

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Multiple Sclerosis Research Program

Concept Award

Funding Opportunity Number: W81XWH-10-MSRP-CA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The Multiple Sclerosis Research Program (MSRP) was established in fiscal year 2009 (FY09) with a \$5 million (M) appropriation to promote innovative research focused on multiple sclerosis (MS). The FY10 appropriation for the MSRP is \$4.5M.

The MSRP challenges the scientific community to design pioneering concepts and high-impact research relevant to the etiology, pathogenesis, assessment, and treatment of MS. The vision of the MSRP is to prevent the occurrence of; cure, reverse, or slow the progression of; and lessen the personal and societal impact of MS.

B. FY10 MSRP Focus Areas

The FY10 MSRP encourages applications that address critical needs of the MS community through understanding the genetic, biological, and environmental factors that contribute to any of the following:

- **Biological basis of disease progression**
 - Primary progressive MS
 - Secondary progressive MS
- **Neurological protection, regeneration, and repair**
- **MS phenotypic heterogeneity**
 - Population subgroups (ancestry, sex, and others)
 - Novel stratification of affected population
- **Gene/environment interactions**
 - Etiology
 - Disease course
- **Biomarkers of disease activity, progression, and drug response**
- **Drug discovery**
 - Assay development
 - Screening of novel compounds
 - Not human clinical trials
- **Biological basis of fatigue, sexual dysfunction, cognitive impairment, affective disorder, and rehabilitation**

C. Award Description

The MSRP Concept Award mechanism is being offered for the first time in FY10. The intent of this award mechanism is to support the exploration of a highly innovative new concept or untested theory that addresses an important problem relevant to MS.

Innovation and novelty of the concept are the most important aspects of this award mechanism. The Concept Award is not intended to support a logical progression of an already established research project but, instead, supports high-risk studies that have the potential to reveal entirely new avenues for investigation. Innovative research may introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities. This may include high-risk, potentially high-gain approaches to MS research, provided that the scientific rationale supports the feasibility and development of the proposed concept. Research that is an incremental advance upon published data is not considered innovative.

Inclusion of preliminary data is strongly discouraged. This award is not intended to support ongoing work; therefore, the existence and presentation of preliminary data suggests that the proposed research would be more appropriately submitted to the FY10 MSRP Idea Award mechanism.

Use of human subjects and human biological substances: Because these awards are designed for preliminary investigations, projects involving human subjects or specimens will not be supported unless they are exempt under Title 32, Code of Federal Regulations, Part 219, Section 101(b)(32 CFR 219.101[b]). Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded. For studies using only commercially available unidentified specimens, a Claim of Exemption Form will be requested. Additional information regarding exempt status may be found on the US Army Medical Research and Materiel Command (USAMRMC) Human Research Protection Office website (<https://mrmc.amedd.army.mil/rodorphrpo.asp>).

D. Eligibility

All investigators are eligible to submit applications. Refer to General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is 1 year.
- The maximum allowable funding for the entire period of performance is **\$75,000** in direct costs.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with the organization's negotiated rate agreement.

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

- Salary
- Research supplies
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings
- Other direct costs as described in the General Application Instructions for the Detailed Budget and Justification

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$1.3M of the \$4.5M FY10 MSRP appropriation to fund approximately 12 Concept Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

F. Award Administration

Changes in PI will not be allowed. Changes in institution are discouraged and will be allowed only at the discretion of the US Army Medical Research Acquisition Activity (USAMRAA) Grants Officer. Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2011. Refer to the General Application Instructions, Appendix 4, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

- **Pre-application Submission Deadline: 5:00 p.m. Eastern time (ET), March 25, 2010**
- **Application Submission Deadline: 11:59 p.m. ET, April 8, 2010**
- **Scientific Peer Review: June/July 2010**
- **Programmatic Review: October 2010**

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline.

III. SUBMISSION PROCESS

Submission is a two-step process requiring both (1) pre-application submission through the CDMRP eReceipt system (<https://cdmrp.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to reject duplicative applications.

