Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Peer Reviewed Medical Research Program

Investigator-Initiated Research Award

Funding Opportunity Number: W81XWH-09-PRMRP-IIRA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Objectives

The Peer Reviewed Medical Research Program (PRMRP) was established in 1999 to provide support for military health-related research of exceptional scientific merit. Appropriations for the PRMRP from Fiscal Year 1999 (FY99) through FY08 (excluding FY07, in which no appropriation was made) totaled $394.5 million (M). The FY09 appropriation is $50M.

The vision of the FY09 PRMRP is to identify and fund the best medical research to protect, support, and advance the health and welfare of military personnel and all beneficiaries. The PRMRP challenges the scientific and clinical communities to address one of the FY09 congressionally directed topic areas with original ideas that foster new directions in basic science and translational research; novel product development leading to improved therapeutic or diagnostic tools, or improvements in clinical policies/guidelines; or clinical trials that address an immediate clinical need. The PRMRP seeks applications in laboratory, clinical, behavioral, and epidemiologic research as well as public health and policy; environmental sciences; nursing; occupational health; alternative therapies; ethics; economics; and strategic research, such as studies designed to shape the development of or to validate clinical policy or guidance. Interdisciplinary and integrative health approaches are welcomed.

B. FY09 PRMRP Congressionally Directed Topic Areas

All applications for PRMRP funding must specifically and clearly address at least one of the topic areas as directed by Congress and have direct relevance to the health care needs of the Armed Forces, their family members, and/or the U.S. Veteran population. *If the proposed research has no relevance to currently advertised PRMRP topic areas, the Government reserves the right to administratively withdraw the application.* The Government also reserves the right to reassign the application's topic area if submitted under an inappropriate topic area. The FY09 PRMRP topic areas as provided by Congress are listed below.

Alcoholism
Autoimmune Diseases
Blood Cancer
Childhood Asthma
Drug Abuse
Epilepsy
Kidney Cancer
Listeria Vaccine for infectious disease and cancer
Lupus
Mesothelioma

Molecular Signatures in Tumors
Neuroblastoma
Osteoporosis and related bone disease
Paget's Disease
Pediatric Cancer
Polycystic Kidney Disease
Social Work Research
Tinnitus
West Nile Virus Vaccine

C. Award Description

The PRMRP Investigator-Initiated Research Award (IIRA) mechanism was first offered in FY99. Since then, 2,481 Investigator-Initiated Research Award proposals have been received, and 239 have been recommended for funding.

This award is intended to support studies that make an important contribution to research and/or patient care in at least one of the congressionally directed FY09 PRMRP topic areas and are responsive to the health care needs of the Armed Forces, their family members, and/or the U.S. Veteran population. All applications must specifically and clearly address the military relevance of the proposed research. Collaboration with military researchers and clinicians is encouraged.

Research projects may focus on any phase of research from basic laboratory research through translational research including preclinical studies in animal models and human subjects, as well as correlative studies associated with an existing clinical trial. Observations that drive a research idea may be derived from a laboratory discovery, population-based studies, or a clinician's first-hand knowledge of patients and anecdotal data.

Applications must include data relevant to the FY09 PRMRP topic area(s) addressed that support the rationale for the proposed study. These data may be unpublished and/or from the published literature.

This award may not be used to conduct clinical trials. Refer to the Application Instructions and General Information, Appendix 6, for helpful information about distinguishing clinical trials and clinical research. Principal Investigators (PIs) seeking funding for a clinical trial should apply to the FY09 PRMRP Clinical Trial Award mechanism.

Partnering PI Option: As a method to bring a new perspective to research and facilitate progress in the field by combined effort, the FY09 PRMRP is offering a Partnering PI option for this award mechanism. The results of this partnering project should significantly advance a project beyond what would be possible through individual efforts. Two investigators may work on a single project, each of whom will be designated as a PI. Developing the research plan should involve a reciprocal flow of ideas and information with equal intellectual input into the design of a single research project. New collaborative efforts are strongly encouraged.

One member of the team 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 will be identified as the Partnering PI 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 as PIs. Multidisciplinary and multi-institutional projects are allowed. If the project is multi-institutional, PIs should include plans for communication between investigators at each institution. Additionally, participating institutions must be willing to resolve potential intellectual and material property issues and to remove any barriers that might interfere with achieving high levels of cooperation to ensure successful completion of this award.

Encouraged DOD alignment: Relevance to the health care needs of the Armed Forces, their family members, and/or the U.S. Veteran population is a key feature of this award. Therefore, PIs are strongly encouraged to collaborate, integrate, and/or align their research projects with military and/or Veterans Affairs (VA) research laboratories and programs. The following websites may be useful in identifying information about ongoing DOD areas of research interest within the FY09 PRMRP topic areas:

Air Force Research Laboratory
http://www.wpafb.af.mil/afrl

Congressionally Directed Medical Research Programs
http://cdmrp.army.mil

Defense Advanced Research Projects Agency
http://www.darpa.mil/

Defense Technical Information Center
http://www.dtic.mil

Naval Health Research Center
http://www.med.navy.mil/sites/nhrc

Navy and Marine Corps Public Health Center
www-nmcphc.med.navy.mil/main.htm

Office of Naval Research
http://www.med.navy.mil/

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics

http://www.acq.osd.mil/

U.S. Army Medical Research Acquisition Activity

http://www.usamraa.army.mil

U.S. Army Medical Research and Materiel Command
https://mrmc.amedd.army.mil

U.S. Army Research Laboratory
http://www.arl.army.mil

U.S. Naval Research Laboratory
www.nrl.navy.mil

U.S. Department of Veterans Affairs, Office of Research and Development
www.research.va.gov

D. Eligibility

PIs must be at or above the level of Assistant Professor (or equivalent). Refer to Application Instructions and General Information, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is 3 years.

