

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Multiple Sclerosis Research Program

Concept Award

Funding Opportunity Number: W81XWH-11-MSRP-CA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-application Submission Deadline:** 5:00 p.m. Eastern time (ET), July 20, 2011
- **Application Submission Deadline:** 11:59 p.m. ET, August 10, 2011
- **Scientific Peer Review:** October/November 2011
- **Programmatic Review:** February 2012

New for fiscal year 2011 (FY11): The Grants.gov Research & Related Budget form is a mandatory component of all Grants.gov application packages.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The Multiple Sclerosis Research Program (MSRP) was established in 2009. Appropriations for the MSRP from FY09 through FY10 totaled \$9.5 million (M). The FY11 appropriation is \$4.8M.

The objective of the FY11 MSRP is to support pioneering ideas and high-impact research relevant to the prevention, etiology, pathogenesis, assessment, and treatment of multiple sclerosis (MS) that will move the research field toward achieving the program's vision to prevent the occurrence; cure, reverse, or slow the progression; and lessen the personal and societal impact of MS.

B. FY11 MSRP Focus Areas (*revised for FY11*)

The FY11 MSRP encourages applications that address critical needs of the MS community in the following focus areas:

- **Biological Basis of Disease Progression**
 - Primary Progressive MS
 - Transition from Relapsing/Remitting to Secondary Progressive MS
 - Long-term stable disease with low disability
- **Risk Factors (Identification and Modification) Leading to Prevention of MS**
 - Microbial influences
 - Hormonal influences
 - Nutritional influences
 - Other environmental influences
- **Biomarkers for Preclinical Detection of MS**
- **Drug Discovery**
 - Assay development
 - Screening of novel compounds
 - Predictors of treatment response
- **Biological Basis of Fatigue, Sexual Dysfunction, Cognitive Impairment, Affective Disorder, and Rehabilitation**

C. Award Information

The MSRP Concept Award mechanism is designed 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 key features 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 anatomical substances is limited. Because this award mechanism is designed to support preliminary investigations, research projects involving human subjects and/or human anatomical substances 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]). In brief, exempt studies may include, but are not limited to, research on normal educational practices, special cases of educational tests and/or surveys, or the collection of existing data, documents, records, or pathological specimens in a de-identified method. Exemption is first determined by the local Institutional Review Board (IRB) of record. Investigators must review their institutional requirements and guidelines for filing with the IRB for exempt status. Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded. 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 Information

- All investigators are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **1** year.
- The maximum allowable direct costs for the entire period of performance is **\$80,000** plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **1** year.

- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget form. In addition, for this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary
- Research Supplies
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$0.84M of the \$4.8M FY11 MSRP appropriation to fund approximately 7 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.

II. SUBMISSION INFORMATION

Submission is a multi-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.

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-11- MSRP-CA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the Principal Investigator (PI) through the CDMRP eReceipt System (<https://cdmrp.org/>).

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 CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

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, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**
- **Required Files – Tab 4**
 - **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the FY11 MSRP Focus Area(s) that the proposed research project will address, if applicable. LOIs 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**

No additional documents are required.

C. Application Submission Content and Form

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative (AOR) through the Grants.gov portal (<http://www.grants.gov/>).

Reviewers will be blinded to the identity of the PI, collaborators, and their organization(s). Due to the blinded nature of the review process, identifying or making references to the PI, collaborators, or their organization(s) in the Technical or Public Abstracts; Project Narrative; or Abbreviations, Acronyms, and Symbols list is prohibited and will result in administrative rejection of the application. In addition, the use of “I,” “our,” “this organization,” or similar phrases that refer to the PI, collaborators, or their organization(s) through the references listed will result in administrative rejection of the application.

Although requested, the Statement of Work, Research & Related Budget form, R & R Subaward Budget Attachments(s) Form (if applicable), biographical sketch and current/pending support, and Project/Performance Site Location(s) Form will not be forwarded for peer or programmatic review. These documents will be used for administrative purposes only.

Grants.gov application package components: For the Concept Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

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

2. Attachments Form

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

Describe the proposed project in detail using the outline below.

- **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 the references cited (including URLs if available) in the project narrative 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). *Do not include URLs that identify the organization(s) of the PI or collaborator(s).*
 - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
 - **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.”

Include an overview of the proposed research project that can be readily understood by lay persons. Clearly describe in one short paragraph, the concept to be studied, the innovative aspect of the research, and the relevance of the project to MS. Do not duplicate the technical abstract.
 - **Attachment 5: Statement of Work (SOW) (one-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information.

- 3. Research & Related Senior/Key Person Profile (Expanded) Form:** Refer to the General Application Instructions, Section II.C., 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. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
 - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

D. Submission Dates and Times

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines shall result in application rejection.

E. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Number System (DUNS) number and register with the Central Contractor Registry (CCR) to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical 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 technical merit, the relevance to the mission of the Department of Defense (DOD) and CDMRP, and the 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 can be found at <http://cdmrp.army.mil/about/fundingprocess.shtml>. Reviewers will be blinded to the identity of the PI, collaborator(s), and their organization(s).

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).

B. Application Review Criteria

1. Peer Review: To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

- **Innovation**
 - How the proposed concept is innovative.
 - Whether the concept is untested.
 - 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 1-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.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influenced the review.

2. Programmatic Review: To determine the application’s relevance to the mission of the DOD and CDMRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

- Adherence to the intent of the award mechanism
- Program portfolio composition
- Ratings and evaluations of the peer reviewers
- Relative innovation
- Relevance to program objectives
- Responsiveness to at least one of the FY11 MSRP Focus Areas

C. Recipient Qualification

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

D. Application Review Dates

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

Each PI and organization will receive notification of the funding recommendation. PIs will receive a scientific peer review summary statement on the strengths and weaknesses of the application.

IV. 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.
- Pre-application is not submitted.
- The PI, collaborators, or their organization(s) are identified or referenced in the Technical or Public Abstracts; Project Narrative; or Abbreviations, Acronyms, and Symbols list.
- Use of “I,” “our,” “this organization,” or similar phrases that refer to the PI, collaborators, or their organization(s) through the references listed.

B. Modification

- Pages exceeding the specified limits will be removed prior to review 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 IV.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:

- FY11 MSRP Integration Panel (IP) member 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 FY11 MSRP IP members may be found at <http://cdmrp.army.mil/msrp/panels/panels11.shtml>.
- 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 Research and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- 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 required 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.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2012. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

Refer to the General Application Instructions, Appendix 4, Section C, for general information regarding administrative and national policy requirements.

C. Reporting

Refer to the General Application Instructions, Appendix 4, Section D, for general information on reporting requirements.

D. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section E, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements and questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 1-301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

Questions related to application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 1-800-518-4726

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.	
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.	
Research & Related Budget	Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	