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

A. Step 1 – Pre-Application Components

All pre-application components must be submitted through the [CDMRP eReceipt system](#) by **5:00 p.m. ET on the deadline.**

The pre-application consists of the following components, which are organized in the CDMRP eReceipt system by separate tabs: (Refer to the General Application Instructions for additional information on pre-application submission.)

- **Proposal Information – Tab 1**
- **Proposal Contacts – Tab 2**
- **Collaborators and Conflicts of Interest – Tab 3**
- **Required Files – Tab 4**

Letter of Intent (LOI) Narrative (one-page limit): Provide a brief description of the research to be conducted. LOI Narratives are used for program planning purposes only (e.g., reviewer recruitment) and ***will not be reviewed*** during either the peer or programmatic review sessions.

- **Submit Pre-application – Tab 5**
- **Other Documents Tab**

Not applicable.

B. Step 2 – Application Components

Applications are submitted by the Authorized Organizational Representative (AOR) through Grants.gov (<http://www.grants.gov/>). Applications must be submitted **by 11:59 p.m. ET on the deadline.**

Each application submission must include the completed application package of forms and attachments identified in Grants.gov for this Program Announcement/Funding Opportunity.

The Grants.gov application package consists of the following components (Refer to the General Application Instructions, Section II.B., for additional information on application submission):

1. SF 424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section II.B., for detailed information.

2. Attachments Form

Reviewers will be blinded to the identity of the PI and the PI's organization. Due to the blinded nature of the review process, identifying or making references to the PI, collaborators, or the organization in the Project Narrative, Public and Technical Abstracts, or list of acronyms and symbols is prohibited and will result in administrative rejection of the proposal. In addition, the use of “I,” “our,” “this organization,” or similar phrases that refer to the PI, collaborators, and/or organization through the references listed will result in administrative rejection of the proposal.

- **Attachment 1: Project Narrative (One-page limit):** Upload as “ProjectNarrative.pdf.”

Describe the proposed project using the following outline:

- **Innovation:** Clearly explain how the proposed research is innovative. Investigating the next logical step or incremental advancement on published data is not considered innovative.
- **Relevance of the Concept:** State the central critical question or problem in MS research to be addressed. Provide a brief statement, in nontechnical terms, describing the importance of this research to MS.
- **Rationale:** State the rationale for the proposed research project. Inclusion of preliminary data is strongly discouraged.
- **Objectives:** State concisely the specific aims and research strategy of the study.
- **Methods:** Briefly describe the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation.
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *Each component has no page limit unless otherwise noted.*
 - **References Cited (five-citation limit):** List all 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). The inclusion of Internet URLs to references is encouraged.
 - **List of Acronyms and Symbols:** Provide a list of acronyms and symbols (e.g., PCR = polymerase chain reaction).
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”
Clearly describe the proposed research in one short paragraph, including the concept to be studied and the objectives, the innovative aspect of the research, and the relevance of the project to MS.
- **Attachment 4: Public Abstract (one-page limit):** Upload as “PublicAbs.pdf.”
Clearly describe in one short paragraph, and in a manner readily understood by lay persons, the concept to be studied, the innovative aspect of the research, and the relevance of the project to MS.
- **Attachment 5: Statement of Work (SOW) (one-page limit):** Upload as “SOW.pdf.”
Refer to the General Application Instructions, Section II.B., for detailed information.

- **Attachment 6: Detailed Budget and Justification (no page limit):** Upload as “Budget.pdf.” Use the Detailed Budget and Justification form (available for download on the Full Announcement page in Grants.gov). Refer to the General Application Instructions, Section II.B., for detailed information.
- **Attachment 7: Subaward Detailed Budget and Justification (if applicable) (no page limit):** Use a separate Detailed Budget and Justification form for each subaward budget. Combine into a single file and upload as “SubBudgets.pdf.” Refer to the General Application Instructions, Section II.B., for detailed information.

3. Research & Related Senior/Key Person Profile (Expanded) Form: Refer to the General Application Instructions, Section II.B., for detailed information.

