

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Peer Reviewed Medical Research Program

Investigator-Initiated Research Award

Funding Opportunity Number: W81XWH-10-PRMRP-IIRA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Appropriations History: 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 FY09 (excluding FY07, in which no appropriation was made) totaled \$444.5 million (M). The FY10 appropriation is \$50M.

FY10 Objectives: The vision of the FY10 PRMRP is to identify and fund the best medical research to protect and support warfighters, veterans, and all beneficiaries, and to eradicate diseases that impact these populations. The PRMRP challenges the scientific and clinical communities to address one of the FY10 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 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; economics; and strategic research, such as studies designed to shape the development of or to validate clinical policy or guidance. Interdisciplinary and integrative health approaches are welcomed.

B. FY10 PRMRP Topic Areas

All applications for PRMRP funding must specifically and clearly address at least one of the topic areas as directed by Congress, and must have direct relevance to the health care needs of the Armed Forces, their family members, and/or the U.S. veteran population. *If the proposed research has no relevance to currently advertised 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 FY10 PRMRP topic areas as provided by Congress are listed below.

Chronic Migraine and Post-traumatic Headache	Neuroblastoma
Dystonia	Osteoporosis and related bone disease
Drug Abuse	Paget's Disease
Epilepsy	Pheochromocytoma
Fragile X Syndrome	Polycystic Kidney Disease
Inflammatory Bowel Disease	Post-traumatic Osteoarthritis
Interstitial Cystitis	Scleroderma
Listeria vaccine for infectious disease	Social Work Research
Lupus	Tinnitus
Mesothelioma	

C. Award Description

The PRMRP Investigator-Initiated Research Award (IIRA) mechanism was first offered in FY99. Since then, 2,481 Investigator-Initiated Research Award proposals have been received, and 239 have been recommended for funding.

This award mechanism 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 FY10 PRMRP topic areas. Research proposals should be responsive to the health care needs of the Armed Forces, their family members, and/or the U.S. veteran population. All applications must specifically and clearly address the military relevance of the proposed research. Collaboration with military and/or US Department of Veterans Affairs (VA) researchers and/or clinicians is encouraged.

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 data relevant to the FY10 PRMRP topic area(s) addressed that support the rationale for the proposed study. These data may be unpublished and/or from the published literature.

This award may not be used to conduct clinical trials. Principal Investigators (PIs) seeking funding for a clinical trial should apply to the FY10 PRMRP Clinical Trial Award mechanism.

Use of human subjects and human biological substances: All DOD-funded research involving human subjects and human biological substances must be reviewed and approved by the USAMRMC Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to local Institutional Review Boards (IRBs). 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. These laws and directives are rigorous and detailed, and will require information in addition to that supplied to the local review board. Allow a minimum of 6 months for regulatory review and approval processes for studies involving human subjects.

Partnering PI option: As a method to bring a new perspective to research and facilitate progress in the field by combined effort, the FY10 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 will work synergistically on a single project, each of whom will be designated as a PI. 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 in a project in a significant way, as well as 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 organizations. 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 this award.

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 as PIs. Multidisciplinary projects are allowed.

Encouraged DOD alignment: Relevance to the health care needs of the Armed Forces, their family members, and/or the U.S. veteran population 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 VA research laboratories and programs. The following websites may be useful in identifying information about ongoing DOD areas of research interest within the FY10 PRMRP topic areas:

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

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

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

Defense Technical Information Center
<http://www.dtic.mil>

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

Navy and Marine Corps Public Health Center
<http://www-nmcphec.med.navy.mil/>

Office of Naval Research
<http://www.med.navy.mil/>

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics

<http://www.acq.osd.mil/>

U.S. Army Medical Research Acquisition Activity

<http://www.usamraa.army.mil>

U.S. Army Medical Research and Materiel Command

<https://mrmc.amedd.army.mil>

U.S. Army Research Laboratory
<http://www.arl.army.mil>

U.S. Naval Research Laboratory
www.nrl.navy.mil

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

D. Eligibility

PIs at or above the level of Assistant Professor (or equivalent) are eligible to submit applications. Refer to General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is 3 years.
- The maximum allowable funding for the entire period of performance is \$725,000 in direct costs.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 3-year period of performance.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with the organization's negotiated rate agreement.
- **Partnering PI Option:** The combined total funding for the Initiating PI and the Partnering PI may not exceed \$725,000 for direct costs for up to a 3-year performance period, plus indirect costs as appropriate.

