

# **Program Announcement**

**Defense Health Program  
Defense Medical Research and Development Program  
Department of Defense  
Congressionally Directed Medical Research Programs**

## **Peer Reviewed Medical Research Program Investigator-Initiated Research Award**

**Funding Opportunity Number: W81XWH-12-PRMRP-IIRA  
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), April 10, 2012
- **Invitation to Submit an Application:** June 2012
- **Application Submission Deadline:** 11:59 p.m. ET, July 31, 2012
- **Peer Review:** September 2012
- **Programmatic Review:** December 2012

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## **I. FUNDING OPPORTUNITY DESCRIPTION**

### **A. Program Description**

Applications for the Peer Reviewed Medical Research Program (PRMRP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. The PRMRP was established in fiscal year 1999 (FY99) to provide support for military health-related research of exceptional scientific merit. Appropriations for the PRMRP from FY99 through FY11 totaled \$544.5 million (M). The FY12 appropriation is \$50M.

The vision of the FY12 PRMRP is to improve the health and well-being of all military service members, veterans, and beneficiaries. The PRMRP challenges the scientific and clinical communities to address one of the FY12 topic areas with original ideas that foster new directions along the entire spectrum of research and clinical care. The program seeks applications in laboratory, clinical, behavioral, epidemiologic, and other areas of research to advance knowledge in disease etiology, improve detection, diagnosis, treatment, and quality of life for those affected by a relevant disease or condition, and to develop and validate clinical care or public health guidelines.

### **B. FY12 PRMRP Congressionally Directed Topic Areas**

All applications for PRMRP funding must specifically address at least one of the topic areas 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 does not specifically address at least one of the FY12 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 FY12 PRMRP topic areas are listed below:

- Arthritis
- Composite Tissue Transplantation
- Drug Abuse
- Dystonia
- Epilepsy
- Food Allergies
- Fragile X Syndrome
- Hereditary Angioedema
- Inflammatory Bowel Disease
- Interstitial Cystitis
- Listeria Vaccine for Infectious Disease
- Lupus
- Malaria
- Nanomedicine for Drug Delivery Science
- Neuroblastoma
- Osteoporosis and Related Bone Disease
- Paget's Disease
- Polycystic Kidney Disease
- Post-Traumatic Osteoarthritis
- Scleroderma
- Tinnitus
- Tuberculosis

## C. Award Information

The PRMRP Investigator-Initiated Research Award (IIRA) is intended to support studies that will make an important contribution toward research and/or patient care for a disease or condition related to at least one of the Congressionally directed FY12 PRMRP topic areas.

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. The rationale for 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 relevant data that support the rationale for the proposed study. These data may be unpublished and/or from the published literature.

***Research involving human subjects and human anatomical substances is permitted; however, this award may not be used to conduct clinical trials.*** A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. Principal Investigators (PIs) seeking funding for a clinical trial should apply to the FY12 PRMRP Clinical Trial Award mechanism.

**Partnering PI Option:** As a method to bring new perspectives to research and facilitate progress in the field through collaborative efforts, the FY12 PRMRP is offering a Partnering PI Option for this award mechanism. The results of this partnering project should significantly advance the research beyond what would be possible through individual efforts. The Partnering PI Option is structured so that two investigators, each of whom will be designated a PI, will work synergistically on a single project. Each PI should bring complementary skills and perspectives to the research project. Developing the research plan should involve a reciprocal flow of ideas and information between the partners. The application should clearly demonstrate that both PIs have equal intellectual input into the design of the project. Each PI must demonstrate that he/she possesses the research experience and resources to function as a PI and must also exhibit an appropriate level of authority and responsibility to direct the project supported by the grant. New and multi-institutional collaborative efforts are strongly encouraged. PIs should include plans for communication between investigators at different organizations, if applicable. Additionally, participating organizations 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 the proposed research project.

One PI will be identified as the Initiating PI and 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 a smaller set of administrative tasks associated with application submission. Separate awards will be made to each PI's organization, even if both PIs are at the same organization. Additional collaborators may be included but will not be designated as PIs.

**Use of Human Subjects and Human Anatomical Substances:** All Department of Defense (DoD)-funded research projects (new and ongoing) involving human subjects and human anatomical substances must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), and the Institutional Review Board of record. 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. Regulatory approval at the time of submission is NOT required. Refer to General Application Instructions, Appendix 5, for general regulatory requirements.

