

# Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Multiple Sclerosis Research Program

Synergistic Idea Award

Funding Opportunity Number: W81XWH-09-MSRP-SIA

## Table of Contents

<b>I. Funding Opportunity Description.....</b>	<b>2</b>
A. Program Objectives.....	2
B. FY09 MSRP Focus Areas.....	2
C. Award Description .....	2
D. Eligibility .....	5
E. Funding .....	5
F. Award Administration .....	5
<b>II. Timeline for Submission and Review .....</b>	<b>6</b>
<b>III. Submission Process .....</b>	<b>6</b>
A. Step 1 – Pre-application Components and Submission .....	6
B. Step 2 – Application Components and Submission.....	8
1. Application Components and Submission for the Initiating PI .....	9
2. Application Components and Submission for the Partnering PI(s) .....	11
<b>IV. Information for Application Review .....</b>	<b>12</b>
A. Application Review and Selection Overview .....	12
B. Review Criteria .....	12
<b>V. Administrative Actions.....</b>	<b>15</b>
<b>VI. Contact Information.....</b>	<b>17</b>

## **I. FUNDING OPPORTUNITY DESCRIPTION**

### **A. Program Objectives**

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

The MSRP challenges the scientific community to design innovative and integrated research that will enhance knowledge relevant to understanding the etiology and pathogenesis of, and to quantifying and treating, MS. The vision of the MSRP is to prevent the occurrence, reverse or slow the progression and disability, and lessen the impact of MS.

### **B. FY09 MSRP Focus Areas**

The FY09 MSRP specifically 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:

- **Etiology:** The search for the cause or trigger of MS
- **Population subgroups:** Elucidate the causes of differences in incidence and severity that are attributable to race and gender, which could be relevant to an understanding of the disease process
- **Primary progressive MS:** The events that lead to primary progressive disability, and identifying ways to stop and reverse progression of MS
- **Relapse-remitting MS:** Define key processes that are involved in the vulnerability of tissue to attack, and the success of repair during this phase of disease
- **Secondary progressive MS:** The events that cause relapsing-remitting MS to develop into secondary progressive MS, and identifying ways to stop and reverse disease progression

### **C. Award Description**

The MSRP Synergistic Idea Award is being offered for the first time in FY09.

The Synergistic Idea Award is designed to promote innovative ideas and scientific collaborations by supporting novel approaches to MS research that will move the field toward the MSRP vision of preventing the occurrence, reversing or slowing the progression and disability, and lessening the impact of MS. This award mechanism is designed to support new ideas, not ideas that are extensions of existing collaborative efforts. Collaborative partnerships must involve at least two, and up to a maximum of four, Principal Investigators (PIs) from different research disciplines. Each collaborative partnership should use synergistic and multidisciplinary perspectives to address a central critical problem or question in MS research.

Proposals should have a high probability of revealing new avenues of investigation. Applications must clearly identify the synergy that will enable or greatly accelerate the evaluation of a single innovative hypothesis through a multidisciplinary approach.

The Synergistic Idea Award requires that the PIs of the collaborative partnership jointly design a single project. However, each partner will be recognized as a PI, submit a separate application, and receive an individual award. The research project should be supported by the unique expertise of each PI, and clearly define the synergistic components that will facilitate and accelerate progress in a way that could not be accomplished through independent efforts. The collaborative partnership should be multidisciplinary; multi-institutional projects are allowed. It is important that each proposed study include clearly stated plans for interactions among all PIs and institutions involved. The plans must include the means to be used for ongoing communication, coordination of research progress and results, and data transfer. Additionally, collaborative partnerships involving multi-institutional applications must provide an intellectual and material property plan to resolve potential intellectual and material property issues and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful completion of this award.

***Clinical trials are not allowed under this mechanism.*** Refer to the Application Instructions and General Information, Appendix 6, for additional information on clinical trials.