Within the guidelines provided in the General Application Instructions, funds can cover:

- 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
- Other direct costs as described in the General Application Instructions for the Detailed Budget and Justification

In addition, each PI must request travel funds, up to \$1,800, to attend one Military Health Research Forum (MHRF) during the award period of performance. The MHRF is a CDMRP-sponsored meeting that is typically held every 2-3 years.

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$28.275M of the \$50M FY10 PRMRP appropriation to fund approximately 26 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.

F. Award Administration

Quarterly technical progress reports may be required if the proposed research project includes recruitment of human subjects. Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2011. Refer to the General Application Instructions, Appendix 4, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

- **Pre-application Submission Deadline: 5:00 p.m. Eastern time (ET), March 11, 2010**
- **Invitation to Submit an Application: June 2010**
- **Application Submission Deadline: 11:59 p.m. ET, August 5, 2010**
- **Scientific Peer Review: September 2010**
- **Programmatic Review: December 2010**

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline.

III. SUBMISSION PROCESS

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/>). *Applications will be invited based on pre-application screening.*

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, both PIs should contribute significantly to the development of the proposed research project including the project narrative, Statement of Work, and other required statements. The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PI. If an application is invited, the Initiating PI will receive a letter of invitation via email by the CDMRP eReceipt system. The letter will provide the information necessary to begin application submission through Grants.gov. Each Partnering PI will subsequently be notified separately by email. Please note that each 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.

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.

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 eReceipt help desk at help@cdmrp.org or 301-682-5507.

A. Step 1 – Pre-Application Components

All pre-application components must be submitted through the CDMRP eReceipt system by **5:00 p.m. ET on the deadline**. 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.*

Pre-application reviewers will be blinded to the identity of the PI, the PI's organization, and collaborators. Due to the blinded nature of the review process, identifying or making references to the PI or the organization in the Preproposal Narrative and Supporting Documentation is prohibited and will result in administrative rejection of the pre-application. In addition, the use of "I," "our," "this institution," or similar phrases that make it possible to identify the PI and/or organization (e.g., through the references listed) will result in administrative rejection of the proposal.

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 for additional information on pre-application submission.)

- **Proposal Information – Tab 1**
- **Proposal 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(s) in the Partnering PI section.

- **Required Files – Tab 4**

Preproposal Narrative (two-page limit): The Preproposal Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

The Preproposal Narrative should include the following:

- **Rationale:** Clearly articulate the rationale for the project by presenting the ideas and reasoning behind the proposed research; include relevant literature citations.
- **Research Idea:** State the hypothesis to be tested or the objective to be reached. State the project's specific aims and briefly describe the experimental design and methodology.
- **Impact:** Describe the potential short- and long-term impact of the results of the proposed study on at least one of the FY10 PRMRP topic areas.

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 all relevant references 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). The inclusion of Internet URLs to references is encouraged.
- **Submit Pre-Application – Tab 5**

- **Other Documents Tab**

Not Applicable.

Pre-Application Screening: Pre-applications will be screened by scientific peer reviewers and the PRMRP Joint Programmatic Review Panel (JPRP) members based on the following criteria:

- **Adherence to the intent of the award mechanism**
- **Impact:** Whether the potential immediate and long range outcome(s)/product(s) (intellectual and/or tangible) of the proposed research, if successful, will impact the field of research and/or patient care in the FY10 PRMRP topic area(s) addressed.
- **Programmatic relevance:** Whether the proposed research idea supports the objectives of the PRMRP, is responsive to at least one FY10 PRMRP topic area, and aids the program in achieving a broad portfolio.
- **Research idea:** How well the proposed project addresses a central critical problem or question in at least one of the FY10 PRMRP topic areas.

Following the pre-application screening, PIs will be notified of whether or not they are invited to submit an application; however, they will not receive feedback (e.g., strengths and weaknesses) on their pre-application.

B. Step 2 – Application Components

Applications will not be accepted unless the PI (the Initiating PI under the Partnering PI option) has received a letter of invitation.

Applications are submitted by the Authorized Organizational Representative (AOR) through Grants.gov (<http://www.grants.gov/>). Applications must be submitted **by 11:59 p.m. ET on the deadline.**

Each application submission must include the completed application package of forms and attachments identified in Grants.gov for this Program Announcement/Funding Opportunity.

