Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Synergistic Idea Development Award

Funding Opportunity Number: W81XWH-10-PCRP-SIDA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The Prostate Cancer Research Program (PCRP) was established in fiscal year 1997 (FY97) to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY09 totaled $970 million (M). The FY10 appropriation is $80M.

The overall goal of the FY10 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 transition 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;
- Promote research into prostate cancer health disparities.

NEW for FY10: PCRP Overarching Challenges

The goals of the FY10 program are aimed towards eliminating death and suffering from prostate cancer. All applications for the PCRP Synergistic Idea Development Award should address at least one of the following PCRP overarching challenges:

- Develop effective treatments for advanced prostate cancer
- Distinguish lethal from indolent disease

PCRP Focus Areas *(revised for FY10)*

Applications for the PCRP Synergistic Idea Development Award should also address at least one of the following FY10 PCRP focus areas:

Biomarkers: Discovery and validation of biomarkers for the detection, 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 imaging technology for the detection and prognosis of prostate cancer, including progression to systemic disease.

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 or molecules for the treatment of prostate cancer.

Tumor Biology: Understanding the heterogeneity and microenvironment for the prognosis and progression of prostate cancer.

B. Award Description

The PCRP Synergistic Idea Development Award mechanism was first offered in FY07. Since then, 199 applications have been received and 20 (representing 44 individual awards) have been recommended for funding.

The Synergistic Idea Development Award supports new ideas that represent innovative approaches to prostate cancer research involving two or three independent, faculty-level (or equivalent) Principal Investigators (PIs). These investigators should use synergistic and complementary perspectives to address a central problem or question in prostate cancer research. ***This award is designed to encourage and support both new and pre-existing partnerships.*** The overall goal of this award is to significantly accelerate advances in prostate cancer research to support the PCRP vision of conquering 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.

The Synergistic Idea Development Award requires that multiple investigators jointly design a single project. However, each partner will be recognized as a PI, submit a separate application, and receive an individual award. The research project must be supported by the unique expertise of each PI, and it must clearly define the synergistic components that will facilitate and accelerate progress in a way that could not be accomplished through independent efforts. Multidisciplinary projects are encouraged, and multi-institutional projects are allowed. Each proposed study must include clearly stated plans for interactions among all PIs and institutions involved. The plans must include communication, coordination of research progress and results, and data transfer. Additionally, multi-institutional applications must provide an intellectual property plan to resolve potential intellectual and material property issues, and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful completion of this award.

The PCRP seeks applications from the wide spectrum of basic to clinical research (excluding clinical trials), that are responsive to at least one of the PCRP overarching challenges, and at least one of the PCRP focus areas. PIs wishing to apply for funding for population-based studies should consider submitting an application for the Population-Based Research Award.

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 PI or member(s) of the collaborating team.

Research involving human subject use is permitted under this funding opportunity, but is restricted to studies without Clinical Trials. In general, a clinical trial is defined as a prospective study where an intervention (e.g., device, drug, behavioral, surgical procedure, or

other) is tested on human subjects for a measurable outcome. Refer to the General Application Instructions, Appendix 5, for additional information about studies involving human subjects, human subjects data, or human anatomical substances.

It is the responsibility of the PIs to clearly and explicitly articulate how the project addresses the following important aspects of the Synergistic Idea Development Award:

1. **Responsiveness to overarching challenges and focus areas:** The relevance of the research problem to at least one of the PCRP overarching challenges ***and*** at least one of the PCRP focus areas.

2. **Synergy:** Synergy is a significant feature of this mechanism. These awards should accelerate research progress through continuous communication and problem solving that approach the research problem from a variety of perspectives. The combined efforts of the PIs should result in a level of productivity that is greater than that achievable by each PI working independently. It should be clear that all PIs have an equal level of intellectual input into the proposed project. Contributions to the project are expected to be balanced between all PIs unless otherwise justified. The PIs' histories of collaborative study with each other or with other investigators will also be evaluated.

3. **Innovation:** Research deemed innovative may represent a new paradigm, challenge current paradigms, or 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.

