

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Peer Reviewed Medical Research Program

Technology/Therapeutic Development Award

Funding Opportunity Number: W81XWH-09-PRMRP-TTDA

TABLE OF CONTENTS

I.	FUNDING OPPORTUNITY DESCRIPTION.....	2
A.	Program Objectives	2
B.	FY09 PRMRP Congressionally Directed Topic Areas	2
C.	Award Description	3
D.	Eligibility.....	4
E.	Funding.....	5
F.	Award Administration.....	5
II.	TIMELINE FOR SUBMISSION AND REVIEW.....	6
III.	SUBMISSION PROCESS	6
A.	Step 1 – Pre-Application Components and Submission	6
B.	Step 2 – Application Components and Submission	6
IV.	INFORMATION FOR APPLICATION REVIEW	9
A.	Application Review and Selection Overview	9
B.	Review Criteria	9
V.	ADMINISTRATIVE ACTIONS.....	12
VI.	CONTACT INFORMATION	13

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	Molecular Signatures in Tumors
Autoimmune Diseases	Neuroblastoma
Blood Cancer	Osteoporosis and related bone disease
Childhood Asthma	Paget's Disease
Drug Abuse	Pediatric Cancer
Epilepsy	Polycystic Kidney Disease
Kidney Cancer	Social Work Research
Listeria Vaccine for infectious disease and cancer	Tinnitus
Lupus	West Nile Virus Vaccine
Mesothelioma	

C. Award Description

The PRMRP Technology/Therapeutic Development Award mechanism was first offered in FY08 as the Advanced Technology/Therapeutic Development Award. Since then, 48 Technology/Therapeutic Development Award proposals have been received, and 4 have been recommended for funding.

This award is intended to support for the translation of promising preclinical findings into products for clinical applications in at least one of the congressionally-directed FY09 PRMRP topic areas. These products should be 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.

The product(s) to be developed may be pharmacologic agents (drugs or biologicals), devices, or clinical guidance. The Principal Investigator (PI) must provide a transition plan (including potential funding and resources) showing how the product will progress to clinical trials and/or delivery to the military or civilian market after the completion of the PRMRP award.

Examples of the types of research that may be supported include, but are not limited to:

- Collection and analysis of data for developing and validating clinical guidance
- Testing new therapeutic modalities (agents, delivery systems, chemical modification of lead compounds) using established or validated novel preclinical systems
- Designing and implementing full-scale, pilot Good Manufacturing Practice (GMP) production of therapeutics and/or delivery systems for use in advanced preclinical and initial clinical trials
- Developing pharmacologic agents through adsorption, distribution, metabolism, excretion, and toxicity (ADMET) phase
- Developing pharmacologic agents to Investigational New Drug (IND) stage for initiation of Phase I clinical trials
- Developing prototype devices for diagnosis or treatment to Investigational Device Exemption (IDE) stage for initiation of Phase I clinical trials
- Optimizing diagnostic or treatment devices for field deployment

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.

Use of human subjects and human biological substances: All DOD-funded research involving human subjects and human biological substances must be reviewed and approved by the USAMRMC Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to local Institutional Review Boards (IRBs). The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and will require information in addition to that supplied to the local review board. Allow a minimum of 6 months for regulatory review and approval processes for studies involving human subjects. Refer to the Application Instructions and General Information, Appendix 6, for detailed information.

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.onr.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 & General Information, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is 4 years.
- The maximum allowable funding for the entire period of performance is \$2M in direct costs.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 4-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 your 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 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 \$5.8M of the \$50M FY09 PRMRP appropriation to fund approximately 2 Technology/Therapeutic Development Award applications, depending on the quality and number of proposals 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 16, 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 \(https://cdmrp.org/\)](https://cdmrp.org/) and (2) an application submission through [Grants.gov \(http://www.grants.gov/\)](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.

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

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 (15-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 proposal.
 - **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 this 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; no page limit)

- 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 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: Transition Plan: One-page limit

Provide information on the methods and strategies proposed to move the product to clinical trials and/or delivery to the military or civilian market after the completion of the PRMRP award. The plan should include details of funding sources, collaborations, and other resources that will be used to provide this continuity of development.

- Attachment 9: 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 topic area addressed. Describe how the study design will replicate field conditions, if applicable, for the selected FY09 PRMRP topic area(s).

- Attachment 10: 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 11: Federal Agency Financial Plan (if applicable)
- Attachments 12-16: 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

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All proposals are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of proposals 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, overall goals of the program, and the 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 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 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 proposals 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, preliminary 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.
- **Transition Plan**
 - The evidence for an established plan for bringing the product to delivery.
 - The evidence that the PI has or can secure the additional funding needed to bring the product to delivery.
 - How appropriate intellectual property, licensing, and/or business professionals have been included or engaged.
 - How the resources proposed to bring the product to delivery support the likelihood of success.
- **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.
- **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 Program Announcement/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

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

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

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. 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.