Program Announcement

Defense Health Program

Defense Medical Research and Development Program

Department of Defense

Congressionally Directed Medical Research Programs

Peer Reviewed Medical Research Program

Technology/Therapeutic Development Award

Funding Opportunity Number: W81XWH-12-PRMRP-TTDA

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 6, 2012
- **Application Submission Deadline:** 11:59 p.m. ET, June 26, 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 $594.5 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 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 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 Technology/Therapeutic Development Award is product-driven award intended to provide support for the translation of promising preclinical findings into products for clinical applications, including prevention, detection, diagnosis, patient care, and/or quality of life, in at least one of the Congressionally directed FY12 PRMRP topic areas. Products in development should be responsive to the health care needs of military service members, veterans, and/or beneficiaries.

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

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

- Developing and validating clinical guidance/guidelines for standard of care;
- Testing new therapeutic modalities (agents, delivery systems, and chemical modification of lead compounds) using established or validated preclinical systems (PIs seeking funding for establishing or validating preclinical systems should apply to the Investigator-Initiated Award mechanism);
- Designing and implementing pilot or full-scale Good Manufacturing Practice (GMP) production of therapeutics and/or delivery systems for use in advanced preclinical and initial clinical trials;
- Developing pharmacologic agents through adsorption, distribution, metabolism, excretion, and toxicity (ADMET) studies;
- Developing pharmacologic agents to Investigational New Drug (IND) stage for initiation of Phase I clinical trials;
- Developing prototype devices to Investigational Device Exemption (IDE) stage for initiation of clinical trials; and
- Optimizing diagnostic or treatment devices for field deployment.

Applications must include relevant data that supports 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 U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to 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. Refer to General Application Instructions, Appendix 5, for general regulatory requirements.

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. PIs seeking funding for a clinical trial should apply to the FY12 PRMRP Clinical Trial Award mechanism.

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 (VA) research laboratories and programs. While not an exhaustive list, the following websites may be useful in identifying information about ongoing DoD and/or VA 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 Medical Research and Development Program
http://dmrdp.fhpr.osd.mil/home.aspx

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

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
https://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

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

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 **$1.5M** 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.

Refer to the General Application Instructions, Section II.C., 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 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)
- Travel between collaborating organizations
- Travel costs of up to $1,800 per year to attend scientific/technical meetings

The CDMRP expects to allot approximately $6.7M of the $50M FY12 appropriation to fund approximately 3 Technology/Therapeutic Development 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 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-TTDA.

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 any changes are 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**

  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 or 1-301-682-5507.

- **Required Files – Tab 4**

  Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the FY12 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**

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

- **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 through the Grants.gov portal (http://www.grants.gov/).

Grants.gov application package components: For the Technology/Therapeutic Development 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 (15-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. Describe previous experience most pertinent to this proposal.
     - Hypothesis or Objective: State the hypothesis to be tested or the objective to be reached.
     - Specific Aims: Concisely explain the project's specific aims. These aims should agree with the primary aims and associated tasks described in the Statement of Work. If the proposed work is part of a larger study, present only aims that this award would fund.

- Research Strategy: Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Include a statistical plan with accompanying power analysis, if applicable. Define the specific study outcomes and how they will be measured. Address potential problem areas and present alternative methods and approaches. Provide a well-developed, well-integrated research strategy that supports the translational feasibility and promise of the approach. 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. Describe the availability of the proposed study population and past successes in recruiting similar populations. This award may not be used to conduct clinical trials.

- **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. 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 objectives, study design, and the relevance of the project to the FY12 PRMRP topic area(s).

  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, the innovative aspect of the research, and the relevance of the project to the FY12 PRMRP topic area(s). 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.

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

  Explain how the product in development is important and relevant to the FY12 PRMRP topic area(s) addressed. Describe the ultimate end user(s) of the technology/therapeutic and indicate how the research, if successful, will develop improvements in prevention, detection, diagnosis, patient care and/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 project, and include a definition of the target end user.

  Describe the long-term impact: Articulate the vision for the final product that is in development. Describe the anticipated long-term gains from this research course, and compare to products currently available, if applicable.

- **Attachment 7: Transition Plan (one-page limit):** Upload as "Transition.pdf."

  Provide information on the methods and strategies proposed to move the product to clinical trial and/or delivery to the military or civilian market upon successful completion of the award, including, if applicable, information regarding transfer to a commercial partner(s) for further clinical development. The transition plan should include the components listed below.

