Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Peer Reviewed Cancer Research Program

Translational New Investigator Award

Funding Opportunity Number: W81XWH-10-PRCRP-TNIA

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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) were $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 Translational New Investigator Award mechanism is being offered for the first time in FY10.

The Translational New Investigator Award supports the development of translational research partnerships among **two** independent investigators to address at least one of the FY10 PRCRP Topic Areas in a ***manner relevant to military beneficiaries.*** Within the partnership, one member must be a laboratory scientist and the other must be a clinician. This award is intended to support a mentoring partnership between a new investigator (the Principal Investigator [PI]) and a mentor (a clinician or laboratory scientist with an established research program in one of the FY10 PRCRP Topic Areas)**.**

The ultimate goal of translational research is to move an observation forward into a clinical application. Research does not have to be performed in the clinic but should include human anatomical substances. The Translational New Investigator Award supports preclinical studies in animal models and/or human anatomical substances that have clear potential for translation into clinical applications. Correlative studies that are associated with an existing clinical trial, and/or projects that develop clinical endpoints for clinical trials may be proposed. Developing the research plan must involve a reciprocal flow of ideas and information within the research team (from bench to bedside, and from bedside to bench).

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. Correlative studies do 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 Translational New Investigator Award will only consider applications that address one or more of the following 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.

Important aspects of the Translational New Investigator Award are as follows:

1. Mentorship/Collaboration: The success of the project depends on the unique skills and contributions of each investigator. The mentor must have experience in the field responsive to the FY10 PRCRP Topic Areas as demonstrated by a record of funding and publications.

2. Translational: The application should provide evidence for the reciprocal transfer of ideas between basic and clinical science in developing and implementing the research plan.

3. Relevance to Military Beneficiaries: The proposed research should address cancers as relevant to service members, veterans, and their families.

4. Impact: The proposed research should have a significant impact on the concepts or methods that are likely to accelerate the movement of promising, militarily relevant ideas in cancer research into clinical applications. Correlative clinical research studies are allowed under this mechanism. ***Clinical trials are not permitted.*** Refer to the General Application Instructions, Appendix 5, for additional information about studies involving human subjects, human subjects data, or human anatomical substances.

5. Innovation: Research deemed innovative may represent 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.

D. Eligibility

The PI of the application is the new investigator. The PI must be an independent investigator. An independent new investigator eligible for this award is defined as an individual who, at the time of pre-application submission:

- Is within 6 years of having completed postdoctoral or fellowship training; and
- Holds a position at the level of Instructor, Assistant Professor, or equivalent; and
- Has received no more than $300,000 in direct costs in aggregate as a PI or co-PI of a federally or privately funded, non-mentored peer reviewed grant (e.g., R01, DOD Idea Development Award); and
- Has acquired sufficient skills and knowledge to function independently; and
- Can provide evidence of institutional support, such as start-up funds provided by the institution and/or use of a technician, space, facilities, and resources.

PIs working within a laboratory team are eligible to apply for this award provided that they can demonstrate that they are independent investigators according to the criteria above.

Mentor: PIs at or above the level of an Associate Professor (or equivalent) are eligible to be the designated mentor.

It is not required that the PI and the mentor be located at the same institution.

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 **$300,000** 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.

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

- Salary
- Research supplies
- Equipment
- Clinical research costs (***Clinical trials are not permitted in this award mechanism.***)
- 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 $4.5M of the $15M FY10 PRCRP appropriation to fund approximately 10 Translational New Investigator 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.***

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 an organizational change is necessary after submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507.

No change in PI will be allowed under this funding opportunity.

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.

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**
- **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, cartoons, and other information needed to judge the pre-application.

  The Preproposal Narrative should include the following:

  - **Personnel**: Clearly state how the PI is eligible for this award. Describe the PI's potential for contributing to the relevant field and to military beneficiaries. Note the expertise provided by the mentor.
  - **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 one or more of the Focus Areas, as well as its relevance to military beneficiaries.
    - **Aims:** Concisely state the project's objective and specific aims. ***This award may not be used to conduct clinical trials.***
  - **Translation:** Describe the reciprocal transfer of ideas between basic and clinical science in developing, implementing, and moving the proposed research into clinical applications.
  - **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. Describe how the proposed

research is responsive to one or more of the relevant Focus Areas within a FY10 PRCRP Topic Area.

