Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Peer Reviewed Medical Research Program (PRMRP)

Translational Research Award

Funding Opportunity Number: W81XWH-08-PRMRP-TRA

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I. HELPFUL INFORMATION

A. Contacts

1. Program Announcement, proposal 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

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

3. 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 proposal 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 to 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.

B. National Technical Information Service

The technical reference facilities of the National Technical Information Service (www.ntis.gov) are available for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. All other sources also should be consulted to the extent practical for the same purpose.

C. Commonly Made Mistakes

- Not obtaining or confirming the organization's DUNS number well before the proposal submission deadline.
- Not obtaining or confirming the organization's registration with the Central Contractor Registry (CCR) well before the proposal submission deadline.
- Failing to request "send me change notification emails" from Grants.gov.
- Not contacting HELP DESKS until just before or after deadlines.
- Not completing the pre-application submission before the mandatory pre-application deadline (pre-application remains in draft status).
- Using an incorrect Grants.gov application package to submit a proposal through Grants.gov. Each Program Announcement/Funding Opportunity requires a specific application package.
- Uploading attachments into incorrect Grants.gov forms.
- Attaching files in the wrong location on Grants.gov forms.
- Submitting attachments that are not PDF documents, except for the R&R Subaward Budget Attachment(s) Form.
- Exceeding page limitations.
- Failing to submit a proposal 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package.
- Failing to submit proposal by submission deadline.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History and Objectives

The PRMRP was established in 1999 to provide support for military health-related research of clear scientific merit. Appropriations for the PRMRP from Fiscal Year 1999 (FY99) through FY06 totaled $344.5 million (M). The FY08 appropriation is $50M.

The vision of the FY08 PRMRP is to find 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 21 FY08 topic areas with innovative ideas to 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 proposals in laboratory, clinical, behavioral, and epidemiologic research as well as public health and policy, environmental sciences, nursing, occupational health, alternative therapies, ethics, and economics.

B. Award Description

The PRMRP Translational Research Award (TRA) mechanism is being offered for the first time in FY08.

This award supports translational research focused on a health-related central problem or question in one of the 21 FY08 PRMRP topic areas. Translational research may be defined as an integration of basic science and clinical observations. 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. While the ultimate goal of translational research is to move an observation forward into the clinical application, PIs should not view translational research as a one-way continuum from bench to bedside.

The PI must have experience in the disease or condition to be studied, gained through laboratory research or as a practicing clinician. All proposals must be responsive to the health care needs of the Armed Forces and Family members, the U.S. Veteran population, and the general public. Research projects may include preclinical studies in animal models and human subjects, including correlative studies associated with an existing clinical trial. Proposals must include preliminary data relevant to the topic area and the proposed study. The proposed work will have an impact on the prevention, detection, diagnosis, or treatment of the specified disease/condition, if successful. Strategic research, such as studies designed to shape the development of or to validate clinical policy or guidance, is encouraged. This award may not be used to conduct clinical trials. PIs seeking funding for a clinical trial should apply to the FY08 PRMRP Clinical Trial Award mechanism.

Encouraged DOD alignment: Alignment with current DOD research is encouraged. The following websites may be useful in identifying information about ongoing DOD areas of research interest within the FY08 PRMRP topic areas:

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

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

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

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

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

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

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

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

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

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

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

Partnering PI Option: As a method to support the development of new ideas in translational research, PRMRP is offering a Partnering PI option. For this option, one partner must be a laboratory scientist and the other must be a practicing clinician. 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 from both partners. A proposed project in which the clinical partner merely supplies tissue samples or access to patients will not meet the intent of this option.

One Initiating and one Partnering PI will each be designated as a PI, and a separate award will be made to each partner'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.

Use of military populations: Research involving military subjects will require a letter of approval for access to the population. A military collaborator is recommended for research involving military troops performed at non-military organizations.

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, 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 Instructions For Regulatory Requirements, Appendix 6, for detailed information.

C. FY08 PRMRP Congressionally Directed Topic Areas

All applications for PRMRP funding must specifically and clearly address one of the topic areas. ***If the research has no relevance to currently advertised PRMRP topic areas, the Government reserves the right to administratively withdraw the proposal.*** The Government reserves the right to reassign the proposal's topic area if submitted under an inappropriate topic area. The FY08 topic areas are listed below.