**Encouraged DoD alignment:** Relevance to the health care needs of military service members, veterans, and beneficiaries 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 U.S. Department of 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 FY12 PRMRP topic areas:

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

Clinical and Rehabilitative Medicine  
Research Program  
<https://crmrp.amedd.army.mil/>

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>

Military Infectious Disease Research  
Program  
<https://midrp.amedd.army.mil/>

Military Operational Medicine Research  
Program  
<https://momrp.amedd.army.mil/>

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

Naval Medical Research Center  
[www.med.navy.mil/sites/nmrc](http://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](http://www.nrl.navy.mil)

U.S. Department of Veterans Affairs,  
Office of Research and Development  
[www.research.va.gov](http://www.research.va.gov)

Walter Reed Army Institute of Research  
<http://wrair-www.army.mil/>

*The office of the Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated by CDMRP-funded research activities be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.*

#### **D. Eligibility Information**

- PIs at or above the level of Assistant Professor (or equivalent) 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 **3** years.
- The maximum allowable direct costs for the entire period of performance are **\$750,000** 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.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.
- 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.
- **Partnering PI Option:** The combined total funding for the Initiating PI and the Partnering PI may not exceed **\$750,000** in direct costs, plus indirect costs as appropriate.
  - The PIs are expected to be equal partners in the research, and direct costs should be divided accordingly, unless otherwise warranted and clearly justified.
  - A separate award will be made to each PI's organization, even if both PIs are at the same organization.

Refer to the General Application Instructions, Section II.C.4, for budget regulations and instructions for the Research & Related Budget. In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel funds of up to \$1,800 for the PI(s) to attend one DoD-sponsored meeting to be specified by the CDMRP during the award performance period.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Clinical research costs (clinical trials are not supported)
- Support for multidisciplinary and multi-institutional collaborations
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

*The CDMRP expects to allot approximately \$25.9M of the \$50M FY12 appropriation to fund approximately 23 IIRA 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/>).

**Partnering PI Option:** The IIRA mechanism is structured to accommodate up to two PIs. One partner will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as the Partnering PI. Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute significantly to the development of the proposed research project including the Project Narrative, Statement of Work, and other required components. The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PI. The Partnering PI will then be notified separately by email. 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. If an application is invited, only the Initiating PI will receive notification of invitation via email from CDMRP.

Submission of the same research project to different funding opportunities within the same program and fiscal year is prohibited. The Government will 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-12-PRMRP-IIRA.

## B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI (or Initiating PI) through the CDMRP eReceipt System (<https://cdmrp.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

**Partnering PI Option:** *The Initiating PI is responsible for submission of all pre-application components.*

PIs and organizations identified in the application should be the same as those identified in the pre-application. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at [help@cdmrp.org](mailto: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 (COI) – Tab 3**

FY12 PRMRP Joint Programmatic Review Panel (JPRP) members should not be involved in any pre-application or application. For questions related to JPRP members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP [Help Desk](#) at [help@cdmrp.org](mailto:help@cdmrp.org) or 1-301-682-5507.

**Partnering PI Option:** The Initiating PI must enter the contact information for the Partnering PI in the Partnering PI section.

- **Required Files – Tab 4**

**Preproposal Narrative (two-page limit):** The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

The Preproposal Narrative should include the following:

- **Topic Area:** Indicate how the proposed project relates to at least one FY12 PRMRP topic area.
- **Rationale:** Clearly articulate the rationale for the project by presenting the ideas and reasoning behind the proposed research; include relevant literature citations.
- **Research Idea:** State the hypothesis to be tested or the objective to be reached. State the project's specific aims and briefly describe the experimental design and methodology. If applying under the Partnering PI Option, describe how the collaborative effort will impact the research plan.
- **Impact:** Describe the potential short-term and long-term impact of the results of the proposed study on at least one of the FY12 PRMRP topic areas.

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application are limited to:

- PI Biographical Sketch (four-page limit)
  - If applying under the Partnering PI Option, include both the Initiating and Partnering PIs' biosketches (four-page limit per individual).

- **Submit Pre-Application – Tab 5**

This tab must be completed for the pre-application to be accepted and processed by CDMRP.

- **Other Documents Tab**

No additional documents are required.

## Pre-Application Screening

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DoD and the PRMRP, pre-applications will be screened by scientific peer reviewers and the PRMRP JPRP members based on the following criteria:

- **Programmatic relevance:** Whether the proposed research idea supports the objectives of the PRMRP and aids the program in achieving a broad portfolio.
- **Research idea:** How well the proposed research demonstrates sound scientific rationale. How well the specific aims support the research hypothesis and/or objectives.
- **Impact:** Whether the potential immediate and long-range outcome(s)/product(s) (intellectual and/or tangible) of the proposed research, if successful, will impact a central critical problem or question in the field of research and/or patient care in the FY12 PRMRP topic area(s) addressed.

