Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Idea Development Award

Funding Opportunity Number: W81XWH-11-PCRP-IDA
Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-application Submission Deadline:** 5:00 p.m. Eastern time (ET)**,** June 2, 2011
- **Invitation to Submit an Application:** July 12, 2011
- **Application Submission Deadline:** 11:59 p.m. ET, August 23, 2011
- **Scientific Peer Review:** October 2011
- **Programmatic Review:** December 2011

New for fiscal year 2011 (FY11): The Grants.gov Research & Related Budget form is a mandatory component of all Grants.gov application packages.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The Prostate Cancer Research Program (PCRP) was established in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY10 totaled $1.05 billion. The FY11 appropriation is $80 million (M).

The overall goal of the FY11 PCRP is to find and fund innovative, high-impact research that will eliminate death and suffering from prostate cancer. Specifically, the PCRP seeks to support innovative, high-risk, high-gain research with potential near-term impact; sponsor multidisciplinary synergistic research; fund translational studies to promote the fluid transfer of knowledge between bedside and bench; invest in research on patient survivorship (quality of life); foster the next generation of prostate cancer investigators through mentored research; and promote research into prostate cancer health disparities.

PCRP Overarching Challenges

Consistent with the program's overall goal, each PCRP funding opportunity either requires or encourages (see Award Information below) applications to address one of the following PCRP overarching challenges:

- Develop effective treatments for advanced prostate cancer (i.e., disease relapse with no available curative therapy)
- Distinguish aggressive from indolent disease

PCRP Focus Areas *(revised for FY11)*

All applications for FY11 PCRP funding opportunities should also address at least one of the following PCRP focus areas:

Biomarkers: Discovery and validation of biomarkers for the detection, prediction of response to therapy, prognosis, and progression of prostate cancer.

Genetics: Understanding the genetics and epigenetics responsible for susceptibility, disease progression, and treatment outcomes for clinically significant prostate cancer.

Imaging: Development of new anatomic and molecular imaging technology for the detection and management of prostate cancer.

Survivorship: Studies on the impact of treatment, nutrition, metabolism, and exercise on the well-being of prostate cancer patients and their families.

Therapy: Identification of new targets, pathways, and therapeutic modalities, including immunotherapy and mechanisms of resistance.

Tumor Biology and Immunology: Understanding prognosis and progression of prostate cancer.

B. Award Information

The PCRP Idea Development Award mechanism was first offered in FY97. Since then, 5,700 Idea Development Award applications have been received, and 971 have been recommended for funding.

The Idea Development Award supports new ideas that represent innovative approaches to prostate cancer research and have the potential to make an important contribution to eliminating death and suffering from prostate cancer. Although groundbreaking research often involves a degree of risk, applications should be based on a sound scientific rationale that is established through logical reasoning and/or critical review and analysis of the literature. Due to this award's emphasis on innovation, presentation of preliminary data relevant to prostate cancer and the proposed project is encouraged but not required. Any preliminary data provided should be from the laboratory of the Principal Investigator (PI) or member(s) of the collaborating team.

All applications for the Idea Development Award are highly recommended to address one of the FY11 PCRP overarching challenges. The PCRP seeks to fund projects from the wide spectrum of basic to clinical research; however, if the proposed project does not address one of the overarching challenges, the application should provide a description to justify how the project will nevertheless address a critical need in the field of prostate cancer research and/or patient care.

PIs wishing to apply for funding for population-based studies should consider submitting an application for the FY11 PCRP Population-Based Research Award.

Research involving human subject use is permitted under this funding opportunity, but is restricted to studies without clinical trials. A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. For more information on clinical research, a Human Subject Resource Document is provided at https://cdmrp.org/Program_Announcements_and_Forms/. PIs seeking funding for a clinical trial should consider submitting an application for the FY11 PCRP Clinical Trial Award.

New Investigator Option: The FY11 Idea Development Award mechanism encourages applications from investigators in the early stages of their careers. The New Investigator Option is designed to allow applicants early in their faculty appointments, or in the process of developing independent research careers, to compete for funding separately from established investigators. Applications from New Investigators and Established Investigators will be peer- and programmatically reviewed in separate groups. PIs using the New Investigator Option are strongly encouraged to strengthen their applications by collaborating with investigators experienced in prostate cancer research and/or possessing other relevant expertise as demonstrated by a record of funding and publications. It is the responsibility of the applicant to describe how collaboration will augment the PI's expertise and better address the research question. All applicants for the New Investigator Option must meet specific eligibility criteria as described below.

