# **Program Announcement**

### **Department of Defense Congressionally Directed Medical Research Programs**

**Peer Reviewed Medical Research Program** 

**Investigator-Initiated Research Award** 

Funding Opportunity Number: W81XWH-11-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), 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.

## TABLE OF CONTENTS

I.	Fu	Funding Opportunity Description		
	A.	Program Description		
	B.	FY11 PRMRP Congressionally Directed Topic Areas	3	
	C.	Award Information	3	
	D.	Eligibility Information	5	
	E.	Funding	6	
II.	Su	bmission Information	7	
	A.	Where to Obtain Application Package	7	
	B.	Pre-Application Submission Content and Form	7	
	C.	Application Submission Content and Form	8	
	D.	Submission Dates and Times	12	
	E.	Other Submission Requirements	12	
III.	Ap	plication Review Information		
	A.	Application Review and Selection Process	13	
	B.	Application Review Criteria	13	
	C.	Recipient Qualification	16	
	D.	Application Review Dates		
	E.	Notification of Application Review Results	16	
IV.	Administrative Actions			
	A.	Rejection	16	
	B.	Modification	17	
	C.	Withdrawal	17	
	D.	Withhold	17	
V.	Award Administration Information			
	A.	Award Notice	18	
	B.	Administrative and National Policy Requirements	18	
	C.	Reporting	18	
	D.	Award Transfers	18	
VI.	Agency Contacts			
	A.	CDMRP Help Desk	18	
	B.	Grants.gov Contact Center	18	
VII.	App	olication Submission Checklist	19	

#### 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 Neuroblastoma

Chronic migraine and post-traumatic headache Osteoporosis and related bone disease

Drug abuse Paget's disease

Dystonia Pancreatitis

Epidermolysis bullosa Pheochromocytoma

Epilepsy Polycystic kidney disease
Fragile X syndrome Posttraumatic osteoarthritis

Inflammatory bowel disease Scleroderma

Interstitial cystitis Social work research

Listeria vaccine for infectious disease Tinnitus

Lupus

#### C. Award Information

The PRMRP Investigator-Initiated Research Award is intended to support studies that will make an important contribution toward understanding mechanisms of initiation, or progression of

and/or improving patient care for a disease or a condition related to at least one of the congressionally directed FY11 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. Observations that drive a research idea may be derived from a laboratory discovery, population-based studies, or a clinician's first-hand knowledge of patients and anecdotal data.

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

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 USAMRMC Office of Research Protections (ORP), Human Research Protection Office (HRPO), and the local 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. Refer to General Application Instructions, Appendix 5, for general regulatory requirements.

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 FY11 PRMRP Clinical Trial Award mechanism.

Partnering PI option: As a method to bring a new perspective to research and facilitate progress in the field by collaborative effort, the FY11 PRMRP is offering a Partnering PI option for this award mechanism. The results of this partnering project should significantly advance a project beyond what would be possible through individual efforts. Two investigators, each of whom will be designated a PI, will work synergistically on a single project. 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. 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 collaborative efforts are strongly encouraged.

Utilizing this option requires a multi-institutional approach. Therefore, the two PIs must be from distinct institutions. 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 the proposed research project.

One member of the team will be identified as the Initiating PI, who will be responsible for the majority of the administrative tasks associated with application submission. The other member will be identified as the Partnering PI and will need to complete administrative tasks associated with application submission. Separate awards will be made to each PI's institution. Additional collaborators may be included but will not be designated PIs.

**Encouraged DOD alignment:** Relevance to the health care needs of the 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 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 <a href="http://www.wpafb.af.mil/afrl">http://www.wpafb.af.mil/afrl</a>

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

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

Defense Technical Information Center <a href="http://www.dtic.mil">http://www.dtic.mil</a>

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

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 <a href="http://www.med.navy.mil/">http://www.med.navy.mil/</a>

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics http://www.acq.osd.mil/

U.S. Army Medical Research Acquisition Activity <a href="http://www.usamraa.army.mil">http://www.usamraa.army.mil</a>

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

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

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
- Equipment
- Clinical research costs (Clinical trials are not supported)
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

The CDMRP expects to allot approximately \$25.875M of the \$50M FY11 PRMRP 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 (<a href="https://cdmrp.org/">https://cdmrp.org/</a>) and (2) application submission through Grants.gov (<a href="https://www.grants.gov/">http://www.grants.gov/</a>).

Partnering PI Option: One partner will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as the Partnering PI. Initiating and Partnering PIs each have different submission requirements; however, 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 and 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 a letter of invitation via email from CDMRP. The letter will provide the information necessary to begin application submission through 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 (<a href="http://www.grants.gov/">http://www.grants.gov/</a>) basic search using the Funding Opportunity Number: W81XWH-11-PRMRP-IIRA.

### B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI (or the Initiating PI for the Partnering PI option) through the CDMRP eReceipt System (<a href="https://cdmrp.org/">https://cdmrp.org/</a>). 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 <a href="https://edmrp.org">help@cdmrp.org</a> 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

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

#### • 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 (<a href="http://www.grants.gov/">http://www.grants.gov/</a>).

**Partnering PI Option:** The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and each Partnering PI. Initiating and Partnering PIs will each be assigned unique and separate 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 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., 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.
- **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.
- 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*.
  - o 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).
  - o List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
  - o 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 US Army Medical Research and Materiel Command (USAMRMC). Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract 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 they must be included. 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 FY11 PRMRP topic area(s) addressed by the proposed research project. Describe the proposed research project including the following elements: Background, hypothesis or objective, study design, and the relevance of the project to at least one FY11 PRMRP topic area(s). If utilizing the Partnering PI option,

articulate how the two investigators will work synergistically on the proposed

research project and communication plan.