- **Notification of Pre-Application Screening Results**

Following the pre-application screening, PIs (or Initiating PIs, if applying under the Partnering PI Option) will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. Pre-application notification dates are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

## C. Application Submission Content and Form

***Applications will not be accepted unless the PI or Initiating PI has received notification of invitation.***

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 through the Grants.gov portal (<http://www.grants.gov/>).

**Partnering PI Option:** *The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and Partnering PI. Initiating and Partnering PIs will each be assigned unique log numbers by the CDMRP eReceipt System. Each Grants.gov application package must be submitted using the unique log number.*

**Application Components for the PI or the Initiating PI (if applying under the Partnering PI Option):**

**Grants.gov application package components:** For the Investigator-Initiated Research 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.1, for detailed information.

**2. Attachments Form**

- **Attachment 1: Project Narrative (12-page limit):** Upload as “ProjectNarrative.pdf.”

Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed research, to include relevant literature citations. Describe previous experience most pertinent to this application. If applying under the Partnering PI Option, describe how the partners bring different strengths to the application and explain why the work should be done together rather than through separate efforts.
- **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 human subjects or the acquisition of samples. If applying under the Partnering PI Option, outline how the PIs will manage the collaboration and workflow to optimize research efforts.
- **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. *There are no page limits for any component unless otherwise noted. Include only those components described below; inclusion of items not requested may result in administrative rejection of the application.*

- 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).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”

State the FY12 PRMRP topic area(s) addressed by the proposed research project. Describe the proposed research project including the following elements: Background, rationale, hypothesis or objective, study design, and the relevance of the project to at least one FY12 PRMRP topic area. If utilizing the Partnering PI option, articulate how the two investigators will work synergistically on the proposed research project.

The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and rely on the technical abstract for appropriate description of the project’s key aspects.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.”

State the FY12 PRMRP topic area(s) addressed by the proposed research project. Include a comprehensive overview of the proposed research project that can be readily understood by lay persons. Clearly describe the central critical problem or question to be addressed and the ultimate applicability and impact of the research. If utilizing the Partnering PI option, articulate the synergy of the proposed research project. Do not duplicate the technical abstract.

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C.2, for detailed information.

*Partnering PI Option: Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI should be noted for each task.*

- **Attachment 6: Impact Statement (one-page limit):** Upload as “Impact.pdf.”

Explain why the proposed research project is important and relevant to understanding the cause or progression of the disease or condition, and/or to developing improvements in detection, diagnosis, patient care, or quality of life in the FY12 PRMRP topic area(s) addressed.

**Describe the short-term impact:** Detail the anticipated outcome(s)/product(s) (intellectual and/or tangible) that will be directly attributed to the results of the proposed research.

**Describe the long-term impact:** Explain the anticipated long-term gains from this research course and compare to information/products currently available, if applicable.

- **Attachment 7: Military Relevance Statement (one-page limit):** Upload as “MilRel.pdf.”

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).

If applicable, show how the proposed research project aligns with DoD areas of research interests.

- **Attachment 8: Letters Confirming Access to Military or VA Population(s), if applicable:** Upload as “Access.pdf.”

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

- **Attachment 9: Data and Research Resources Sharing Plan (two-page limit):** Upload as “SharingPlan.pdf.” Describe how data and resources generated during the performance of the project will be shared with the research and consumer

advocacy communities. Refer to the General Application Instructions, Appendix 4, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

**3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.3, 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.”
  - Include the Partnering PI, if applying under the Partnering PI Option.
- Key Personnel Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
  - Include the Partnering PI, if applying under the Partnering PI Option.

**4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4, for detailed information.

- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”

*Partnering PI Option: Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for the Partnering PI. The combined total direct costs for the Initiating and Partnering PI’s budgets cannot exceed \$750,000.*

**5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5, for detailed information.

**6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6, for detailed information.

**Additional Application Components for the Partnering PI, if applying under the Partnering PI Option:**

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

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

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

**2. Attachments Form**

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C.2, for detailed information on completing the SOW. *Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI should be noted for each task.*

**3. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4, for detailed information.

- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”

*Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are at the same organization. The combined total direct costs for the Initiating and Partnering PI’s budgets cannot exceed \$750,000.*

**4. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5, for detailed information.

**5. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6, for detailed information.

**D. Submission Dates and Times**

All submission dates and times are indicated on the [title page](#) of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines will 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, USAMRMC, based on technical merit, the relevance to the mission of the DoD and PRMRP 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>.