Alcoholism Research

Amyotrophic Lateral Sclerosis

Blood Cancer
Drug Abuse
Epilepsy Research
Eye and Vision Research
Integrated Tissue Hypoxia Research
Interstitial Cystitis
Inflammatory Bowel Disease
Leishmaniasis
Lupus
Kidney Cancer
Mesothelioma
Multiple Sclerosis
Nutrition and Health Promotion
Paget's Disease
Polycystic Kidney Disease
Pulmonary Hypertension
Scleroderma
Social Work Research
Tinnitus

D. Eligibility

PIs must be independent investigators at any academic level (or equivalent) and/or practicing clinicians. A practicing clinician is any licensed health professional. Refer to Application Instructions, Appendix 1, for general eligibility information.

E. Funding

Funding for a Translational Research Award can be requested for up to $900,000 for direct costs for up to a 3-year performance period, plus indirect costs as appropriate.

Partnering PI Option:

The combined total funding for the Initiating PI and the Partnering PI can be requested for up to $900,000 for direct costs for up to a 3-year performance period, plus indirect costs as appropriate.

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

- Salary
- Research supplies
- Equipment
- Clinical costs
- Travel to scientific/technical meetings
- Travel between collaborating institutions

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

The CDMRP expects to allot approximately $8.1M of the $50M FY08 PRMRP appropriation to fund approximately 6 Translational Research Award proposals, depending on the quality and number of proposals received. Funding of proposals 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, Appendix 5, for general award administration information.

III. TIMELINE FOR SUBMISSION AND REVIEW

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

- **Pre-application Submission Deadline: 5:00 p.m. Eastern time, June 4, 2008**
- **Proposal Submission Deadline: 11:59 p.m. Eastern time, July 2, 2008**
- **Peer Review: September 2008**
- **Programmatic Review: December 2008**

Awards will be made approximately 4 to 6 months after receiving the funding notification letter, but no later than September 30, 2009.

IV. 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) a proposal submission through Grants.gov (http://www.grants.gov/). The Translational Research Award is structured to support the development of new ideas in translational research by either one PI or two PIs through the Partnering PI option.

PIs and Organizations identified in the proposal 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.

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 proposals.

Partnering PI Option:

One partner will be identified as the Initiating PI, who will be responsible for the majority of the administrative tasks associated with proposal submission. The other partner will be referred to as the Partnering PI. ***The Initiating PI must begin the pre-application process and submit contact information for the Partnering PI.***

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***. Refer to the Application Instructions 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.
- The Initiating PI must enter the contact information for the Partnering PI in the "Partnering PI" section.
- The Partnering PI will be contacted via email by the CDMRP eReceipt system and provided the information necessary to begin proposal 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 or her grant application package with that of the Initiating PI.

B. Step 2: Proposal Components and Submission

Proposal submission will not be accepted unless a pre-application was submitted by the pre-application deadline. Proposals must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov). No paper copies will be accepted.

The Translational Research Award is structured to support the development of new ideas in translational research by either one PI or two PIs through the Partnering PI option.

Each proposal submission must include the completed Grants.gov application package of forms and attachments identified in 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 for detailed requirements of each component.

A. Proposal Submission Components:

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. ***Proposals must include preliminary data relevant to the topic area and the proposed 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 this proposal 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. For partnering PIs, clearly delineate the contribution of each partner to the development and execution of the research strategy. 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 clinician, 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 and Public Abstracts: One-page limit per abstract.
- Attachment 4: Statement of Work (SOW): Two-page limit.

- Attachment 5: Impact Statement: One-page limit.

Describe the potential impact of this study on research and/or patient care in the topic area addressed. 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 their proposals:

  - Has the potential to advance the field of research and/or patient care in the topic area addressed
  - Has the potential to change the standard of care for the disease or condition of the topic area
  - Proposes new paradigms or challenges existing paradigms in the field of research and/or patient care in the topic area addressed in one or more of the following ways: Concept or question, research methods or technologies, adaptations of existing methods or technologies
  - Contributes to development or validation of evidence-based policy or guidelines for patient evaluation and care

- Attachment 6: Translation Statement: One-page limit.

Describe how the proposed translational research is more than just a one-way continuum from bench to bedside. Show how the proposed research incorporates reciprocal transfer of ideas between basic and clinical science.