The overall goal of this award is to accelerate advances in MS research. The MSRP seeks applications from all areas of basic, preclinical, and epidemiological MS research. The following are significant features of this award mechanism:

**1. Synergy:** It is important that applications clearly identify the synergy that will enable or greatly accelerate the implementation and conduct of a single innovative MS research proposal. Synergistic research projects are those that will significantly advance a project beyond what would be possible through individual efforts. Contributions to the synergy of this mechanism are expected to be balanced between the PIs unless otherwise justified. It should be clear that each PI has contributed significantly to the intellectual development of the proposed project. New collaborations are strongly encouraged but not required. Examples of a collaborative partnership that is ***not*** synergistic and, thus, will not be considered for funding under this award mechanism include, but are not limited to:

- Reagents supplied by one PI and molecular studies completed by the other PI
- Service function or core support providing laboratory investigations or statistical analyses
- A project that can be accomplished in a single PI's laboratory

**2. Innovation:** Innovative MS research may introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities.

Examples of research that are ***not*** innovative and will not be considered for funding under this award mechanism include:

- Proposing research that is merely the next logical step or obvious incremental advancement
- Using a published series of in vitro assays to further characterize a model system
- Incorporating known biomarkers into in vitro or clinical models of MS

**3. Impact:** Research that has high impact will, if successful, significantly advance current methods and concepts toward the MSRP vision of preventing the occurrence, reversing or slowing the progression and disability, and lessening the impact of MS.

**4. Preliminary Data:** Submission of preliminary data relevant to MS and the proposed project is encouraged but not required. If preliminary data is provided, it must have been generated from the laboratory of at least one of the PI members of the collaborative partnership. Although groundbreaking research often involves a degree of risk due to unforeseen difficulties or results, proposals should be based on a sound scientific rationale that is established through logical reasoning and/or critical review and analysis of the literature.

**5. Collaborative Partnerships:** This award mechanism is designed to accommodate multiple PIs as a method to bring a new perspective to research and facilitate progress in the field of MS research. Therefore, each PI must demonstrate that he or she possesses the research experience and resources to function as a PI in a synergistic project in a significant way, as well as an appropriate level of authority and responsibility to direct the project supported by the grant. While not required, new collaborations are strongly encouraged. A minimum of two, and up to a maximum of four, investigators may work as collaborative partners on a single project; each investigator will be designated a PI. Developing the research plan should involve a reciprocal flow of ideas and information with significant intellectual input from all PIs into the design of a single research project. One member of the collaborative partnership will be identified as the Initiating PI, who will be responsible for the majority of the administrative tasks associated with application submission. The other member(s) will be identified as the Partnering PI(s) and will need to complete administrative tasks associated with application submission. Separate awards will be made to each PI's institution. Additional collaborators may be included but will not be designated PIs.

**6. Multidisciplinary Research:** The proposed MS research project should utilize a multidisciplinary approach to answer an important question in MS research. For this award, major disciplines include, but are not limited to, biology, biochemistry, clinical medicine, computational biology, endocrinology, environmental sciences, epidemiology, genetics, immunology, mathematics, microbiology, neuroscience, nutrition, physics, physiology, and statistics.

## **D. Eligibility**

Investigators at or above the level of Assistant Professor (or equivalent) are eligible to submit applications.

Refer to the Application Instructions and General Information, Appendix 1, for general eligibility information.

## **E. Funding**

- The maximum period of performance for this award mechanism is 2 years.
- The combined total maximum allowable funding for one collaborative partnership is **\$400,000** in direct costs, regardless of whether there are two, three, or four PIs. While Initiating and Partnering PIs are expected to each contribute significantly to the execution of the proposed research, direct cost funding should reflect the tasks performed by each PI.
- The applicants may request the entire maximum direct cost amount for a project that may be less than the maximum 2-year period of performance.
- Regardless of the period of performance proposed, the budget may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with the institution's negotiated rate agreement.

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

- Salary
- Research supplies
- Equipment
- Clinical research costs (*Clinical trials will not be supported*)
- Travel to scientific/technical meetings
- Travel between collaborating institutions

***The CDMRP expects to allot \$3M of the \$5M FY09 MSRP appropriation to fund approximately five Synergistic Idea Award collaborative partnerships (representing at least 10 individual awards), depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent on the availability of Federal funds for this program.***

## **F. Award Administration**

Refer to the Application Instructions and General Instructions, Appendix 5, for general award administration information.