C. Eligibility Information

- The PI must be an independent investigator at or above the level of Assistant Professor (or equivalent), unless applying for the New Investigator Option.

  New Investigator Option: To be eligible for this option, the PI must, by the application submission deadline date, have:

  - The freedom to pursue individual aims without formal mentorship, ***and***
  - Not previously received a PCRP New Investigator Award; ***and***
  - Not previously received a PCRP Idea Development Award-New Investigator Option; ***and***
  - Either completed at least 3 years of postdoctoral training or fellowship ***or*** are within 5 years of having begun first independent faculty position (or equivalent).

  New Investigators working within a laboratory team are eligible to apply for this award provided that they can demonstrate that they have the freedom to pursue individual aims without formal mentorship. The PI is required to submit an Eligibility Statement to verify these qualifications. Graduate students and junior postdoctoral fellows (i.e., fellows with less than 3 years postdoctoral training) are not eligible for this award.
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **3** years.
- The maximum allowable direct costs amount for the entire period of performance is **$375,000** plus indirect costs**.** If applying for the New Investigator Option, the maximum allowable direct costs amount for the entire period of performance is **$225,000** plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget form. In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel to one 3½-day PCRP IMPaCT (Innovative Minds in Prostate Cancer Today) Meeting, which is held to disseminate the results of PCRP-sponsored research.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Clinical research costs (other than costs for clinical trials, which are not allowed)
- Travel between collaborating organizations
- Travel costs of up to $1,800 per year to attend scientific/technical meetings

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $31.8M of the $80M FY11 PCRP appropriation to fund approximately 38 Established Investigator and 25 New Investigator Idea Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

Submission is a multi-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (https://cdmrp.org/) and (2) application submission through Grants.gov (http://www.grants.gov/).

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to reject duplicative applications.

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (http://www.grants.gov/) basic search using the Funding Opportunity Number: W81XWH-11-PCRP-IDA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (https://cdmrp.org/). 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.

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 CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

When starting the pre-application, PIs should ensure that they have selected the appropriate mechanism category, i.e., "Idea Development Award-Established Investigator" OR "Idea Development Award-New Investigator Option."

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**
- **Required Files – Tab 4**

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

  Pre-applications will be screened based on the merit of the proposed research idea and strategy. Therefore, reviewers will be blinded to the identity of the PI, collaborators, and their organizations(s). Due to the blinded nature of the review process, identifying or making references to the PI, collaborators, or their organization(s) within the Preproposal Narrative is prohibited and will result in administrative rejection of the application. The use of "I," "our," "this organization," or similar wording in phrases that refer to the PI, collaborators, or their organization(s) through the references listed will result in administrative rejection of the pre-application and preclude invitation to submit a full application.

  The Preproposal Narrative should include the following:

  - **Rationale:** Clearly articulate the rationale for the project by presenting the ideas and reasoning that support it; include relevant literature citations.
  - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
  - **Innovation:** Describe how the proposed study is innovative. Research deemed innovative may represent a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities. Innovative research may include high-risk approaches to prostate cancer research. Research that is an incremental advance upon published data is not considered innovative.
  - **Research Strategy:** State the project's specific aims and briefly describe the experimental design and methodology. ***This award may not be used to conduct clinical trials.***
  - **Impact:** Describe the potential short-term and long-term impact of this study on prostate cancer research and/or patient care. Research that has high impact will, if successful, significantly accelerate the elimination of death and suffering from prostate cancer.
  - **Overarching Challenges and Focus Areas:** Describe how the proposed study is responsive to one of the PCRP overarching challenges. If the proposed project does

not address at least one of the overarching challenges, provide a description to justify how the project will nevertheless address a critical need in the field of prostate cancer research and/or patient care. In addition, state at least one of the PCRP focus areas to which the proposed study is responsive.

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; ***however, to comply with blinded review, do not include URLs that incorporate the name or abbreviation of the organization(s) of the PI or collaborator.***
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols. ***Do not include information that will identify the organization(s) of the PI or collaborator.***

- **Submit Pre-application – Tab 5**
- **Other Documents Tab**

  No additional documents are required**.**

Pre-Application Screening

- **Pre-Application Screening Criteria**

  To determine the technical merits of the pre-application and the relevance to the mission of the Department of Defense (DOD) and CDMRP, pre-applications will be screened based on the criteria shown below. Of these, Innovation and Impact are equally most important, with the remaining criteria listed in decreasing order of importance.