4. **Impact:** Research that has high impact will, if successful, significantly accelerate the elimination of death and suffering from prostate cancer.

5. **PI Experience:** This award mechanism is designed to accommodate multiple PIs. Therefore, each PI must demonstrate that he/she possesses the research experience and resources to function as a PI in a synergistic project among equals, as well as an appropriate level of authority and responsibility to direct the project supported by the grant.

C. Eligibility

Each PI must be an independent investigator at or above the level of Assistant Professor (or equivalent). Refer to General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **3** years.
- The maximum allowable funding for the entire period of performance is $**750,000** in direct costs. The combined total budgets proposed by all PIs must not exceed the maximum allowable funding limit.

- 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.

The PIs are expected to be equal partners in the research, so direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

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

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

In addition, funding must be requested for each PI to travel to one PCRP IMPaCT (Innovative Minds in Prostate Cancer Today) Meeting.

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $7.2M of the $80M FY10 PCRP appropriation to fund approximately six Synergistic Idea Development Award applications (representing 12-18 individual awards), 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.

E. 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), March 3, 2010**
- **Invitation to Submit an Application: April 21, 2010**
- **Application Submission Deadline: 11:59 p.m. ET, June 9, 2010**
- **Scientific Peer Review: July/August 2010**
- **Programmatic Review: October 2010**

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

III. SUBMISSION PROCESS

Submission is a two-step process requiring both (1) pre-application submission through the CDMRP eReceipt system (https://cdmrp.org/) and (2) application submission through Grants.gov (http://www.grants.gov/). ***A letter of invitation is mandatory for submission of an application. Applications will be invited based on pre-application screening.***

The Synergistic Idea Development Award mechanism is structured to accommodate two or 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.

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**

  The Initiating PI must enter the contact information for the Partnering PI(s) in the Partnering PI section.

- **Required Files – Tab 4**

  Preproposal Narrative (three-page limit): The Preproposal Narrative is inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and/or cartoons. The preproposal narrative should include the following:

  - **Rationale:** Present the ideas and reasoning behind the proposed research, to include relevant literature citations.
  - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
  - **Research Strategy:** Concisely describe the project's specific aims.
  - **Synergy:** Describe how the combined efforts of the PIs will result in a level of productivity that is greater than that achievable by each PI working independently. Describe how the combined efforts are centered around a unified objective.
  - **Innovation:** Describe how the proposed study is innovative.
  - **Impact:** Describe the potential impact of this study on prostate cancer and how it may significantly accelerate the elimination of death and suffering from prostate cancer.
  - **Overarching Challenges and Focus Areas:** Describe how the proposed study is responsive to at least one of the PCRP overarching challenges ***and*** at least one of the PCRP focus 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.
- List of Acronyms and Symbols: Provide a list of acronyms and symbols (e.g., PCR = polymerase chain reaction).

- **Submit Pre-application – Tab 5**
- **Other Documents Tab (not applicable)**

Pre-Application Screening: Pre-applications will be screened by scientific peer review based on the following criteria:

- **Synergy:** How well the proposed study represents a synergistic collaboration.
- **Innovation:** How well the proposed research is uniquely creative and represents more than an incremental advance upon published data.
- **Impact:** To what degree the proposed study could make an important contribution that will significantly accelerate 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 and Focus Areas:** Whether the proposed research addresses at least one of the PCRP overarching challenges ***and*** at least one of the focus areas.

Following 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 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.

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 of the project.

CDMRP requires separate Grants.gov application package submissions for the Initiating PI and each Partnering PI. Initiating and Partnering PIs will each be assigned unique and

separate log numbers by the CDMRP eReceipt system. Each PI must submit his/her Grants.gov application package using only his/her unique log number.

Application Components for the Initiating PI:

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 (15-page limit):** Upload as "ProjectNarrative.pdf."

  Describe the proposed research in detail using the following outline. ***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, including each PI's history of synergistic and collaborative study with one another and/or with other investigators.
  - **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. Include specific examples of synergistic elements incorporated into the research design. 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.***
  - **Project Coordination and Communication:** Describe plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all PIs and institutions participating in the project.
  - **Overarching Challenges and Focus Areas:** Describe (a) how the proposed research addresses at least one of the PCRP overarching challenges, ***and*** (b) how the proposal is responsive to at least one of the PCRP focus areas.