- PI Biographical Sketch (four-page limit): Upload as “Biosketch_LastName.pdf.”
- PI Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch_LastName.pdf.”
- Key Personnel Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”

4. Project/Performance Site Location(s) Form: Refer to the General Application Instructions, Section II.B., for detailed information.

Although requested, the Statement of Work, Detailed Budget and Justification, Subaward Detailed Budget and Justification (if applicable), Biographical Sketch, and Research & Related Project/Performance Site Location(s) Form will not be forwarded for peer or programmatic review. These documents will be used for administrative purposes only.

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 applications to each other and makes recommendations for funding to the Commanding General, USAMRMC, based on scientific merit, the overall goals of the program, and specific intent of the award mechanism. The highest scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP may be found at <http://cdmrp.army.mil/fundingprocess.htm>. Reviewers will be blinded to the identity of the PI and the PI’s institution.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a non-

disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, 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.

B. Review Criteria

1. Peer Review: All applications will be evaluated according to the following criteria, which are of equal importance:

- **Innovation**
 - How the proposed concept is innovative.
 - Whether the concept is untested (no preliminary data).
 - Whether the project proposes new paradigms or challenges existing paradigms.
 - How the proposed research represents more than an incremental advance.
- **Methods**
 - How the rationale, experimental design, and methodology are appropriate to answer the question.
 - Whether the proposed research project can be completed within a one-year performance period.
- **Relevance of the Concept**
 - Whether the proposed research addresses a central critical problem in MS. How the study is important to the field of MS research.

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

- **Application Presentation**
 - How the writing and components of the application influenced the review.

2. Programmatic Review: The following criteria are used by programmatic reviewers to make funding recommendations.

- Adherence to the intent of the award mechanism
- Program portfolio composition
- Ratings and evaluations of the peer reviewers
- Relative innovation
- Relevance to the program objectives
- Responsiveness to at least one of the FY10 MSRP focus areas

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).
- PI or collaborator name(s) or institution is included in the Project Narrative, Technical and Public Abstracts, or list of acronyms and symbols.
- Use of “I,” “our,” “this institution,” or similar phrases in the Project Narrative, Technical and Public Abstracts, or list of acronyms and symbols that make it possible to identify the PI, collaborators, and/or organization through the references listed.

B. Modifications

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
- Documents not requested will be removed.
- Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section V-A, Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY10 MSRP Integration Panel (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 FY10 MSRP IP members may be found at <http://cdmrp.army.mil/10msrppanel.htm>.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the detailed budget form exceed maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- Inclusion of studies that do not qualify for exempt status under Title 32, Code of Federal Regulations, Part 219, Section 101(b) (32 CFR 219.101[b]).

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 US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

VI. CONTACT INFORMATION

A. CDMRP Program Announcement Help Desk: Questions related to Program Announcement/Funding Opportunity content or submission requirements should be directed to the CDMRP Program Announcement help desk, which is available Monday through Friday from 7:30 a.m. to 4:00 p.m. ET. 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
Email: cdmrp.pa@amedd.army.mil

B. CDMRP eReceipt System Help Desk: Questions related to the submission of the pre-application through the eReceipt system should be directed to the CDMRP eReceipt system help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

Phone: 301-682-5507
Email: help@cdmrp.org

C. Grants.gov Contact Center: Questions related to application submission through the Grants.gov portal should be directed to Grants.gov help desk, which is available 24 hours a day, 7 days a week. Please note that the CDMRP Program Announcement and eReceipt system help desks are unable to provide technical assistance regarding Grants.gov submissions.

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

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1	
	Upload Supporting Documentation (Support.pdf) as Attachment 2	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3	
	Upload Public Abstract (PublicAbs.pdf) as Attachment 4	
	Upload Statement of Work (SOW.pdf) as Attachment 5	
	Upload Detailed Budget and Justification (Budget.pdf) as Attachment 6	
	Upload Subaward Detailed Budget and Justification (SubBudgets.pdf) as Attachment 7	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field	
Project/Performance Site Location(s) Form	Complete form as instructed	