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:

- **Personnel**: Whether the PI is eligible and demonstrates potential for contributing to the field. Whether the mentor is eligible and has a demonstrable record of research in the FY10 PRCRP Topic Area for the project. How the mentor will contribute to the expertise of the PI.
- **Research Idea**: How the rationale and specific aims support the project's objective.
- **Translation:** How these studies will move basic scientific ideas into clinical applications.
- **Innovation**: How well the research represents more than an incremental advance on published data.
- **Impact**: How well the proposed research addresses one or more of the Focus Area(s), and what impact these studies will have on one or more of the FY10 PRCRP Topic Area(s) 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. Applications will not be accepted unless a PI has been invited. Do not submit an application unless a letter of invitation has been received.

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.

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 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 listed FY10 PRCRP Topic Areas and one or more of the Focus Areas.

  - **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 to be supported by this application.
  - **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, appropriately powered statistical plan 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.
  - **Personnel:** Describe how the PI's record of accomplishment indicates his/her potential for contributing to the relevant FY10 PRCRP Topic Areas, Focus Areas, and to military beneficiaries. Describe how the mentor will contribute to the proposed research.

- **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.
  - Letter from the Mentor (two-page limit): Provide a signed letter from the mentor indicating recommendation, support, and planned interaction with the PI for the proposed work.
  - Letters of Collaboration (if applicable) (two-page limit per letter): Provide a signed letter from each collaborating individual (other than the mentor) 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.
- Translation: Briefly describe how the proposed project will translate basic research into clinical applications.
- 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) (two-page limit):** Upload as "SOW.pdf." 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.

- **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 how the proposed research will have an impact on one or more of the FY10 PRCRP Topic Areas including military beneficiaries.
- **Attachment 9: Innovation Statement (one-page limit):** 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: Statement of Eligibility (one-page limit):** Upload as "Eligibility.pdf." Use the Statement of Eligibility template (available for download on the Full Announcement page in Grants.gov) signed by the Department Chair, Dean, or equivalent official verifying that the eligibility requirements (as described in the Program Announcement/Funding Opportunity) will be met by the time of proposal submission.
- **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.

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.htm.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

B. Review Criteria

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

- **Personnel**
  - Whether the PI meets the eligibility requirements.
  - The PI's potential for contributing to one or more of the relevant FY10 PRCRP Topic Areas based on his/her background and experience.
  - How the PI's record of accomplishment demonstrates his/her ability to accomplish the proposed work.
  - How well the PI meets the criteria established for this award mechanism (i.e., new and established scientists or clinicians across a broad spectrum of relevant disciplines).
  - How well the levels of effort by the PI, the mentor, and other key personnel will ensure success of the proposed work.

- The expertise of the mentor based on his/her background and experience in the field. To what extent the mentor's efforts and collaboration will contribute to the successful development of the PI and the proposed research.

- **Innovation**
  - How the project proposes new paradigms or challenges existing paradigms.
  - To what extent the proposed research is innovative in one or more ways (e.g., concept or question, research methods or technologies, adaptations of existing methods or technologies).
  - How well the proposed research represents more than an incremental advance to published data.
- **Impact**
  - If successful, how the proposed research will have an impact on the field.
  - To what extent the proposed research contributes to the goal of advancing research in one or more of the indicated FY10 PRCRP Topic Areas and Focus Areas and is relevant to military beneficiaries.
- **Translation**
  - To what extent these studies will accelerate the movement of basic scientific findings or principles to the clinic
  - How the mentor – new investigator partnership will aid in the reciprocal transfer of ideas between basic and clinical science in developing, implementing, and moving the proposed research into clinical applications.
- **Research Strategy and Feasibility (preliminary data not required)**
  - To what extent 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.

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

- **Environment**
  - How well the scientific environment is appropriate for the proposed research.
  - How well 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 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.

B. Modifications

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative.

- Documents not requested will be removed.
- Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section 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.htm.
- 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.

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	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 Public Abstract (PublicAbs.pdf) as Attachment 4	
	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	
	Upload Innovation Statement (Innovation.pdf) as Attachment 9	
	Upload Statement of Eligibility (Eligibility.pdf) as Attachment 10	
	Upload Relevance to Military Beneficiaries Statement (MilBen.pdf) as Attachment 11	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field	
Project/Performance Site Location(s) Form	Complete form as instructed	