- Attachment 7: Letter of approval for access to military populations (if applicable)

If the proposed study involves military recruits or subjects, military-controlled study materials, databases, and restricted facilities (e.g., biological or chemical containment facilities), a letter of support signed by the responsible commander (Installation, Troop, or Institute Commander) confirming access to recruits/military subjects and military materials is required.

- Attachment 8: Federal Agency Financial Plan (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 Budget Form**
   - Budget Justification
5. **Research & Related Project/Performance Site Location(s) Form**
6. **R&R Subaward Budget Attachment(s) Form (if applicable)**

B. Proposal Submission Components for Partnering PI Option:

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

Proposal Components for the Initiating PI:

The Initiating PI must submit components 1-6 from the numbered list above.

Proposal Components for the Partnering PI:

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

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

1. **SF-424 (R&R) Application for Federal Assistance Form**
2. **Attachments Form**
   - Attachment 4: SOW: The Initiating and Partnering PIs must create a joint SOW.
   - Attachment 9: Federal Agency Financial Plan (if applicable)
4. **Research & Related Budget Form**
   - Budget Justification
5. **Research & Related Project/Performance Site Location(s) Form**
6. **R&R Subaward Budget Attachment(s) Form (if applicable)**

V. INFORMATION FOR PROPOSAL REVIEW

A. Proposal 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 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 program review processes are conducted confidentially and anonymously to maintain the integrity of the merit-based selection process. Each tier review requires panelists to sign a non-disclosure statement attesting that proposal 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 correcting actions. Correspondingly, institutional personnel

and PIs are prohibited from contacting persons involved in the proposal review process to gain protected evaluation information or to influence the evaluation process. Violations of this prohibition will result in the administrative withdrawal of the institution's proposal. Violations by panelists or PIs that compromise the confidentiality or anonymity of the peer review and program review processes may also result in suspension or debarment of their employing institutions from Federal awards.

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, Translation Statement, etc.).

B. Review Criteria

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

- **Translational Potential**
  - How the proposed work is more than a one-way continuum from bench to bedside.
  - The evidence for reciprocal transfer of ideas between basic and clinical science in developing and implementing the research plan.
- **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 well potential problems are acknowledged and alternative approaches are addressed.
- **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.
- **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 contributed substantially to the development and implementation of the research plan, and to the reciprocal flow of ideas.

- How the background and expertise of the Initiating PI and Partnering PI demonstrate their ability to accomplish the proposed work.
- How the levels of effort of the Initiating PI and Partnering PI support the proposed 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**
  - How the budget is appropriate for the proposed research.

2. Programmatic Review: Criteria used by the Joint Programmatic Review Panel (JPRP) members to make funding recommendations that maintain the program's broad portfolio include:

- Responsiveness to FY08 PRMRP topic areas,
- Ratings and evaluations of the peer reviewers,
- Programmatic relevance,
- Relative impact,
- Military relevance,
- Program portfolio balance, and
- Adherence to the intent of the award mechanism.

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 JPRP members and recommended for funding to the Commanding General, USAMRMC.

VI. COMPLIANCE GUIDELINES

Compliance guidelines have been designed to ensure the presentation of all pre-applications and proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format. Failure to adhere to formatting guidelines makes documents difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in pre-application or proposal rejection. **Pre-applications or proposals missing required components as specified in the Program Announcement/Funding Opportunity may be administratively rejected.**

If the research has no relevance to currently advertised PRMRP topic areas, the Government reserves the right to administratively withdraw the proposal.

The following will result in administrative rejection of the entire proposal:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Margins are less than specified in the formatting guidelines.
- Print area exceeds that specified in the formatting guidelines.
- Spacing is less than specified in the formatting guidelines.
- Budget and/or budget justification are missing.
- FY08 JPRP members are included in any capacity in the pre-application process, the proposal, budgets, and any supporting document. A list of the FY08 JPRP members may be found at http://cdmrp.army.mil.

For any other sections of the pre-application or proposal with a defined page limit, pages exceeding the specified limit will be removed and not forwarded for peer review.

Material submitted after the submission deadline, unless specifically requested by the Government, will not be forwarded for peer review.

Proposals that appear to involve any allegation of research misconduct will be withheld from further consideration pending institutional investigation. The institution will be requested to perform an investigation and provide those findings to the Grants Officer for a determination of the final disposition of the application.