Program Announcement

for the

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-13-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 24, 2013
- **Invitation to Submit an Application:** August 2013
- **Application Submission Deadline:** 11:59 p.m. ET, October 8, 2013
- **Peer Review:** December 2013
- **Programmatic Review:** February 2014

This Program Announcement is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2013 (FY13) Peer Reviewed Medical Research Program (PRMRP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The PRMRP was initiated in fiscal year 1999 (FY99) to provide support for military health-related research of exceptional scientific merit. Appropriations for the PRMRP from FY99 through FY12 totaled $594.5 million (M). The FY13 appropriation is $50M. The PRMRP is administered by the U.S. Army Medical Research and Materiel Command (USAMRMC) through the Congressionally Directed Medical Research Programs (CDMRP).

The vision of the FY13 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 FY13 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. FY13 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 FY13 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 FY13 PRMRP Topic Areas are listed below:

- Chronic Kidney Disease
- Chronic Migraine and Posttraumatic Headaches
- Composite Tissue Transplantation
- Dengue
- DNA Vaccine Technology for Postexposure Prophylaxis
- Dystonia
- Epilepsy
- Food Allergies
- Fragile X Syndrome
- Hantavirus
- Hereditary Angioedema
- Inflammatory Bowel Disease
- Interstitial Cystitis
- Leishmaniasis
- Lupus
- Malaria
- Nanomedicine for Drug Delivery Science
- Pancreatitis
- Polycystic Kidney Disease
- Post-Traumatic Osteoarthritis
- Pulmonary Hypertension
- Rheumatoid Arthritis
- Scleroderma
- Tinnitus

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 FY13 PRMRP Topic Areas.

The rationale for a research idea may be derived from a laboratory discovery, population-based studies, a clinician's first-hand knowledge of patients, or anecdotal data. Applications must include relevant data that support the rationale for the proposed study. These data may be unpublished or from the published literature.

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. ***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 FY13 PRMRP Clinical Trial Award mechanism.

Military Relevance: Relevance to the health care needs of military service members, Veterans, and beneficiaries is a key feature of this award. Investigators are encouraged to consider the following characteristics as examples of how a project may demonstrate military relevance:

- Explanation of how the project addresses an aspect of the target disease/condition that has direct relevance to military service members, Veterans, or other military health system beneficiaries
- Use of military or Veteran populations or data in the proposed research
- Collaboration with Department of Defense (DoD) or Department of Veterans Affairs (VA) investigators
- Involvement of military consultants (Army, Air Force) or specialty leaders (Navy, Marine Corps) to the Surgeons General in a relevant specialty area

PIs are strongly encouraged to collaborate, integrate, and/or align their research projects with DoD and/or VA research laboratories and programs. The following websites may be useful in identifying information about ongoing DoD and VA areas of research interest within the FY13 PRMRP Topic Areas:

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

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

Combat Casualty Care Research Program
https://ccc.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

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. Department of Defense Blast Injury Research Program
https://blastinjuryresearch.amedd.army.mil/

U.S. Naval Research Laboratory
http://www.nrl.navy.mil

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

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

Partnering PI Option: As a method to bring new perspectives to research and facilitate progress in the field through collaborative efforts, the FY13 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 s/he 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. As noted above, collaborations with DoD researchers and clinicians are encouraged, and ***partnerships that include a DoD researcher or clinician as one of the PIs will be considered in determining relative military relevance during programmatic review.***

A separate Grants.gov submission is required for each partner, even if both PIs are at the same organization. Details are provided in Section II.C., Application Submission Content and Form. 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 PIs.

Use of Active Duty Military and VA Populations: If the proposed research plan involves access to active duty military and/or VA patient populations or resources, the PI is responsible for establishing such access. If possible, access to target active duty military and/or VA patient populations/resources should be confirmed at the time of application submission by inclusion of a letter of support, signed by the lowest ranking person with approval authority, for studies involving active duty military service members, Veterans, military and/or VA controlled study materials, and military and/or VA databases. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources. Note that access to a Veteran population for clinical studies may only be obtained by either collaboration with a VA investigator where the VA investigator has a substantial role in the research, or by advertising to the general public.