  - **Innovation:** To what degree the proposed research is uniquely creative and represents more than an incremental advance upon published data.
  - **Impact:** To what degree the proposed study could, whether short-term or long-term, make a significant impact on prostate cancer research and/or patient care, including its potential contribution to the elimination of death and suffering from prostate cancer.
  - **Research Strategy:** How well the specific aims support the scientific rationale/research idea and feasibility.
  - **Responsiveness to Overarching Challenges:** How well the proposed research addresses one of the PCRP overarching challenges or is otherwise justified as addressing another critical issue in prostate cancer research and/or patient care.

- **Notification of Pre-Application Screening Results**

  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., a

critique of strengths and weaknesses) on their pre-application. Pre-application notification dates are indicated on the title page of this Program Announcement/ Funding Opportunity.

C. Application Submission Content and Form

Applications will not be accepted unless the PI has received a letter of invitation.

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative (AOR) through the Grants.gov portal (http://www.grants.gov/). .

Grants.gov application package components: For the Idea Development Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

2. **Attachments Form**

   - **Attachment 1: Project Narrative (10-page limit):** Upload as "ProjectNarrative.pdf."

     Describe the proposed project in detail using the outline below. The inclusion of preliminary data relevant to prostate cancer and the proposed project is encouraged but not required. Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team.

     - **Background:** Present the ideas and reasoning behind the proposed research; 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. If this application is part of a larger study, present only tasks that this 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.***
     - **Collaboration (if applicable; encouraged for the New Investigator Option):** Describe the specific contributions of the collaborator(s) to the research project.

- **Overarching Challenges and Focus Areas:** Describe how the proposed study is responsive to one of the PCRP overarching challenges. If the proposed project does not address at least one of the overarching challenges, provide a description to justify how the project will nevertheless significantly address a critical need in the field of prostate cancer research and/or patient care. In addition, state at least one of the PCRP focus areas to which the proposed study is responsive.

- **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 the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
  - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
  - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the 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:
    - ***New Investigator Option (if applicable):*** Investigators applying for the New Investigator option are strongly encouraged to provide a signed letter from each collaborating individual or organization that describes how he/she will support the project, to include unique expertise and/or availability of and access to research resources. If the PI is likely to change organizations during the award period of performance (e.g., New Investigators transitioning into their first independent faculty position), describe how the collaboration will be maintained.
    - ***Other:*** For all other investigators, provide a signed letter from each collaborating individual or organization (if applicable) that specifically describes the support to be provided.

- 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."

  Describe the proposed research project, including the following elements: Background, Objective/Hypothesis, Study Design and Specific Aims, Innovation, and Impact. The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and rely on the technical abstract for appropriate description of the project's key aspects.

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

  Public abstracts should be written using the outline below. Do not duplicate the technical abstract. The public abstract is used by consumer peer reviewers along with other components of the application package.

  - Describe the scientific objective and rationale for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine***.
  - 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.C., for detailed information.

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

  Explain in detail why the proposed research project is important.

  Describe the short-term impact: Detail the anticipated outcome(s)/product(s) that will be directly attributed to the results of the proposed research.

  Describe the long-term impact: Explain the anticipated long-term gains from the proposed research, including the long-term anticipated advantages that the new understanding may ultimately contribute to the goal of eliminating death and suffering from prostate cancer.

  PCRP Overarching Challenges: Summarize how the proposed project addresses one of the PCRP overarching challenges or another critical issue in prostate cancer research and/or patient care.

- **Attachment 7: Innovation Statement (one-page limit).** Upload as "Innovation.pdf."

  Describe how the proposed work is innovative. Proposing research that represents an incremental advancement on published data is not considered innovative.

  The following examples of ways in which the proposed work may be innovative, although not all-inclusive, are intended to help the PI frame the innovative features of his/her application:

  - Study concept – Investigation of a novel idea and/or research question.
  - Research method or technology – Use of novel research methods or new technologies, including technology development, to address a research question.
  - Novel method or technology – Development of a novel method or technology for prevention, detection, diagnosis, or treatment.
  - Existing methods or technologies – Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.

