Government:** By submitting a proposal, the applicant understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. The USAMRMC will obtain a written agreement from the evaluator that proprietary information in the proposal will only be used for evaluation purposes and will not be further disclosed or used. Funded proposals may be subject to public release under the Freedom of Information Act; proposals that are not selected for funding are not subject to public release.

**B. Government Obligation:** Applicants are cautioned that only an appointed Contracting/Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government to fund preparation of a proposal or to support research should be inferred from discussions with a technical project officer. Applicants who, or organizations that, make financial or other commitments for a research effort in the absence of an actual legal obligation signed by the USAMRAA Contracting/Grants Officer do so at their own risk.

**C. Information Service:** Offerors may use the technical reference facilities of the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161, 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.

**D. Inquiry Review Panel:** Applicants may submit a letter of inquiry to the USAMRMC in response to funding decisions made for a given proposal. Members of the CDMRP staff, the USAMRMC Judge Advocate General staff, and USAMRAA Grants Officers constitute an Inquiry Review Panel and review each inquiry to determine whether factual or procedural errors in either peer or programmatic review have occurred, and if so, what action should be taken.

**E. Title to Inventions and Patents:** In accordance with the Bayh-Dole Act (35 USC 200 et seq.), title to inventions and patents resulting from such Federally funded research may be held by the grantee or its collaborator, but the US Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents.

**F. J-1 Visa Waiver:** It is the responsibility of the awardee to ensure that the research staff is able to complete the work without intercession by the DOD for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.

## **IX. ACRONYM LIST**

ACURO	Animal Care and Use Review Office
CR	Contract Representative
CCR	Central Contractor Registration
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
DOD	Department of Defense
DODGAR	Department of Defense Grants and Agreements Regulations
EPLS	Excluded Parties List System
FAR	Federal Acquisition Regulations
FY	Fiscal Year
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
hES	Human Embryonic Stem
HSRRB	Human Subjects Research Review Board
IRB	Institutional Review Board
M	Million
NIH	National Institutes of Health
OMB	Office of Management and Budget
PDF	Portable Document Format
SOW	Statement of Work
TSCRIP	Tuberous Sclerosis Complex Research Program
URL	Uniform Resource Locator
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code