- 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 a comprehensive overview of the proposed research project that can be readily understood by lay persons. Clearly describe the central critical problem or quantion to be addressed the innervative expect of the research and the relevance of
  - question to be addressed, the innovative aspect of the research, and the relevance of the project to at least one FY11 PRMRP topic area(s). 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., for detailed information.

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

• Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf."

Explain why the proposed research project in the FY11 PRMRP topic area(s) addressed is important and relevant to understanding the causes and progression of the disease or condition, and/or to developing improvements in patient care or quality of life.

**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. Articulate the long-term anticipated advantages to understanding the causes and progression of disease, and/or to the development of new diagnostic or treatment options.

• 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: Human Subjects Plan (if applicable) (one-page limit): Upload as "HumSub.pdf."

Describe the availability of the proposed study population, whether the PI and/or key personnel of the application currently have access to this population, and how access to potential human subjects will be coordinated. Outline the recruitment strategy and past successes for recruiting similar populations.

• Attachment 9: Approval for Access to Military Populations (if applicable): Upload as "MilPop.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-controlled study materials; databases; and/or restricted facilities (e.g., biological or chemical containment facilities).

- **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."
    - o **Partnering PI Option:** Include the Biographical Sketch for the Partnering PI.
  - Key Personnel Current/Pending Support (no page limit): Upload as "Support LastName.pdf."
    - o **Partnering PI Option:** Include the Current/Pending Support for the Partnering PI.
- **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."

Partnering PI Option: Initiating and Partnering PIs must each submit a budget and justification as part of their separate Grants.gov application packages. The Research & Related Budget form for the Initiating PI should not include budget information for the Partnering PI.

- **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.

### **Partnering PI Option: Application Components for the Partnering PI:**

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., for detailed information on completing the SOW.

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

- **3. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., 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 as part of their separate Grants.gov application packages. The Research & Related Budget form for the Partnering PI should not include budget information for the Initiating PI.
- **4. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- **5. 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 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.

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:

#### 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.
- o If applicable, whether the human subjects plan is appropriate.
- Whether the proposed research can be completed in the proposed period of performance.

#### • Impact

- How the proposed research project in the FY11 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 the scientific rationale supports the project as demonstrated by a critical review and analysis of the literature, supporting data, and logical reasoning.
- How the hypotheses or objectives, aims, experimental design, methods, data collection procedures and analyses are developed.
- How adequate is the statistical plan, including sample size projections and power analysis, for the study and all proposed correlative studies.
- How consistent is the data analysis plan with the study objectives.
- If applicable, how well the clinical study is constructed and whether it is appropriate for the study objectives (to include the appropriateness of the study population).

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

### • Budget

• Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

#### • Environment

- o 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).
- o The quality and extent of institutional support.

#### Personnel

 How the levels of effort by the PI and other key personnel are appropriate to ensure success of this project.

- o Partnering PI Option (if applicable)
  - Evidence that both the Initiating PI and the Partnering PI had equal intellectual input into the development of the research plan, and will contribute substantially to its implementation.
  - Evidence that the Initiating PI and the Partnering PI are from distinct institutions (multi-institutional).

## 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 the proposed research project has the potential to make an important contribution to research and/or patient care.
- o Partnering PI option (if applicable):
  - Whether the project is synergistic, i.e. greater than what can be accomplished in the laboratory of a single PI
  - Whether the project is multi-institutional

### Military relevance

- o How well the proposed research project is responsive to documented health care needs of the military service members, veterans, and beneficiaries.
- Whether the PI has access to the proposed study population (active duty military, military families, veteran population[s], and/or non-military), if applicable, and how this population is appropriate for the proposed study objectives.
- How the non-military population to be used for the proposed research project simulates the targeted military population (i.e. military service members, veterans, and beneficiaries), if applicable.
- 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 (search PRMRP awards at <a href="http://cdmrp.army.mil/search.aspx">http://cdmrp.army.mil/search.aspx</a>), and therefore would 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 strengths identified outweighing the weaknesses.

### • Relative impact

o FY11 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 <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 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 application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter of invitation was not received.
- 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.
- 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 pre-application or 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 JPRP members may be found at <a href="http://cdmrp.army.mil/prmrp/panels/panel11">http://cdmrp.army.mil/prmrp/panels/panel11</a>.
- 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 or contains a clinical trial.
- The proposed research project is not relevant to any of the congressionally directed FY11 PRMRP topic areas.
- The PI does not meet the eligibility criteria.
- Partnering PI option: The Initiating and Partnering PIs are not from distinct institutions.

#### 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

Quarterly technical progress reports may be required. 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.

#### 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	PI (or Initiating PI) Completed	Partnering PI Completed (if applicable)
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.  Upload Technical Abstract (TechAbs.pdf) as Attachment 3.  Upload Public Abstract (PublicAbs.pdf) as Attachment 4.		
Attachments Form	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 Human Subject Plan (HumSub.pdf), if applicable, as Attachment 8.		
	Upload Approval for Access to Military Populations (MilPop.pdf), if applicable, as Attachment 9.		
	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
Research & Related Senior/Key Person Profile	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.		
(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.		