## II. TIMELINE FOR SUBMISSION AND REVIEW

Submission is a two-step process consisting of (1) pre-application submission and (2) an application submission. *Pre-application submission is a required first step.*

- **Pre-application Submission Deadline: August 13, 2009, 5:00 p.m. Eastern time**
- **Invitation to Submit a Proposal: October 1, 2009**
- **Application Submission Deadline: November 24, 2009, 11:59 p.m. Eastern time**
- **Scientific Peer Review: February 2010**
- **Programmatic Review: April 2010**

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

## III. SUBMISSION PROCESS

Submission is a two-step process consisting of (1) a pre-application submission through the [CDMRP eReceipt system \(https://cdmrp.org/\)](https://cdmrp.org/) and (2) an application submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/). Applications will be invited based on pre-application screening.

The Synergistic Idea Award mechanism is structured to accommodate at least two, and up to a maximum of four, PIs. One partner will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as the Partnering PI(s). Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute significantly to the development of the proposed research project including the project narrative, Statement of Work, and other required statements. The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PI(s). If an application is invited, the Initiating PI will receive a letter of invitation via email by the CDMRP eReceipt system. The letter will provide the information necessary to begin application submission through Grants.gov. The Partnering PI(s) will subsequently be notified separately by email. Please note that the Partnering PI(s) must follow the link in this email and register with CDMRP eReceipt in order to associate his or her grant application package with that of the Initiating PI.

Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative applications.

### A. Step 1 – Pre-Application Components and Submission

The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the [CDMRP eReceipt system](https://cdmrp.org/) by **5:00 p.m. Eastern time on the pre-application deadline.**

The PIs and Organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. The Initiating and Partnering PIs will each be assigned unique and separate log numbers by the CDMRP eReceipt system. Each PI must submit his or her Grants.gov application package using only his or her unique log number. If there is a change in PI or Organization after the submission of the pre-application, the PI must contact the eReceipt help desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507. In addition to the award-specific instructions below, refer to the Application Instructions and General Information for detailed information on pre-application components and submission. ***The Initiating PI is responsible for submission of all pre-application components.***

- **Proposal Information:** The Initiating PI must enter the Application Information before continuing the pre-application. Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title, research objectives, or FY09 MSRP focus area(s) after the pre-application is submitted.
- **Proposal Contacts:** The Initiating PI must enter his or her contact information.
- **Collaborators and Conflicts of Interest (COI):** The Initiating PI must enter the contact information for the Partnering PI(s) in the Partnering PI section.
- **Preproposal Narrative:** The Preproposal Narrative has a ***three-page limit*** inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the preproposal. The Preproposal Narrative should address the following:
  - State which of the FY09 MSRP focus areas this application addresses, if applicable.
  - Identify the synergy through a description of how the combined efforts of the PIs will result in a level of productivity that is greater than that achievable by each PI working independently, and are centered around a unified research objective.
  - Address the innovative aspect(s) of the proposed study.
  - Explain the potential impact of the proposed MS research and how it will, if successful, significantly advance current methods and concepts toward the MSRP vision of preventing the occurrence, reversing or slowing the progression and disability, and lessening the impact of MS.
  - Clearly articulate the rationale for the project by presenting the ideas and reasoning behind the proposed research.
  - State the hypothesis to be tested or the objective to be reached. Concisely describe the project's specific aims.
  - Identify the disciplines to be integrated into the proposed research project and explicitly articulate how these disciplines are distinct.

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application are:
  - References Cited (one-page limit)
  - Biographical Sketches: Include biographical sketches for the Initiating PI, each Partnering PI, and other key collaborators (four-page limit per PI).