Use of Human Subjects and Human Anatomical Substances: All DoD-funded research involving new and ongoing research with human subjects and human anatomical substances must be reviewed and approved by the USAMRMC Office of Research Protections, Human Research Protection Office (HRPO) in addition to the Institutional Review Board (IRB) of record. IRB approval at the time of submission is not required. Time and level of effort for IRB approval(s) should be considered in planning. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is supported by the DoD. These laws and directives will require information in addition to that supplied to the IRB. In addition to time for IRB approval(s), allow for a minimum of 2-3 months for HRPO review and approval processes. Refer to General Application Instructions, Appendix 5, for more information.

The CDMRP intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity 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.
    - **Partnering PI Option:** Any two investigators at or above the level of Assistant Professor (or equivalent), each of whom brings complementary skills and perspectives to the research project.

- Cost sharing/matching is not an eligibility requirement.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations. Both intramural (i.e., DoD) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity.
- 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.
- If applying under the traditional ***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 period of performance, plus indirect costs as appropriate. A separate award will be made to each PI's organization.
- 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.4., for budget regulations and instructions for the Research & Related Budget. ***For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply and are so noted in Section II.C.4. of the General Application Instructions.***

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. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Clinical research costs (clinical trials are not supported)

- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to $1,800 per year to attend scientific/technical meetings in addition to the required meeting described above

Intramural (DoD) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. However, all applicants to this Program Announcement/ Funding Opportunity must submit through Grants.gov. Therefore, all applicants must be familiar with Grants.gov requirements, including the need for System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural organizations will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Direct transfer of funds from the recipient to a federal organization or agency is not allowed except under very limited circumstances. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers.

The CDMRP expects to allot approximately $26.775M of the $50M FY13 PRMRP appropriation to fund approximately 21 Investigator-Initiated Research 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 two-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. For applications submitted under the 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. 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 applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application.

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-13-PRMRP-IIRA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI (for single PI applicants) or Initiating PI (for applicants submitting under the Partnering PI Option) 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 pre-application should be the same as those intended for the subsequent application submission. 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 (COI) – Tab 3**
- **Partnering PI Option:** The Initiating PI must enter the contact information for the Partnering PI in the Partnering PI section.

  FY13 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 (301)-682-5507.
- **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. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application. ***Note: At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.***

The Preproposal Narrative should include the following:

- **Topic Area:** Indicate how the proposed project relates to at least one FY13 PRMRP Topic Area.
- **Research Idea:** Clearly articulate the rationale for the project by presenting the ideas and reasoning behind the proposed research; include relevant literature citations.
- **Research Strategy:** State the hypothesis to be tested or the objective to be reached. State the project's specific aims and briefly describe the experimental approach. 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 FY13 PRMRP Topic Areas and its related research field(s) and patient population(s).

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

- References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal 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 used in the Preproposal Narrative.
- PI Biographical Sketch (four-page limit per individual): Include a biographical sketch for the PI only or, if applying under the Partnering PI Option, the Initiating and Partnering PIs only.

- **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 DHP and the PRMRP, pre-applications will be screened based on the following criteria:

  - **Research Idea:** How well the rationale for the research idea is supported by the reasoning and information presented as background.
  - **Research Strategy:** How well the specific aims and proposed methodology support the research idea and 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 FY13 PRMRP Topic Area(s) addressed.
- **Programmatic relevance:** Whether the proposed research idea supports the objectives of the PRMRP.

- **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. The estimated timeframe for notification of invitation to submit an application is 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 the Partnering PI, even if the PIs are located within the same organization. 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 (for single PI applicants) 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., for detailed information.

2. **Attachments Form**

   - **Attachment 1: Project Narrative (12-page limit):** Upload as "ProjectNarrative.pdf." The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an

unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature. Describe previous experience most pertinent to the project. Include relevant preliminary data; these data may be unpublished or from the published literature. 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. Describe the statistical and other data analyses to be used to justify the number of research subjects (animal or human) and assess the collected data. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, describe the study population and include a detailed plan for the recruitment of human subjects or the acquisition of samples. ***Clinical trials are not allowed under the Investigator-Initiated Research Award.*** 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 of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal 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 whether or not Government-furnished facilities or equipment are proposed for

use. If so, reference should be made to the original or present Government 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, confirming 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.
- Letters Confirming Access to Military or VA Patient Populations or Resources (if applicable): If the proposed research plan involves access to active duty military and/or VA patient populations or resources, include a letter of support, signed by the lowest ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about the CDMRP expectations for making data and research resources publicly available.

