

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Peer Reviewed Cancer Research Program

Idea Award

Funding Opportunity Number: W81XWH-10-PRCRP-IDA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The Peer Reviewed Cancer Research Program (PRCRP) was established in 2009 to provide support for cancer research not addressed by the breast cancer, prostate cancer, lung cancer, and ovarian cancer research programs executed and managed by the Office of the Congressionally Directed Medical Research Programs (CDMRP). Appropriations for the PRCRP for fiscal year 2009 (FY09) was \$16 million (M). The FY10 appropriation is \$15M.

The goal of the PRCRP is to improve quality of life by decreasing the impact of cancer on service members, their families, and the American public. The PRCRP fosters groundbreaking and collaborative research to accelerate progress in cancer prevention, detection, and therapeutic interventions.

B. FY10 PRCRP Topic Areas

FY10 PRCRP funds appropriated by Congress are directed for research in the following areas:

- Melanoma and other skin cancers;
- Pediatric brain tumors;
- Genetic cancer research and genomic medicine;
- Kidney cancer;
- Blood cancers;
- Colorectal cancer;
- *Listeria* vaccine for cancer;
- Radiation protection utilizing nanotechnology.

Applications must not propose breast, prostate, lung, or ovarian cancer research.

C. Award Description

The PRCRP Idea Award mechanism was first offered in FY09. Since then, 38 Idea Award applications have been received, and 6 have been recommended for funding.

The Idea Award is intended to promote the exploration of ideas that are still in the early stages of development yet have the potential to yield high-impact results and open new avenues of investigation in the relevant FY10 PRCRP Topic Areas. This mechanism supports conceptually innovative, high-risk/high-reward research that could ultimately lead to critical discoveries or major advancements.

Preliminary data are not required. However, research projects should include a well-formulated, testable hypothesis based on a strong scientific rationale.

Research involving human subject participation is permitted under this funding opportunity but is restricted to studies without clinical trials. Clinical trials are not permitted under this award mechanism. In general, a clinical trial is defined as a prospective study where an intervention (e.g., a device, drug, behavioral, surgical procedure) is tested on human subjects for a measurable outcome. Correlative Human Subject Use (clinical research) studies are permitted, and the study may be associated with a Clinical trial but it does not seek the main outcomes of the clinical trial. Correlative studies are defined as a prospective or retrospective collection of human anatomical substances (tissue, blood, nail clippings, bone marrow, behavioral documentation, etc.) to be used in research to answer a question regarding the disease and /or interventions. It does not include the direct testing for the *outcome* of *any intervention* for the prevention, diagnosis, treatment, or evaluation of the quality of life of the patient. Correlative Human Subject Use may require informed consent of the human subject, and may include identifiable information. Refer to the General Application Instructions, Appendix 5, for additional information about studies involving human subjects, human subjects data, or human anatomical substances.

For FY10, the PRCRP Idea Award will only consider applications that address one or more of the FY10 PRCRP Topic Areas. Within each FY10 PRCRP Topic Area, the following Focus Areas have been identified.

Applicants are encouraged to respond to one or more of the Focus Areas within a FY10 PRCRP Topic Area.

- **Melanoma and other skin cancers:** Analysis of the molecular and immunological pathways relevant to progression is sought to improve the approach to diagnosis and therapy of melanoma and other skin cancers. Applicants are encouraged to address one or more of the following Focus Areas:
 - The role of mutations in genes that drive melanoma progression (BRAF, c-KIT, and others) both in relation to the tumor cell and the immune response, and induction of durable remissions of advanced disease;
 - The basis of tumor-induced immunosuppression for more rational and effective interventions against primary tumor, regional, and/or distant sites;
 - Identification and validation of prognostic or predictive biomarkers of disease, including the role of inflammation at the primary, regional, and/or distant sites;
 - Studies upon precursor lesions and the role of atypical/dysplastic nevi in melanoma prevention.