Partnering PI Option: *For contractual reasons, 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 PI must submit his/her Grants.gov application package using only his/her unique log number.*

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

The Grants.gov application package consists of the following components (Refer to the General Application Instructions, Section II.B., for additional information on application submission):

- 1. SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.B., 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. Applications must include preliminary data relevant to the FY10 PRMRP topic area(s) to be addressed and the proposed research project.

- **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 subjects or the acquisition of samples. ***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. ***Each component has no page limit unless otherwise noted.***
 - **References Cited:** List all relevant references 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). The inclusion of Internet URLs to references is encouraged.
 - **List of Acronyms and Symbols:** Provide a list of acronyms and symbols (e.g., PCR = polymerase chain reaction).
 - **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. If the PI is a practicing clinical physician, the institution must clearly demonstrate a commitment to the clinician’s research.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the 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. PIs utilizing the Partnering PI option should include an Intellectual and Material Property Plan.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”
State the FY10 PRMRP topic area 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 FY10 PRMRP topic area. If utilizing the Partnering PI option, articulate the synergy of the proposal research project.
- **Attachment 4: Public Abstract (one-page limit):** Upload as “PublicAbs.pdf.”
State the FY10 PRMRP topic area addressed by the proposed research project. Clearly describe, in a manner readily understood by lay persons, the central critical problem or question to be addressed, the innovative aspect of the research, and the relevance of the project to at least one FY10 PRMRP topic area. If utilizing the Partnering PI option, articulate the synergy of the proposal research project. Do not duplicate the technical abstract; the public abstract is used by consumer peer reviewers along with other components of the application package.
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.”
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.* Refer to the General Application Instructions, Section II.B., for detailed information.
- **Attachment 6: Detailed Budget and Justification (no page limit):** Upload as “Budget.pdf.” Use the Detailed Budget and Justification form (available for download on the Full Announcement page in Grants.gov). Refer to the General Application Instructions, Section II.B., for detailed information.
Partnering PI Option: *Initiating and Partnering PIs must each submit a unique and separate detailed budget and justification.*
- **Attachment 7: Subaward Detailed Budget and Justification (if applicable) (no page limit):** Use a separate Detailed Budget and Justification form for each subaward budget. Combine into a single file and upload as “SubBudgets.pdf.”

Refer to the General Application Instructions, Section II.B., for detailed information.

- **Attachment 8: Impact Statement (one-page limit):** Upload as “Impact.pdf.”

Explain why the proposed research project in the FY10 PRMRP topic area(s) addressed is important and relevant to understanding the causes and progression, and/or to developing improvements in patient care and 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 9: Military Relevance Statement (one-page limit):** Upload as “MilRel.pdf.”

Demonstrate how the proposed study is responsive to the health care needs of the Armed Forces, their family members, and/or the U.S. veteran population. If active duty military, military families, 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 using 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., Armed Forces, their family members, and/or the U.S. veteran population). Show how the proposed study complements ongoing DOD areas of research interest in the FY10 PRMRP topic area(s) addressed.

- **Attachment 10: Human Subject 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 proposal currently have access to this population, and how access to potential participants will be coordinated. Outline the recruitment strategy and past successes for recruiting similar populations.

- **Attachment 11: 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.B., 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. Project/Performance Site Location(s) Form: Refer to the General Application Instructions, Section II.B., 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 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 (s) should be noted for each task.*
- **Attachment 6: Detailed Budget and Justification:** Use the Detailed Budget and Justification form (available for download on the Full Announcement page in Grants.gov). Upload as “Budget.pdf.” *Initiating and Partnering PIs must each submit a unique and separate detailed budget and justification.*
- **Attachment 7: Subaward Detailed Budget and Justification (if applicable):** Use a separate Detailed Budget and Justification form for each subaward budget. Combine into a single file and upload as “SubBudgets.pdf.”

3. Project/Performance Site Location(s) Form

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific 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 scientific merit, the overall goals of the program, and 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 may be found at <http://cdmrp.army.mil/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 nondisclosure 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. Review Criteria

1. Peer Review: All applications will be evaluated according to the following criteria, which are of equal importance:

- **Feasibility**
 - How the PI acknowledges potential problems and addresses alternative approaches.
 - How the background and expertise of the PI (including the Partnering PI, if applicable) and other key personnel demonstrate their ability to perform the proposed work.
 - How the proposed methods are appropriate to test the hypothesis or achieve the objectives.
 - If applicable, 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 FY10 PRMRP topic area(s) addressed, if successful, will:
 - Make important scientific advances in the field,
 - Promote our 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 constructed is the clinical study and is it appropriate for the study objectives (to include the appropriateness of the study population).
 - If applicable, how well constructed is the clinical study and is it appropriate for the study objectives (to include the appropriateness of the study population).