- **Attachment 8: *(New Investigator Option only)*: Eligibility Statement (one-page limit).** Upload as "Eligibility.pdf."

  Use the Eligibility Statement template (available for download on the Full Announcement page in Grants.gov) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met at the application submission deadline.

3. **Research & Related Senior/Key Person Profile (Expanded) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

   - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
   - PI Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
   - Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
   - Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.

   - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."

5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

D. Submission Dates and Times

All submission dates and times are indicated on the title page of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines shall result in application rejection.

E. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Number System (DUNS) number and register with the Central Contractor Registry (CCR) to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, USAMRMC, based on technical merit, the relevance to the mission of the DOD and CDMRP, and the specific intent of the award mechanism. The highest scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

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

1. **Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, of these criteria, Innovation and Impact are equally the most important, with the remaining criteria listed in decreasing order of importance:

- **Innovation**
    - How well the research proposes new paradigms, challenges existing paradigms, or is otherwise uniquely creative in one or more of the following ways: Concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways**.**
    - To what degree the proposed research represents more than an incremental advance upon published data.
- **Impact**
    - To what degree the proposed study could, whether short-term or long-term, make a significant impact on prostate cancer research and/or patient care, including its potential contribution to the elimination of death and suffering from prostate cancer.
    - How well the proposed research addresses one of the PCRP overarching challenges or is otherwise justified as significantly addressing another critical issue in prostate cancer research and/or patient care.
- **Research Strategy and Feasibility**
    - How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, prostate cancer-relevant preliminary data, and/or logical reasoning.
    - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
    - How well the PI acknowledges potential problems and addresses alternative approaches.
- **Personnel**
    - To what degree the research team's background and prostate cancer-related expertise are appropriate with respect to its ability to perform the proposed work.
    - To what degree the levels of effort are appropriate for successful conduct of the proposed work.
    - ***New Investigator Option only:***
        - How well the PI's record of accomplishment demonstrates his/her potential for contributing to the prostate cancer research field and completing the proposed work.
        - If applicable, how well the proposed contributions of collaborators will complement the New Investigator's ability to perform the proposed work.

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

- **Environment**
  - To what degree the ***s***cientific 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).
  - To what degree the quality and extent of organizational support are appropriate.
- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influenced the review.

2. **Programmatic Review:** To determine the application's relevance to the mission of the DOD and CDMRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:
   - Adherence to the intent of the award mechanism
   - Programmatic relevance
   - Ratings and evaluations of the peer reviewers
   - Relative innovation and impact
   - Program portfolio composition

C. Recipient Qualification

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

D. Application Review Dates

All application review dates and times are indicated on the title page of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

Each PI and organization will receive notification of the funding recommendation. PIs will receive a scientific peer review summary statement on the strengths and weaknesses of the application.

IV. 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.
- PI or collaborator's name or organization is included in the Preproposal Narrative or List of Abbreviations, Acronyms, and Symbols.
- Use of "I," "our," "this institution," or similar phrases in the Preproposal Narrative that refer to the PI, collaborators, and/or their organizations in 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.
- Submission of an application for which a letter of invitation was not received.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.
- Documents not requested will be removed.
- Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- FY11 PCRP Integration Panel (IP) member is found to be involved in the preapplication 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 FY11 PCRP IP members may be found at http://cdmrp.army.mil/pcrp/panels/panel11.
- 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 Research and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- The proposed research is or includes a clinical trial.
- 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 required 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.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2012. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

Refer to the General Application Instructions, Appendix 4, Section C, for general information regarding administrative and national policy requirements.

C. Reporting

Refer to the General Application Instructions, Appendix 4, Section D, for general information on reporting requirements.

D. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section E, for general information on organization or PI changes.

Changes in PI are strongly discouraged for recipients using the New Investigator Option of this award. Extenuating circumstances necessitating a change of PI will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

To assist New Investigators who are transitioning into their first independent faculty position, the submitting organization must agree to relinquish the award when the PI obtains an independent faculty position, or equivalent, at another institution so that it can be transferred to the new institution.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements and questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 1-301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

Questions related to application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 1-800-518-4726

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Public Abstract (PublicAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact Statement (Impact.pdf) as Attachment 6.	
	Upload Innovation Statement (Innovation.pdf) as Attachment 7.	
	New Investigator Option only: Upload Eligibility Statement (Eligibility.pdf) as Attachment 8.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	