- **Pediatric brain tumors:** To advance understanding and treatment biology of low grade gliomas, infant brain tumors, diffuse infiltrating pontine gliomas, and other pediatric brain tumors, applicants are encouraged to address one or more of the following Focus Areas:
 - Elucidation of pathways associated with the developmental biology of pediatric brain tumors, especially low grade gliomas, infant brain tumors, and infiltrating pontine gliomas;
 - Identification and validation of pathways associated with the tumor pathogenesis;
 - Development of valid animal models to promote understanding of the tumorigenesis, safety, and toxicity of therapies;
 - Development of non-invasive biomarkers for targeted therapies, including imaging;
 - Identification of novel therapeutic targets and/or resistance mechanisms.

- **Genetic cancer research and genomic medicine:** Genetic and epigenetic changes in cells caused by environmental factors (physical and chemical exposures as well as lifestyle factors associated with military environments) can be critical events in the cancer risk, initiation, progression, and/or promotion of normal cells to cancers. Applicants are encouraged to address one or more of the following Focus Areas:
 - Understanding molecular mechanisms by which environmental influences associated with military exposures (chemical, physical, biological, stress, diet, lifestyle, etc.) alter gene structure, stability, and expression;
 - Understanding differences in cancer risks and susceptibility associated with gene/environment interactions, including transgenerational epigenetic changes, and ethnic and racial differences;
 - Studies into improved diagnostics, such as those related to imaging, and advanced methodologies for tumor tissue interrogation for early identification/validation of tumor characteristics and therapeutic targets.

- **Kidney cancer:** Renal cell carcinoma (RCC) is emerging as an important cancer increasing in incidence. Major advances will depend on strategies that improve early detection, identify patients at high risk for disease recurrence, or identify novel molecular strategies for therapy and/or overcoming drug resistance. Applicants are encouraged to address one or more of the following Focus Areas:
 - Development of noninvasive strategies for detection of RCC;
 - Novel bioinformatic approaches to analyzing complex genomic and molecular data for molecular pathway identification;

- Genetic and environmental risk factors of military relevance for RCC.
- **Blood cancers:** Research into blood cancers (lymphoma, leukemia, multiple myeloma, myelodysplastic syndrome) is sought as related to specific types of exposures in various military environments. Applicants are encouraged to address one or more of the following Focus Areas:
 - Understanding the relationship of environmental exposures (chemical, physical, biological, stress, diet, lifestyle, etc.) that may alter gene expression and stability, resulting in increased risk;
 - Studies to improve the understanding of ethnic and transgenerational risks associated with environment and genetic/epigenetic interactions as related to military exposures and environments;
 - Identification of biomarkers that may lead to prevention, early detection/diagnosis, and/or improved treatment modalities;
 - Studies of drug toxicities and resistance utilizing material before, during, and after treatment, leading to less toxic and target-specific effective therapies.
- **Colorectal cancer:** To advance progress in the early diagnosis and treatment of colorectal cancer, research into the processes leading to tumorigenesis and metastasis is sought. Applicants are encouraged to address one or more of the following Focus Areas:
 - Tissue interrogation studies leading to identification and validation of diagnostic, prognostic, and predictive biomarkers, including those associated with therapeutic outcomes;
 - The development of animal models;
 - Immunological and inflammatory responses as well as the microenvironment in the development of colorectal cancers;
 - Studies addressing quality of life and survivorship post-treatment, especially for patients with rectal cancer.
- **Listeria vaccine for cancer:** New approaches to identify the molecular mechanisms of *Listeria* vaccines are sought, that will define the molecular basis of its immunotherapeutic effect. Applicants are encouraged to define the therapeutic impact of *Listeria* vaccines in human malignancies where the role of immunosuppression has been established, and define the impact of the intervention in terms of specific immune responses to the tumor. Applicants are encouraged to address one or more of the following Focus Areas:
 - Induction and analysis of CD4 and CD8 T cell responses to tumor-restricted antigens;

