Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Peer Reviewed Medical Research Program

Discovery Award

Funding Opportunity Number: W81XWH-11-PRMRP-DA Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

• Pre-application Submission Deadline: 5:00 p.m. Eastern time (ET), June 14, 2011

• **Application Submission Deadline:** 11:59 p.m. ET, July 5, 2011

• Scientific Peer Review: September 2011

Programmatic Review: December 2011

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

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The 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 FY10 (excluding FY07, in which no appropriation was made) totaled \$494.5 million (M). The FY11 appropriation is \$50M.

FY11 Objectives: The vision of the FY11 PRMRP is to improve the health and well-being of all military service members, veterans, and beneficiaries. Through four different award mechanisms, the PRMRP challenges the scientific and clinical communities to address one of the FY11 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 FY11 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; and economics.

B. FY11 PRMRP Congressionally Directed Topic Areas

All applications for PRMRP funding must specifically address at least one of the topic areas as directed by Congress, and must be directly relevant to the health care needs of the military service members, veterans, and/or beneficiaries. If the proposed research is not relevant to FY11 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 FY11 PRMRP topic areas are listed below.

Chronic fatigue syndrome

Chronic migraine and post-traumatic headache

Drug abuse Dystonia

Epidermolysis bullosa

Epilepsy

Fragile X syndrome

Inflammatory bowel disease

Interstitial cystitis

Listeria vaccine for infectious disease

Lupus

Neuroblastoma

Osteoporosis and related bone disease

Paget's disease Pancreatitis

Pheochromocytoma

Polycystic kidney disease Posttraumatic osteoarthritis

Scleroderma

Social work research

Tinnitus

C. Award Information

The intent of the PRMRP Discovery Award is to support innovative, untested, high-risk/potentially high-reward concepts, theories, paradigms, and/or methods. Studies supported by

this award are expected to develop robust preliminary data that will lay the groundwork for future avenues of scientific investigation. The proposed research project should include a well-formulated, testable hypothesis based on strong scientific rationale and study design.

The Discovery Award is not intended to support a logical progression of an already established research project. *The proposed research project should be novel and innovative*. Innovative research may introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities. Research that is an incremental advance upon published data is not considered innovative and will not be considered for funding under this award mechanism.

Inclusion of preliminary data is strongly discouraged. The outcome of research supported by this award should be the generation of robust preliminary data that can be used as a foundation for future research projects to understand the mechanisms of initiation, or progression of and/or improving patient care for a disease or condition. This award is not intended to support ongoing work; therefore, inclusion of preliminary data other than serendipitous findings or in very small numbers is not consistent with the exploratory nature of this award. The presentation of substantial preliminary data suggests that the proposed research project would be more appropriately submitted to a different award mechanism.

Use of human subjects and human anatomical substances is limited. Because this award mechanism is designed to support preliminary investigations, research projects involving human subjects or human anatomical substances will not be supported unless they are exempt under Title 32, Code of Federal Regulations, Part 219, Section 101(b)(32 CFR 219.101[b]). In brief, exempt studies may include, but are not limited to, research on normal educational practices, special cases of educational tests and/or surveys, or the collection of existing data, documents, records, or pathological specimens in a de-identified method. Exemption is first determined by the local Institutional Review Board (IRB) of record. Investigators must review their institutional requirements and guidelines for filing with the IRB for exempt status. Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded. Additional information regarding exempt status may be found on the US Army Medical Research and Materiel Command (USAMRMC) Human Research Protection Office website (https://mrmc.amedd.army.mil/rodorphrpo.asp).

Department of Defense (DOD) alignment is encouraged. Relevance to the health care needs of the military service members, veterans, and beneficiaries is a key feature of this award. Therefore, Principal Investigators (PIs) are strongly encouraged to collaborate, integrate, and/or align their research projects with military and/or U.S. Department of Veterans Affairs research laboratories and programs. The following websites may be useful in identifying information about ongoing DOD areas of research interest within the FY11 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

Naval Medical Research Center www.med.navy.mil/sites/nmrc

Navy and Marine Corps Public Health Center

http://www.nmcphc.med.navy.mil/

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 Information

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

E. Funding

- The maximum period of performance is **18** months.
- The maximum allowable direct costs for the entire period of performance is \$125,000 plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 18 months.