**Pre-Application Screening:** Pre-applications will be screened by the FY09 MSRP Integration Panel (IP), which is composed of scientists, clinicians, and consumer advocates, based on the following criteria:

- **Adherence to the intent of the award mechanism**
  - **Synergy:** How well the proposed study represents a synergistic collaboration between the Initiating PI and Partnering PI(s).
  - **Innovation:** How well the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: Concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
  - **Impact:** How well the proposed research, if successful, will significantly advance current methods and concepts toward the MSRP vision of preventing the occurrence, reversing or slowing the progression and disability, and lessening the impact of MS.
  - **Multidisciplinary Research:** How well the research project utilizes a multidisciplinary approach.
- **Research Idea:** How well the proposed project addresses a central critical problem or question in MS research.
- **Responsiveness to FY09 MSRP Focus Areas:** Whether the proposed research addresses one or more of the FY09 MSRP focus areas.

## **B. Step 2 – Application Components and Submission**

***Applications will not be accepted unless the Initiating PI has received a letter of invitation.***

Applications must be submitted electronically by the Authorized Organizational Representative through Grants.gov ([www.grants.gov](http://www.grants.gov)). The PIs and Organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application; however, if there is a change in PI or Organization after the submission of the pre-application, the PI must contact the CDMRP eReceipt help desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.



Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title, research objectives, or focus area(s).

*For contractual reasons, the CDMRP requires separate Grants.gov application package submissions for Initiating and Partnering PIs. The Initiating and Partnering PIs will each be assigned unique and separate log numbers by the CDMRP eReceipt system. Each PI must submit his or her Grants.gov application package using only his or her unique log number. Each PI must also submit an identical copy of a joint Statement of Work (SOW).*

## **1. Application Components and Submission for the Initiating PI**

Each application submission must include the completed Grants.gov application package of forms and attachments identified in <http://www.grants.gov/> for the US Army Medical Research Acquisition Activity (USAMRAA) program announcement. In addition to the specific instructions below, please refer to the Application Instructions and General Information for detailed requirements of each component.

The Initiating PI package includes:

### **1. SF-424 (R&R) Application for Federal Assistance Form**

### **2. Attachments Form**

- Attachment 1: Project Narrative (eight-page limit)

Describe the proposed research in detail using the following outline.

**Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application. Discuss the qualifications of the multidisciplinary research team that will enable them to successfully complete the proposed work. The inclusion of preliminary data relevant to MS and the proposed project is encouraged but not required. However, if preliminary data is provided, the data must have been generated from the laboratory of at least one of the PI members of the collaborative partnership.

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

**Specific Aims:** Concisely explain the project's specific aims to be funded by this application.

**Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls and statistical plan in sufficient detail for analysis. Include specific examples of synergistic elements incorporated into the research design. Describe the multidisciplinary nature of the research project. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a plan for the recruitment

of subjects or the acquisition of samples. ***This award may not be used to conduct clinical trials.***

**Project Coordination and Communication:** Describe plans for ongoing communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among the Initiating and Partnering PIs and institutions participating in the proposed research project.

- Attachment 2: Supporting Documentation
  - References Cited
  - Acronyms and Symbol Definitions
  - Facilities & Other Resources
  - Description of Existing Equipment
  - Publications and/or Patent Abstracts (five-document limit)
  - Letters of Institutional Support
  - Letters of Collaboration (if applicable)
  - Intellectual and Material Property Plan (if applicable)
- Attachment 3: Technical Abstract (one-page limit)
- Attachment 4: Public Abstract (one-page limit)
- Attachment 5: Statement of Work (SOW; three-page limit)

The Initiating and Partnering PI(s) must submit identical, jointly created SOWs.

- Attachment 6: Detailed Budget and Justification
- Attachment 7: Impact Statement (one-page limit)

State explicitly how the proposed MS research will, if successful, significantly advance current methods and concepts toward the MSRP vision of preventing the occurrence, reversing or slowing the progression and disability, and lessening the impact of MS.

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

Summarize how the proposed work is innovative. Investigating the next logical step or an incremental advancement on published data is not considered innovative.