  - Details of the funding strategy that will be used to bring the outcomes to clinical trial and/or delivery to the military or civilian market (e.g., specific potential industry partners, specific funding opportunities to be applied for).

- A description of collaborations and other resources that will be used to provide continuity of development. For any industry partners, include a description of prior product development and/or marketing experience.
- A schedule and milestones for bringing the outcome(s) to clinical trial and/or delivery to the military or civilian market, including detailed plans for meeting FDA requirements (if applicable).
- A risk analysis for cost, schedule, manufacturability, and sustainability.
- A description of relevant product patents and intellectual property ownership, and their potential impact on product development.

- **Attachment 8: 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 and/or VA areas of research interest.

- **Attachment 9: 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).

3. **Research & Related Senior/Key Person Profile (Expanded):** 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 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 Numbering 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 background, expertise, and proposed level of effort of the PI 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.
  - How the PI acknowledges potential problems and addresses alternative approaches.
  - If applicable, how well the application provides evidence of availability of and access to the necessary study populations and/or resources.
  - Whether the proposed research can be completed in the proposed period of performance.

- **Impact**
  - How the anticipated short-term outcome(s)/product(s) (intellectual and/or tangible) of the proposed research project will impact the research field of the specified disease/condition.
  - Whether the end user of the outcome(s) is well defined and part of a population relevant to at least one FY12 PRMRP topic area.
  - The degree to which the proposed research project, if successful, will develop a product that is important and relevant to improving prevention, detection, diagnosis, patient care, and/or quality of life.
  - How well the final envisioned product compares to pharmacologic agents, devices, and/or clinical guidance currently available, if applicable.

- **Research Strategy**
  - How the scientific rationale supports the project as demonstrated by a critical review and analysis of the literature, preliminary data, and logical reasoning.
  - How the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
  - The degree to which the expected outcome(s) that will result after completion of the proposed research project are specific and measurable.

- How adequate is the statistical plan, including sample size projections and power analysis, for the study and all proposed correlative studies (if applicable).
- How consistent is the data analysis plan with the study objectives.
- If applicable, how well constructed is the clinical study, and its appropriateness to the study objectives (to include the appropriateness of the study population).

- **Transition Plan**
  - Whether the funding strategy described to bring the outcome(s) to clinical trial and/or delivery to the military or civilian market is appropriate.
  - Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.
  - How the schedule and milestones for bringing the outcome(s) to clinical trial and/or delivery to the military or civilian market, including meeting FDA requirements as applicable, is appropriate.
  - How well the potential risk analysis for cost, schedule, manufacturability, and sustainability is developed.
  - How well the application identifies intellectual property ownership, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development.

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

- **Environment**
  - The appropriateness of the scientific environment for the proposed research.
  - How the research requirements are supported adequately by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - The quality and extent of institutional support.

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of 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 is focused on development of a product (pharmacologic agent, device, or clinical guidance) with the potential to make an important contribution to prevention, detection, diagnosis, patient care, or quality of life in one or more of the FY12 PRMRP topic areas.
     - Whether the transition plan for the product was sufficiently detailed to indicate that the PI understands how to move the product of this award to a clinical trial, to a manufacturer, and/or delivery to the military or civilian market, and is capable of accomplishing the transition.
   - **Military relevance**
     - How responsive the proposed research project is to health care needs of the military service members, veterans, and/or 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 the population/resource is appropriate for the proposed study objectives.
     - How the proposed research project aligns with DoD and/or VA areas of research interest, if applicable.
   - **Program portfolio composition**
     - Whether the proposed study complements the overall balance of research and development within a topic and across topic areas.
   - **Ratings and evaluations from the peer reviewers**
     - Whether the application was assessed as scientifically meritorious, with the strengths 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 applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the application:

- Pre-application is not submitted.
- 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.

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, 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 application:

- A FY12 PRMRP Joint Programmatic Review Panel (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 project is not relevant to any of the Congressionally directed FY12 PRMRP topic areas.
- The proposed research is, or requests funding for, a clinical trial.
- The PI 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

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.	
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 Transition Plan (Transition.pdf) as Attachment 7.	
	Upload Military Relevance Statement (MilRel.pdf) as Attachment 8.	
	Upload Letters Confirming Access to Military or VA Populations (Access.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 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.	