- Induction and maturation of dendritic cell responses to tumor antigens;
- Modulation of T cell and other effector cell trafficking to the tumor.
- **Radiation protection utilizing nanotechnology:** Nanomaterials have been developed with properties associated with protective effects against radiation-induced damage. To translate these compounds into the clinical treatment setting, further research on the biocompatibility and toxicity of nanomaterials as well as the selectivity of the protection in non-malignant tissues is required. Applicants are encouraged to address one or more of the following Focus Areas:
 - Development of novel biocompatible nanomaterials with strong radioprotective effects;
 - Evaluation of the in vivo toxicity of nanomaterials used for radiation protection during radiation therapy;
 - Novel mechanisms to enhance the radioprotective effect of nanomaterials selectively in normal tissues but not in tumors.

Innovation and Impact are the most important aspects of the Idea Award.

1. **Innovation:** Research deemed innovative may introduce a new paradigm, challenge existing paradigms, or look at existing problems from new perspectives. Research may be innovative in study concept, research methods or technology, or adaptations of existing methods or technologies. Research that represents an incremental advance on previously published work is not considered innovative.
2. **Impact:** The proposed research should have a significant impact on the concepts or methods that drive the field and its relevance to military beneficiaries. The proposed research is expected to make original and important contributions to the goal of advancing this area of research. ***Clinical trials are not permitted under this mechanism.*** Refer to the General Application Instructions, Appendix 5, for additional information about studies involving human subjects, human subjects data, or human anatomical substances.

NEW FOR FY10! COLLABORATIVE OPTION: This award mechanism encourages applications that include meaningful and productive collaborations between investigators. The Collaborative Option under this award mechanism is structured to accommodate two to three Principal Investigators (PIs), an Initiating PI and one or two Partnering PIs. The Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute to the preparation of a single application. The collaborative partners may have expertise in similar or disparate scientific disciplines but are expected to bring different strengths to the application. New collaborations are encouraged, but not required. The Collaborative Option is designed to support collaborations on completely new research ideas (***with a requirement of a single research idea per collaboration***); therefore, merely continuing an existing or previous collaborative research project between investigators is not considered innovative and does not

meet the intent of the Idea Award mechanism. It is the responsibility of the collaborating investigators to describe how their combined expertise in the collaboration will better address the research question, and explain why the work should be done together rather than through separate efforts. *Applications submitted by a mentor and trainee as Initiating and Partnering PIs do not meet the intent of the Collaborative Option.*

D. Eligibility

Investigators at all academic levels (or equivalent) are eligible to submit applications. Refer to General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

Applications with a single PI:

- The maximum period of performance is **3** years.
- The maximum allowable funding for the entire period of performance is **\$375,000** 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.

Applications with the **Collaborative Option**:

- A separate award will be made to each PI's institution. Initiating PI and the partnering PI(s) may be at the same or different institutions.
- Maximum period of performance is **3** years.
- Maximum allowable, combined funding of initiating PI and all partnering PIs for the entire period of performance is **\$750,000** in direct costs.
- Applications requesting the higher level of funding that do not include a collaborative PI will have their budget reduced as appropriate.

Applications with the **Collaborative Option** must include a compelling justification for requesting the increased levels of funding that are allowed.

- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 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.

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

- Salary
- Research supplies
- Equipment
- Clinical research (*Clinical trials are not permitted in this award mechanism*)
- Support for multidisciplinary collaborations
- 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, funding must be requested for the PI to attend the 3.5-day Department of Defense Military Health Research Forum meeting, which is held to disseminate the results of CDMRP sponsored research (anticipated date will be in 2012).

The CDMRP expects to allot approximately \$8.44M of the \$15M FY10 PRCRP appropriation to fund approximately 12 Idea 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

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), July 14, 2010**
- **Invitation to Submit an Application: September 8, 2010**
- **Application Submission Deadline: 11:59 p.m. ET, October 20, 2010**
- **Scientific Peer Review: December 2010**
- **Programmatic Review: February 2011**

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. Applications will not be accepted unless a PI has been invited. Do not submit an application unless a letter of invitation has been received.***

Under the Collaborative Option, this award mechanism is structured to accommodate at least two, and up to a maximum of three, PIs. One partner will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as the Partnering PI(s). 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 statements. The Initiating PI must complete the pre-application submission process and submit the contact information for each 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.