***Although not all inclusive***, the following examples are ways in which proposed work may be innovative; these examples are intended to help PIs frame the innovative features of the research proposed:

- Study concept – Investigation of a novel idea and/or research question
- Research method or technology – Use of novel research methods or new technologies, including technology development, to address a research question
- Novel method or technology – Development of a novel method or technology for prevention, detection, diagnosis, or treatment
- Existing methods or technologies – Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended
- Attachment 9: Synergy Statement (one-page limit)

Discuss in detail the advantages of addressing this problem through the combined expertise of the PIs and how this contributes to the synergy of the research proposal. Describe the elements of interdependence in the proposed work and the contributions of each PI to the overall synergy of the project. Describe how the combined efforts of the PIs will result in a level of productivity that is greater than that achievable by each PI working independently.

- Attachment 10: Federal Agency Financial Plan (if applicable)
- Attachments 11-15: Subaward Detailed Budget and Justification (if applicable)

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

- PI Biographical Sketch
- PI Current/Pending Support
- Key Personnel Biographical Sketches (Include each Partnering PI)
- Key Personnel Current/Pending Support (Include each Partnering PI)

### **4. Research & Related Project/Performance Site Location(s) Form**

## **2. Application Components and Submission for the Partnering PI(s)**

*The Partnering PI(s) must follow the link in the email from CDMRP eReceipt and complete the registration process prior to the application submission deadline in order to associate their grant application package with that of the Initiating PI.*

The application submission process for the Partnering PI(s) uses an abbreviated application package of forms and attachments from Grants.gov.

The Partnering PI package includes:

- 1. SF-424 (R&R) Application for Federal Assistance Form**
- 2. Attachments Form**

- Attachment 5: Statement of Work (three-page limit)  
The Initiating and Partnering PIs must submit identical, jointly created SOWs.
- Attachment 6: Detailed Budget and Justification
- Attachment 10: Federal Agency Financial Plan (if applicable)
- Attachments 11-15: Subaward Detailed Budget and Justification (if applicable)

### **3. Research & Related Project/Performance Site Location(s) Form**

## **IV. INFORMATION FOR APPLICATION REVIEW**

### **A. Application Review and Selection Overview**

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit and overall goals of the program. Additional information about the two-tier review process used by the CDMRP may be found at <http://cdmrp.army.mil/fundingprocess>

The peer review and programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a nondisclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the nondisclosure statement can result in the dissolving of a panel(s) and other correcting actions. Correspondingly, institutional personnel and PIs are prohibited from contacting persons involved in the application 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 institution's application. Violations by panelists or PIs that compromise the confidentiality of the peer review and programmatic review processes may also result in suspension or debarment of their employing institutions from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

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

### **B. Review Criteria**

- 1. Peer Review:** All applications will be evaluated according to the following criteria. Of these, Synergy and Innovation are equally the most important, with the remaining criteria listed in decreasing order of importance.

- **Synergy**

- How well the proposed collaborative partnership between independent PIs is likely to facilitate or greatly accelerate a significant achievement in MS research and could not otherwise be accomplished through the efforts of a single laboratory.
- How well the application outlines the contributions of each PI to the overall synergy of the project.
- How well the proposed project is centered on a unified theme that addresses a single research question rather than an additive set of unrelated subprojects.
- How well the application addresses processes for ongoing communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all participating PIs and institutions.

- **Innovation**

- How well the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: Concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
- How well the proposed research represents more than an incremental advance upon published data.

- **Impact**

- How the project, if successful, will have an impact on MS and how the expected results of the project will advance goals to prevent the occurrence, reverse or slow the progression, and lessen the impact of MS.

- **Research Strategy and Feasibility**

- How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, MS-relevant preliminary data, and/or logical reasoning.
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
- How well the PIs acknowledge potential problems and address alternative approaches.
- Whether the proposal includes an appropriate statistical plan with power analysis, if applicable.
- How well the research project utilizes a multidisciplinary approach and the different disciplines involved.

The following aspects will not be individually scored, but may impact the global score.