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

Must be requested for:

• Travel funds, up to \$1,800, to attend one Military Health Research Forum (MHRF) during the award period of performance. The MHRF is a Congressionally Directed Medical Research Programs (CDMRP)-sponsored meeting that is typically held every 2-3 years.

May be requested for (not all-inclusive):

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

The CDMRP expects to allot approximately \$3.75M of the \$50M FY11 PRMRP appropriation to fund approximately 20 Discovery Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

Submission is a multi-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (https://cdmrp.org/) and (2) application submission through Grants.gov (http://www.grants.gov/).

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to reject duplicative applications.

A. Where to Obtain the Application Package

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

B. Pre-Application Submission Content and Form

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

PIs and organizations identified in the application should be the same as those identified in the pre-application. If a change in PI or organization is necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- Application Information Tab 1
- Application Contacts Tab 2
- Collaborators and Conflicts of Interest Tab 3

Required Files – Tab 4

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the FY11 PRMRP topic area(s) under which the application will be submitted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.

- Submit Pre-application Tab 5
- Other Documents Tab

No additional documents are required.

C. Application Submission Content and Form

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

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

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

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

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

2. Attachments Form

• Attachment 1: Project Narrative (three-page limit): Upload as "ProjectNarrative.pdf."

Describe the proposed project in detail using the outline below.

 Hypothesis: State concisely the new concept, theory, paradigm, and/or method that addresses an important problem relevant to at least one of the FY11 PRMRP topic areas.

- Rationale: State concisely the rationale for the proposed research. Inclusion of preliminary data is strongly discouraged.
- o **Innovation:** State concisely how the proposed research is novel and innovative.
- Significance/Relevance: Briefly describe how the proposed research addresses at least one of the FY11 PRMRP topic areas. Briefly state the expected results from the proposed research and how they will be used as a foundation for future research projects.
- o **Objectives:** State the specific aims and research strategy of the study.
- Methods: Describe the experimental design and methodology in sufficient detail for evaluation.
- Attachment 2: Supporting Documentation. Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *Each component has no page limit unless otherwise noted*.
 - References Cited: List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e. author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). Do not include URLs that identify the PI, the collaborator(s) or their organizations.
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf." State the FY11 PRMRP topic area(s) addressed by the proposed research project. Clearly describe the proposed research including the idea to be studied and the objectives, the innovative aspect of the research, and the expected results and how they will be used as a foundation for future research projects.
- Attachment 4: Public Abstract (one-page limit): Upload as "PublicAbs.pdf."

 State the FY11 PRMRP topic area(s) addressed by the proposed research project. Include an overview of the proposed research project that can be readily understood by lay persons. Clearly describe the *idea* to be studied, the innovative aspect of the research, and the expected results and how they will be used as a foundation for future research projects. Do not duplicate the technical abstract.
- Attachment 5: Statement of Work (SOW) (one-page limit): Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information.
 - **Attachment 6: Military Relevance Statement (one-page limit):** Upload as "MilRel.pdf." Reviewers will be blinded to the identity of the PI, collaborators, and their organization(s).

Describe how the proposed study is responsive to the health care needs of military service members, veterans, and/or beneficiaries. Provide information about the incidence and/or prevalence of the disease or condition to be studied in military service members, veterans, and/or beneficiaries, if appropriate and available.

If active duty military, military families, and/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 accessing 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. military service members, veterans, and/or beneficiaries). Proposed research projects using human subjects or human biological substances must be exempt under Title 32, Code of Federal Regulations, Part 219, Section 101(b)(32 CFR 219.101[b]).

If appropriate, show how the proposed research project aligns with DOD areas of research interests.