For the Collaborative Option: The Initiating PI is responsible for submission of all pre-application components.

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**

For the Collaborative 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, and other information needed to judge the pre-application.

The Preproposal Narrative should address the following:

- **Research:**
 - **Idea:** State the ideas and reasoning on which the proposed work is based and how the application addresses one or more of the FY10 PRCRP Topic Areas, and its relevance to military beneficiaries.
 - **Aims:** Concisely state the project’s objective and specific aims. ***This award mechanism may not be used to conduct clinical trials.***
- **Innovation:** Describe how the research represents more than an incremental advance on published data.
- **Impact:** Briefly state how the proposed research, if successful, will impact one or more of the relevant FY10 PRCRP 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 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.
- Key Personnel Biographical Sketches (four-page limit per individual)
- **Submit Pre-application – Tab 5**
- **Other Documents Tab**

Pre-Application Screening: Pre-applications will be screened by the PRCRP Integration Panel (IP), which is composed of scientists, clinicians, and consumer advocates. The pre-application screening criteria are as follows:

- **Innovation:** How the research represents more than an incremental advance on published data.
- **Impact:** What impact these studies will have on the FY10 PRCRP Topic Areas addressed.
- **Responsiveness to Intent:** How well the proposed research idea and aims address one or more of the FY10 PRCRP Topic Areas and its relevance to military beneficiaries.

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 has received a letter of invitation.

For the Collaborative Option: Applications will not be accepted unless the Initiating PI 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.

If applying under the Collaborative Option, please note that, 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.

A Grants.gov application package including a detailed budget and justification for the partnering PI(s) is required even if the Initiating PI and the partnering PI(s) are at the same institution.

Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title, research objectives, or FY10 PRCRP Topic Area(s).

Application Components for Single PIs or for Initiating PIs under the Collaborative 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 (six-page limit):** Upload as “ProjectNarrative.pdf.”

Describe the proposed research project in detail using the outline below. *The presentation of preliminary data is not required.* However, PIs must demonstrate logical reasoning and sound scientific rationale established through a critical review and analysis of the literature for the proposal to be competitive. Throughout the

Project Narrative, indicate how the proposed research is innovative and note the potential impact it will have on one or more of the FY10 PRCRP Topic Areas.

- **Background:** Present the ideas and reasoning behind the proposed research, to include relevant literature citations. Describe previous studies 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 to be supported by this application.
- **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.***
- **Impact:** Provide a brief statement regarding the potential impact of this work on one or more of the FY10 PRCRP Topic Areas. ***It is the responsibility of the applicant to clearly and explicitly articulate the project's impact on military beneficiaries.*** Describe how the project will lead to an original and important contribution to the goal of advancing basic, translational, or clinical cancer research, or on the quality of life of individuals with cancer.
- **References:** Cite relevant literature references using Attachment 2.

The six-page limit of the Project Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal.

- **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.
- Letters of Collaboration (if applicable) (two-page limit per letter): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”
Technical abstracts should be written using the outline below.
 - Background: Present the ideas and reasoning behind the proposed work.
 - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
 - Specific Aims: State the specific aims of the study.
 - Study Design: Briefly describe the study design including appropriate controls.
 - Innovation: Briefly describe how the proposed project uses innovation to advance the prevention, detection, diagnosis, and/or treatment of cancer.
 - Impact: Briefly describe how the proposed project will have an impact on cancer research or patient care
- **Attachment 4: Public Abstract (one-page limit):** Upload as “PublicAbs.pdf.”
Public abstracts should be written using the outline below.
 - Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposed work.
 - Do not duplicate the technical abstract.
 - Describe the ultimate applicability of the research. – What types of patients will it help, and how will it help them?
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected time it may take to achieve a patient-related outcome?
 - If the research is too basic for clinical applicability, describe the interim outcomes.