- The maximum allowable funding for the entire period of performance is $750,000 in direct costs.

- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 3-year period of performance.

- 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 institution's negotiated rate agreement.

- **Partnering PI Option:** The combined total funding for the Initiating PI and the Partnering PI may not exceed $750,000 for direct costs for up to a 3-year performance period, plus indirect costs as appropriate.

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

- Salary

- Research supplies

- Equipment

- Clinical research costs (Clinical trials are not supported)

- Travel to scientific/technical meetings

- Travel between collaborating institutions

- Other direct costs as described in Application Instructions & General Information for Detailed Budget and Justification

In addition, each PI must request travel funds to attend one Military Health Research Forum (MHRF) during the award period of performance. The MHRF is a CDMRP-sponsored meeting that is typically held every 2-3 years.

The CDMRP expects to allot approximately $30.45M of the $50M FY09 PRMRP appropriation to fund approximately 28 Investigator-Initiated Research 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

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

II. TIMELINE FOR SUBMISSION AND REVIEW

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

- **Pre-application Submission Deadline:** **5:00 p.m. Eastern time, March 19, 2009**
- **Application Submission Deadline:** **11:59 p.m. Eastern time, April 23, 2009**
- **Scientific Peer Review:** **July 2009**
- **Programmatic Review:** **October 2009**

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

III.   SUBMISSION PROCESS

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

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

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

Partnering PI Option:

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 will be identified as the Partnering PI. Initiating and Partnering PIs each have different submission requirements; however, both PIs should contribute to the preparation of the proposal. ***The Initiating PI must begin the pre-application process and submit contact information for the Partnering PI.***

The CDMRP requires separate Grants.gov application package submissions for Initiating and Partnering PIs. The CDMRP eReceipt system assigns a unique log number to each PI that must be used when submitting his/her Grants.gov application package. To obtain his/her unique log number, before submitting his/her application to Grants.gov, the Partnering PI must associate him- or herself with the Initiating PI's application by accepting the link sent by the CDMRP eReceipt system. ***Both PIs also must submit an identical copy of a jointly created SOW.***

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 by *5:00 p.m. Eastern time on the deadline date*. Refer to the Application Instructions and General Information for detailed information.

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

Partnering PI Option: The Initiating PI must complete the pre-application components listed above and must enter the contact information for the Partnering PI in the "Partnering PI" section.

B.   Step 2 – Application Components and Submission

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

Each application submission must include the completed application package of forms and attachments identified in www.grants.gov for this US Army Medical Research Acquisition Activity (USAMRAA Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information for detailed requirements of each component.

The package includes:

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

2. **Attachments Form**

- Attachment 1: Project Narrative (12-page limit)

  Describe the proposed project in detail using the outline below. Applications must include preliminary data relevant to the FY09 PRMRP topic area(s) to be addressed and the proposed research project.

  ○ **Background:** Present the ideas and reasoning behind the proposed research, to include relevant literature citations. Describe previous experience most pertinent to this application.

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

  ○ **Specific Aims:** Concisely explain the project's specific aims. These aims should agree with the primary aims and associated tasks described in the Statement of Work. If the proposed work is part of a larger study, present only aims that the DOD award would fund.

  ○ **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. ***This award may not be used to conduct clinical trials.***

- Attachment 2: Supporting Documentation

  ○ References Cited

  ○ Acronyms and Symbol Definitions

  ○ Facilities & Other Resources

  ○ Description of Existing Equipment

- ○ Publications and/or Patent Abstracts: Five-document limit

  ○ Letters of Institutional Support: Two-page limit per letter

    If the PI is a practicing clinical physician, the institution must clearly demonstrate a commitment to the clinician's research.

  ○ Letters of Collaboration (if applicable): Two-page limit per letter

  ○ 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

- Attachment 6: Detailed Budget and Justification

- Attachment 7: Impact Statement: One-page limit

  Describe the potential impact of this study on the field of research and/or patient care in the FY09 PRMRP topic area(s) addressed. Include an assessment of the likelihood that a successful outcome to the research project will lead to practical applications in patients. The following are examples of ways in which proposed studies, if successful, may have an impact. ***Although not all-inclusive***, these examples are intended to help PIs frame the impact of the proposed research:

  ○ Has the potential to advance the field of research in the FY09 PRMRP topic area(s) addressed

  ○ Has the potential to change the standard of care for the disease or condition of the FY09 PRMRP topic area(s) addressed

  ○ Contributes to development or validation of evidence-based policy or guidelines for patient evaluation and care

- Attachment 8: Military Relevance Statement: One-page limit

  Demonstrate how the proposed study is responsive to the health care needs of the Armed Forces, their family members, and/or the U.S. Veteran population. If active duty military, military families, or veteran population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed study, and the feasibility of using the population. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., Armed Forces, their family members, and/or the U.S. Veteran population). Show how the proposed study complements ongoing DOD areas of research interest in the FY09 PRMRP topic area(s) addressed.