The following will not be individually scored, but may impact the overall evaluation of the application:

- **Personnel**
 - How the levels of effort by the PI and other key personnel are appropriate to ensure success of this project.
 - Partnering PI Option (if applicable)
 - Evidence that both the Initiating PI and the Partnering PI had equal intellectual input into the development, and will contribute substantially to the implementation of the research plan.
 - Evidence that the Initiating PI and the Partnering PI are from distinct organizations (multi-institutional).

- **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**
 - How the writing and components of the application influenced the review.

2. Programmatic Review: The following equally weighted criteria are used by programmatic reviewers to make funding recommendations.

- **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
 - 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**
 - How well the proposed research project is responsive to documented health care needs of the Armed Forces, their family members, and/or the U.S. veteran population.
 - 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., Armed Forces, their family members, and/or the U.S. veteran population), if applicable.
 - How the proposed study complements ongoing DOD areas of research interest.
- **Program portfolio composition**
 - Whether the proposed study specifically addresses research areas that are underrepresented in the existing PRMRP portfolio (Click here to search PRMRP awards <http://cdmrp.army.mil/search.aspx>) and would therefore add to the overall balance of research and development efforts in the existing portfolio.

- **Ratings and evaluations of the peer reviewers**
 - Whether the application was assessed as scientifically meritorious with the strengths identified outweighing the weaknesses.
- **Relative impact**
 - FY10 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 mission of the PRMRP to “Provide support for military health-related research of exceptional scientific merit.”

V. ADMINISTRATIVE ACTIONS

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

A. Rejection

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Use of “I,” “our,” “this institution,” or similar phrases in the Preproposal Narrative that make it possible to identify the PI, collaborators, and/or organization through the references listed.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Submission of an application for which a letter of invitation was not received.
- Initiating or Partnering PI(s) application is not submitted by the deadline, if the Partnering PI option was identified during Pre-application process.

B. Modifications

- 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, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section V-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:

- FY10 JPRP member(s) 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 FY10 JPRP members may be found at <http://cdmrp.army.mil/prmrp/panels/panel10>
- 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 detailed budget form exceed maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- The PI does not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.
- The proposed research is or contains a clinical trial.
- The proposed research is not relevant to any of the congressionally directed FY10 PRMRP topic areas.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested 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.

VI. CONTACT INFORMATION

A. CDMRP Program Announcement Help Desk: Questions related to Program Announcement/Funding Opportunity content or submission requirements should be directed to the CDMRP Program Announcement help desk, which is available Monday through Friday from 7:30 a.m. to 4:00 p.m. ET. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079
Email: cdmrp.pa@amedd.army.mil

B. CDMRP eReceipt System Help Desk: Questions related to the submission of the pre-application through the eReceipt system should be directed to the CDMRP eReceipt system help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

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

C. Grants.gov Contact Center: Questions related to application submission through the Grants.gov portal should be directed to Grants.gov help desk, which is available 24 hours a day, 7 days a week. Please note that the CDMRP Program Announcement and eReceipt system help desks are unable to provide technical assistance regarding Grants.gov submissions.

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. 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 (Partnering PI Option)
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed		
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1		Not Applicable (N/A)
	Upload Supporting Documentation (Support.pdf) as Attachment 2		N/A
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3		N/A
	Upload Public Abstract (PublicAbs.pdf) as Attachment 4		N/A
	Upload Statement of Work (SOW.pdf) as Attachment 5		
	Upload Detailed Budget and Justification (Budget.pdf) as Attachment 6		
	Upload Subaward Detailed Budget and Justification (SubBudgets.pdf) as Attachment 7		
	Upload Impact Statement (Impact.pdf) as Attachment 8		N/A
	Upload Military Relevance Statement (MilRel.pdf) as Attachment 9		N/A
	Upload Human subject plan (HumSub.pdf) as Attachment 10		N/A
	Upload Approval for access to military populations (MilPop.pdf) as Attachment 11		N/A
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field		N/A
	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field		N/A
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field		N/A
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field		N/A
Project/Performance Site Location(s) Form	Complete form as instructed		N/A