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, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 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:

- **Feasibility**
  - How the PI acknowledges potential problems and addresses alternative approaches.
  - How the background and expertise of the PI (including the Partnering PI, if applicable) and other key personnel demonstrate their ability to perform the proposed work.
  - How the proposed methods are appropriate to test the hypothesis or achieve the objectives.
  - If applicable, how well the application provides evidence of availability of and access to the necessary study populations and/or resources.
  - Whether the research can be completed in the proposed period of performance.

- **Impact**
  - How the proposed research project in the FY12 PRMRP topic area(s) addressed, if successful, will:
    - Make important scientific advances in the field,
    - Promote greater understanding of the causes and progression,
    - Promote the development of improvements in patient care, and/or
    - Promote the development of improvements in quality of life.
  - How well the anticipated short-term outcome(s)/product(s) (intellectual and/or tangible) are described.
  - How well the anticipated long-term gains from this research course are described and compared to information/products currently available, if applicable.
- **Research Strategy**
  - How well the scientific rationale supports the project as demonstrated by a critical review and analysis of the literature, supporting data, and logical reasoning.
  - How well the hypotheses or objectives, aims, experimental design, methods, data collection procedures, and analyses are developed and integrated into the project.
  - The degree to which the data analysis plan is consistent with the study objectives.
  - For applications submitted under the Partnering PI Option, how the collaborative effort will support implementation of the research plan.

The following unscored criteria will also contribute to the overall evaluation of the application:

- **Environment**
  - How the scientific environment is appropriate for the proposed research.
  - How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - How the quality and extent of organizational support are appropriate for the proposed research.
- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
  - 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 PRMRP, 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 the proposed research project has the potential to make an important contribution to research and/or patient care in one or more of the FY12 PRMRP topic areas.
  - If applying under the Partnering PI Option, whether the project is synergistic, i.e., greater than what can be accomplished in the laboratory of a single PI.
- **Military relevance**
  - How responsive the proposed research project is to health care needs of the military service members, veterans, and beneficiaries.
  - If applicable, how the proposed study involves military (i.e., military service members, veterans, and beneficiaries) populations or resources, or how a non-military population/resource simulates the targeted military population/resource, and how those populations/resources are appropriate for the proposed study objectives.
  - How the proposed research project aligns with DoD areas of research interests, if applicable.
- **Program portfolio composition**
  - Whether the proposed study complements the overall balance of research and development with a topic and across topic areas.
- **Ratings and evaluations of the peer reviewers**
  - Whether the application was assessed as scientifically meritorious, with the strengths identified outweighing the weaknesses.
- **Relative impact**
  - FY12 PRMRP applications will be compared to identify those projects with the highest relative potential impact.
- **Relevance to program objectives**
  - Whether the proposed research project supports the vision of the PRMRP to “Improve the health and well-being of all military service members, veterans, and beneficiaries.”

### **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 [title page](#) of this Program Announcement/Funding Opportunity.

## **E. Notification of Application Review Results**

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

## **IV. ADMINISTRATIVE ACTIONS**

After receipt of pre-applications from CDMRP eReceipt or applications from Grants.gov, the following administrative actions may occur:

### **A. Rejection**

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- Submission of an application for which a letter of invitation was not received.
- **Partnering PI Option:** All associated (Initiating and Partnering PI) applications are not submitted by the deadline.

### **B. Modification**

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI 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 pre-application or application:

- A FY12 PRMRP JPRP member is named as being involved in the research proposed or is found to have assisted 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 FY12 PRMRP JPRP members can be found at <http://cdmrp.army.mil/prmrp/panels/panel12>.
- 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 & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- The proposed research is a clinical trial.
- The proposed research project is not relevant to any of the Congressionally directed FY12 PRMRP topic areas.
- The PI(s) does not meet the eligibility criteria.

## **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 U.S. 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, 2013. 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 D, for general information regarding administrative and national policy requirements.

## **C. Reporting**

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

Quarterly technical progress reports may be required.

## **D. Award Transfers**

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

## **VI. AGENCY CONTACTS**

### **A. CDMRP Help Desk**

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as 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](mailto: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](mailto: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	PI/Initiating PI Completed	Partnering PI Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.		
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.		
	Upload Supporting Documentation (Support.pdf) as Attachment 2.		
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.		
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.		
	Upload Statement of Work (SOW.pdf) as Attachment 5.		
	Upload Impact Statement (Impact.pdf) as Attachment 6.		
	Upload Military Relevance Statement (MilRel.pdf) as Attachment 7.		
	Upload Letters Confirming Access to Military or VA Population(s) (Access.pdf) as Attachment 8.		
	Upload Data and Research Resources Sharing Plan (SharingPlan.pdf) as Attachment 9.		
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.		
	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.		