- Attachment 9: Approval for access to military populations (if applicable): One-page limit

  A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving: active duty military, military families, or

veterans; military-controlled study materials; databases; and/or restricted facilities (e.g., biological or chemical containment facilities).

- 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 Form)**

- PI Biographical Sketch (four-page limit)
- PI Current/Pending Support
- Key Personnel Biographical Sketches (four-page limit each)
- Key Personnel Current/Pending Support

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

Application Submission Components for Partnering PI Option:

The CDMRP eReceipt system assigns a unique and separate log number to each PI (Initiating and Partnering) that must be used when submitting the Grants.gov application package. To obtain his or her unique log number, before submitting the application to Grants.gov, the Partnering PI must associate him- or herself with the Initiating PI's application by accepting the link sent by the CDMRP eReceipt system.

Application Components for the Initiating PI:

The Initiating PI must submit components 1–4 from the numbered list above.

Application Components for the Partnering PI:

The application submission process for the Partnering PI uses an abbreviated application package of forms and attachments from Grants.gov. The Partnering PI will be contacted via email by the CDMRP eReceipt system and provided with the information necessary to begin application submission through Grants.gov. Please note that the Partnering PI must follow the link in this email and register with CDMRP eReceipt in order to associate his/her grant application package with that of the Initiating PI.

The Partnering PI package includes only the following from the list above:

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

2. **Attachments Form**
- Attachment 5: Statement of Work (SOW): Three-page limit

   The Initiating and Partnering PI must submit an identical, jointly created SOW.

- 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 applications for funding based on scientific merit, the overall goals of the program, and specific intent of the award mechanism. Additional information about the two-tier review process used by the CDMRP may be found at http://cdmrp.army.mil/fundingprocess

The peer review and programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Institutional personnel and PIs are prohibited from contacting persons involved in the application review process to gain protected evaluation information or to influence the evaluation process. Violations of 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).

B. Review Criteria

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

- **Research Strategy and Feasibility**
  - How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, supporting data, and logical reasoning.
  - How the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
  - How the PI acknowledges potential problems and addresses alternative approaches.

- **Impact**
  - How the proposed study addresses an important need in the topic area addressed.
  - The potential contribution of the proposed study to research and/or patient care in the topic area addressed.

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

- **Personnel**
  - How the background and expertise of the PI and other key personnel demonstrate their ability to perform the proposed work.
  - How the levels of effort by the PI and other key personnel are appropriate to ensure success of this project.
  - Partnering PI Option (if applicable)
    - Evidence that both the Initiating PI and the Partnering PI had equal intellectual input the development and will contribute substantially to the implementation of the research plan.
    - How the background and expertise of the Initiating PI and Partnering PI demonstrate their ability to accomplish the proposed work.

- **Environment**
  - The appropriateness of the scientific environment for the proposed research.
  - How the research requirements are supported adequately by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - The quality and extent of institutional support.

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of the award mechanism.

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

2. Programmatic Review: The following equally weighted criteria are used by programmatic reviewers to make funding recommendations that maintain the program's broad portfolio:

- Adherence to the intent of the award mechanism
- Military relevance
- Programmatic relevance
- Program portfolio balance
- Ratings and evaluations of the peer reviewers
- Relative impact

- Responsiveness to at least one FY09 PRMRP topic area

Scientifically sound applications that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by the Joint Programmatic Review Panel (JPRP) members and recommended for funding to the Commanding General, USAMRMC. The highest scoring applications from the first tier of review are not automatically recommended for funding. All applications are carefully considered to ensure that the funds available are allocated to those applications that best fulfill the goals and objectives of the program.

V.   ADMINISTRATIVE ACTIONS

After receipt of applications from Grants.gov, the following administrative actions may occur:

A.   Rejection

The following will result in administrative rejection of the application:

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

B.   Modifications

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
- Documents not requested will be removed.
- *NEW for FY09:* Following the application deadline, you may be contacted by 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 within 48 hours of the date and time the email was sent. Otherwise, the application will be peer reviewed as submitted.

C.   Withdrawal

The following may result in administrative withdrawal of the application:

- The proposed research is not relevant to any of the congressionally directed FY09 PRMRP topic areas.
- The proposed research project is or contains a clinical trial.
- FY09 JPRP 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 JPRP members may be found at
http://cdmrp.army.mil/prmrp/panels/panel09

- 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/Program Announcement description to an extent that precludes appropriate scientific peer and/or 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

A. Program Announcement/Funding Opportunity 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

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

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

C. Grants.gov contacts: Questions related to submitting applications through the 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. 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

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.