- What are the likely contributions of this study to advancing the field of research?
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.B., for detailed information.
For Collaborative 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.
- **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.
For Collaborative Option: Initiating and Partnering PIs, even if they are at the same institution, 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:** Upload as “Impact.pdf.” Explain how the proposed research will have an impact on one or more of the FY10 PRCRP Topic Areas and military beneficiaries. Describe how the proposed research will provide original and important contributions to the goal of advancing research in this field.
- **Attachment 9: Innovation Statement:** Upload as “Innovation.pdf.” Summarize how the proposed research is innovative. Investigating the next logical step or an incremental advancement on published data is not considered innovative.
- **Attachment 10: Collaboration Statement (if applicable, one-page limit):** Upload as “Collaboration.pdf.” For applications submitted under the Collaborative Option only, describe the expertise of the Initiating and Partnering PIs. Describe the contribution and the time commitment of each collaborator toward the proposed research project. Describe how the collaborative effort will better address the research question, and explain why the work should be done together rather than through separate efforts.
- **Attachment 11: Relevance to Military Beneficiaries Statement (one-page limit):** Upload as “MilBen.pdf.” Describe the impact either short-term or long-term of the proposed research on the health and welfare of service members, their families, and other military beneficiaries. Describe how the proposed project is responsive to one or more of the FY10 PRCRP Topic Areas with respect to its significance to military beneficiaries. Describe how the study design will replicate field conditions, if appropriate. If active duty military, military families, or U.S. 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).

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.

For the Collaborative Option: Application Components for the Partnering PI(s):

Each 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(s) 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 PIs 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. A detailed budget and justification for each of the partnering PI(s) is required even if the Initiating PI and/or the partnering PI(s) are at the same institution.*

- **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 all of equal importance:

- **Innovation**
 - How the project proposes new paradigms or challenges existing paradigms.
 - How the proposed research is innovative in one or more ways (e.g., concept or question, research methods or technologies, or adaptations of existing methods or technologies).
 - How the proposed research represents more than an incremental advance to current data.

- **Impact**
 - If successful, how the proposed research will have an impact on the field.
 - How the proposed research will provide original and important contributions to the goal of advancing research in one or more of the indicated FY10 PRCRP Topic Areas and is relevant to military beneficiaries.
- **Research Strategy and Feasibility (no preliminary data required)**
 - How the scientific rationale supports the research project and its feasibility, as demonstrated by a critical review and analysis of the literature.
 - How well the hypotheses or objectives, experimental design, methods, and analyses are developed, and how well these support completion of the aims.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
 - For projects applying for the Collaborative Option, whether the added value of working together is justified to accomplish the proposed research.

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

- **Personnel**
 - The research team's background, experience, and expertise with respect to the proposed work.
 - The appropriateness of the levels of effort by the PI and other key personnel to ensure success of the proposed work.
 - For projects applying for the Collaborative Option, how the partners' expertise and levels of effort support the proposed project.
- **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 institutional 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**
 - 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,

- Ratings and evaluations of the peer reviewers,
- Programmatic relevance,
- Relative innovation and impact,
- Responsiveness to the FY10 PRCRP Topic Areas and Focus Areas, and
- Program portfolio balance with consideration of relevance to military beneficiaries.

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).

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.
- Pre-application is not submitted.
- If submitting under the Collaborative Option, Initiating or Partnering PI(s) application is not submitted by the deadline.

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 PRCRP IP 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 PRCRP IP members may be found at <http://cdmrp.army.mil/prcrp/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.

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	Single PI (or Initiating PI) Completed	Each Partnering PI Completed (Collaborative 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 Innovation Statement (Innovation.pdf) as Attachment 9		N/A
	Upload Collaboration Statement (Collaboration.pdf) as Attachment 10 (if applicable)		N/A
	Upload Relevance to Military Beneficiaries Statement (MilBen.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