- **3.** Research & Related Senior/Key Person Profile (Expanded) Form: Refer to the General Application Instructions, Section II.C., for detailed information.
 - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
 - PI Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
 - Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
 - Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
- **4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
 - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."
- **5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- **6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

D. Submission Dates and Times

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

E. Other Submission Requirements

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

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Number System (DUNS) number and register with the Central Contractor

Registry (CCR) to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, US Army Medical Research and Materiel Command (USAMRMC), based on technical merit, the relevance to the mission of the Department of Defense (DOD) and CDMRP, and the specific intent of the award mechanism. The highest scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess. Reviewers will be blinded to the identity of the PI, collaborators, and their organization(s).

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

B. Application Review Criteria

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

Innovation

- o How the proposed ideas, theories, paradigms, and/or methods are innovative.
- o Whether the ideas, theories, paradigms, and/or methods are untested.
- o Whether the project proposes new paradigms or challenges existing paradigms.
- How the proposed research represents more than an incremental advance.

Significance/Relevance

 How the proposed research project addresses an important scientific question relevant to at least one of the FY11 PRMRP topic areas.

- Whether the research will generate robust preliminary data that can be used as a foundation for future research projects.
- o How the proposed study is responsive to the health care needs of military service members, veterans, and/or beneficiaries.

Research Strategy

- How the rationale, experimental design, and methodology are appropriate to test the hypothesis.
- Whether the proposed research project can be completed in an 18-month performance period.

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

• Application Presentation

- o To what extent the writing, clarity, and presentation of the application components influenced the review.
- **2. Programmatic Review:** To determine the application's relevance to the mission of the DOD, and CDMRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

• Adherence to the intent of the award mechanism

 Whether a novel, innovative idea was proposed; not an extension of an existing project.

• Military relevance

- How well the proposed research project is responsive to documented health care needs of the military service members, veterans, and beneficiaries.
- How the proposed research project aligns with DOD areas of research interests, if applicable.

• Program portfolio composition

 Whether the proposed study specifically addresses research areas that are underrepresented in the existing PRMRP portfolio (Click here to search PRMRP awards http://cdmrp.army.mil/search.aspx) and would therefore add to the overall balance of research and development efforts in the existing portfolio.

• Ratings and evaluations of the peer reviewers

• Whether the application was assessed as scientifically meritorious, with the identified strengths outweighing the weaknesses.

Relative innovation

o FY11 PRMRP applications will be compared to identify those projects with the highest relative innovation.

Relevance to program objectives

 Whether the proposed research project supports the mission of the PRMRP to "Provide support for military health-related research of exceptional scientific merit."

C. Recipient Qualification

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

D. Application Review Dates

All application review dates and times are indicated on the <u>title page</u> of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

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

IV. ADMINISTRATIVE ACTIONS

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

A. Rejection

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Pre-application is not submitted.
- The PI, collaborators, or their organization(s) are identified or referenced in the Technical or Public Abstracts; Project Narrative; Military Relevance Statement; or Abbreviations, Acronyms, and Symbols list.
- Use of "I," "our," "this organization," or similar phrases that refer to the PI, collaborators, or their organization(s) through the references listed.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

• Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY11 PRMRP Joint Programmatic Review Panel (JPRP) member is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY11 PRMRP JPRP members may be found at http://cdmrp.army.mil/prmrp/panels/panel11.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- The proposed research project is not relevant to any of the congressionally directed FY11 PRMRP topic areas.
- The proposed research project does not qualify for exempt status under Title 32, Code of Federal Regulations, Part 219, Section 101(b) (32 CFR 219.101[b]).

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

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

B. Administrative and National Policy Requirements

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

C. Reporting

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

D. Award Transfers

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

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

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

Phone: 1-301-682-5507 Email: help@cdmrp.org

B. Grants.gov Contact Center

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

Phone: 1-800-518-4726

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
Attachments Form	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
Attachments Form	Upload Public Abstract (PublicAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Military Relevance Statement (MilRel.pdf) as Attachment 6.	
	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
Research & Related	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.	
Senior/Key Person Profile (Expanded)	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	