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

  Describe the proposed research project including the following elements:

  Background, rationale, hypothesis or objective, study design, long-term and short-term impact to the relevant research field and patient population(s), and the relevance of the project to at least one FY13 PRMRP Topic Area.

  The technical abstract is used by all reviewers; of particular importance, programmatic reviewers typically do not have access to the full application and rely on the technical abstract for appropriate description of the project's key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

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

  State the FY13 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. 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, including guidance on appropriate SOW formats.

  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 FY13 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. Compare to the information known/products currently available, if applicable. Explain the long-range vision for how the research will impact clinical care.

- **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 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(s). 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.

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 Previous/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's biographical sketch, if applying under the Partnering PI Option.
    - Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
        - Include the Partnering PI's previous/current/pending support document, if applying under the Partnering PI Option.

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 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, even if they are located within the same organization. The combined total direct costs for the Initiating and Partnering PIs' budgets cannot exceed $750,000.***

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.

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., 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., 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 PIs' budgets cannot exceed $750,000.

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 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. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an "Active" status 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 makes recommendations for funding to the Commanding General, USAMRMC, based on technical merit, the relevance to the mission of the DHP and the 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. Panel members sign a non-disclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations 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 panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment 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 listed in decreasing order of importance:

   - **Research Strategy and Feasibility**
     - How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, supporting data, and logical reasoning.
     - How well the hypotheses or objectives and aims are developed.
     - How well the experimental design, methods, data collection procedures, and analyses are developed and support completion of the aims.
     - How well the application 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.
     - If the application includes the Partnering PI Option, how well the research project is supported by the nature of the collaboration.
     - Whether the research can be completed within the proposed period of performance.

   - **Impact**
     - For the FY13 PRMRP Topic Area (s) addressed, how the proposed research project, if successful, will:

        - Make important scientific advances in the relevant field of research,
        - Promote greater understanding of the causes and progression of the relevant disease(s)/condition(s),
        - Promote the development of improvements in patient care, and/or
        - Promote the development of improvements in quality of life.
    - How well the project addresses a critical problem in research or patient care for a FY13 PRMRP Topic Area.
    - To what degree the proposed project could, if successful, make a significant impact on the lives of relevant patient populations in the short-term or long-term.

- **Personnel**
    - How the background and expertise of the PI(s) and other key personnel demonstrate their ability to perform the proposed work.
    - How the levels of effort by the PI(s) and other key personnel are appropriate to ensure the successful conduct of the project.
    - How the PI(s)'s record(s) of accomplishment demonstrates his/her ability to accomplish the proposed work.
    - For applications submitted under the Partnering PI Option (if applicable):
        - The potential for the proposed partnership to advance research beyond what would be possible through individual efforts.
        - How well the skills and perspectives of the Initiating and Partnering PI complement each other.
        - How well the application supports the requirement that the partners have equal intellectual input into the design of the project.

In addition, 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 make funding recommendations, the following criteria are used by programmatic reviewers:
    a. **Ratings and evaluations of the peer reviewers**
    b. **Relevance to the mission of the DHP and PRMRP, as evidenced by the following:**
        - Adherence to the intent of the award mechanism
        - Military relevance
        - Program portfolio composition
        - Relative impact
        - Relevance to program objectives

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

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 peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from the CDMRP eReceipt System 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:

- Submission of an application for which a letter of invitation was not received.

- 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.
- **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 FY13 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 FY13 PRMRP JPRP members can be found at http://cdmrp.army.mil/prmrp/panels/panel13.
- 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.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.

- The proposed research is, or includes, a clinical trial.
- The proposed research project is not relevant to any of the Congressionally directed FY13 PRMRP Topic Areas.
- The PI or, if applicable, Partnering 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 USAMRAA 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, 2014. 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.

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: 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: 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 or by responding to the prompt provided by Grants.gov when first downloading the application package. 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	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.		
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
	Attach PI Previous/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 Previous/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.		