- **Personnel**

- Whether the Initiating and Partnering PI(s) meet the eligibility requirements.
- The degree to which each PI possesses the research experience to function as a PI in a synergistic project.
- How well the research team's background and MS-relevant expertise are appropriate with respect to its ability to perform the proposed work.
- To what degree the levels of effort are appropriate for successful conduct of the proposed work.
- How the PIs plan to maintain ongoing communication, coordination of research progress and results, and data transfer throughout the life of the proposed research project.

- **Environment**

- How well the scientific environment is appropriate for the proposed research.
- How well the research requirements are supported by the availability of and accessibility to facilities and resources.
- How well the quality and extent of institutional support are appropriate.

- **Budget**

- Whether the budgets are appropriate for the proposed research and within the limitations of the award mechanism.
- Whether the resources are divided appropriately among all PIs.

- **Application Presentation**

- How the writing and components of the application influenced the review.

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

- Adherence to the intent of the award mechanism
- Program portfolio balance
- Programmatic relevance
- Ratings and evaluations of the peer reviewers
- Relative synergy, innovation, and impact
- Responsiveness to FY09 MSRP focus areas

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

## V. ADMINISTRATIVE ACTIONS

After CDMRP receives the applications from Grants.gov, they will be administratively reviewed for inclusion of appropriate components in accordance with this program announcement. If components are missing or not appropriate, the following administrative actions may occur:

### A. Rejection

The following will result in administrative rejection of the pre-application:

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

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).
- Initiating and/or Partnering PI(s) application is not submitted by the deadline.
- Submission of an application for which a letter of invitation was not received.

### B. Modifications

- Pages exceeding the specified limits will be removed for all documents other than the preproposal narrative or project narrative.
- Documents not requested will be removed.
- **NEW FOR FY09:** Following the application deadline you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed directly above in Section A, Rejection). The missing documents must be provided by 5:00 p.m. Eastern time on the second full business day following the date the email was sent. Otherwise, the application will be reviewed without the missing documents.

### C. Withdrawal

The following may result in administrative withdrawal of the application:

- The proposed research project is or contains a clinical trial.
- FY09 IP member(s) is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY09 IP members may be found at <http://cdmrp.army.mil/09msrppanel>

- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.
- The application does not conform to this funding opportunity description to an extent that precludes appropriate scientific peer and programmatic review.
- Direct costs as shown on the detailed budget form exceed maximum allowed by award mechanism.
- Inclusion of URLs with the exception of links to published references.

#### **D. Withhold**

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



## VI. CONTACT INFORMATION

**1. Program announcement, application format, or required documentation:** To view all funding opportunities offered by the Congressionally Directed Medical Research Programs (CDMRP), perform a Grants.gov basic search using the CFDA Number 12.420. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079

Fax: 301-619-7792

Email: [cdmrp.pa@amedd.army.mil](mailto:cdmrp.pa@amedd.army.mil)

**2. eReceipt system:** Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time.

Phone: 301-682-5507

Website: <https://cdmrp.org>

Email: [help@cdmrp.org](mailto:help@cdmrp.org)

**3. Grants.gov contacts:** Questions related to submitting applications through the [Grants.gov](http://www.grants.gov/) (<http://www.grants.gov/>) portal should be directed to Grants.gov help desk. Deadlines for application submission are 11:59 p.m. Eastern time on the deadline date. Therefore, there is an approximate 3-hour period during which the Grants.gov help desk will NOT be available. Please plan ahead accordingly, as the CDMRP help desk is not able to answer questions about Grants.gov submissions.

Phone: 800-518-4726, Monday through Friday, 7:00 a.m. to 9:00 p.m. Eastern time

Email: [support@grants.gov](mailto:support@grants.gov)

***Grants.gov will notify Principal Investigators (PIs) of changes made to this Program Announcement and/or Application Package ONLY if the PI clicks on the “send me change notification emails” link and subscribes to the mailing list on the Opportunity Synopsis Page for this announcement. If the PI does not subscribe and the Application Package is updated or changed, the original version of the Application Package may not be accepted.***