- **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 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.
    - Synergy: Summarize how the project is synergistic.
    - Innovation: Briefly describe how the proposed project uses innovation to yield critical discoveries, new avenues of investigation, or major advancements to accelerate prostate cancer research.

- Impact: Summarize how the proposed project will have an impact on the elimination of death and suffering from prostate cancer.
- Overarching Challenges and Focus Areas: Summarize how the proposed project addresses at least one of the PCRP overarching challenges ***and*** at least one of the PCRP focus areas.

- **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.

  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.

  Initiating and Partnering PIs must each submit a unique and separate detailed budget and justification.

- **Attachment 7: Subaward Detailed Budget and Justification (if applicable) (no page limit):** Use a separate Detailed Budget and Justification form for each subaward budget. Combine into a single file and upload as "SubBudgets.pdf." Refer to the General Application Instructions, Section II.B., for detailed information.

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

  State explicitly how the proposed work will, if successful, have an impact on prostate cancer research and/or clinical care, and how the expected results of the

project will contribute to the goals of eliminating death and suffering from prostate cancer.

- **Attachment 9: Innovation Statement (one-page limit).** Upload as "Innovation.pdf."

  Summarize 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 PIs frame the innovative features of the proposals:

  - 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 10: Synergy Statement (one-page limit).** Upload as "Synergy.pdf."

  Discuss in detail the advantages of addressing this problem through the combined expertise of the PIs, and how this contributes to the synergy of the application. Describe the elements of interdependence in the proposed work and the contributions of each PI to the overall synergy of the project. Describe how the combined efforts of the PIs will result in a level of productivity that is greater than that achievable by each PI working independently.

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.

Application Components for the Partnering PI(s):

The Partnering PI must follow the link in the email from CDMRP eReceipt and complete the registration process prior to the application submission deadline in order to associate his/her grant application package with that of the Initiating PI.

The application submission process for the Partnering PI uses an abbreviated application package of forms and attachments from Grants.gov that includes:

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

2. Attachments Form

- **Attachment 5: Statement of Work (SOW) (two-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions for detailed information. ***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. ***Initiating and Partnering PIs must each submit a unique and separate detailed budget and justification.***
- **Attachment 7: Subaward Detailed Budget and Justification (if applicable) (no page limit):** Use a separate Detailed Bud***g***et 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.

3. 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 .

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).

The Government reserves the right to review all applications based on one or more of the required attachments or supporting documentation (e.g., Impact Statement, Innovation Statement, or Synergy Statement).

B. Review Criteria

1. Peer Review: All applications will be evaluated according to the following criteria. Of these, Synergy, Innovation, and Impact are equally the most important, with the remaining criteria listed in decreasing order of importance.

- **Synergy**
  - To what degree the proposed partnership between independent PIs is likely to result in a level of productivity that is greater than that achievable by each PI working independently.
  - To what degree the contributions of each PI to the overall synergy of the project are appropriately balanced.
  - To what degree the proposed project is centered on a unified theme that addresses a single research question rather than an additive set of unrelated subprojects.
  - How well the application addresses processes for ongoing communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all participating PIs and institutions.

- **Innovation**
  - To what degree the research proposes new paradigms or 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 project, if successful, will make an original and significant contribution to prostate cancer research and/or clinical care, and how the expected results of the project will contribute to the goal of eliminating death and suffering from prostate cancer.
- **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 PIs acknowledge potential problems and address alternative approaches.

- **Personnel**
  - To what degree each PI possesses the research experience to function as a PI in a synergistic project.
  - How 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.

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

- **Responsiveness to Overarching Challenges and Focus Areas**
  - Whether the proposed research project is responsive to at least one of the PCRP overarching challenges ***and*** at least one of the PCRP focus areas toward the goal of eliminating death and suffering from prostate cancer.
- **Environment**
  - To what degree 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).
  - 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

- Whether the resources are divided appropriately among all PIs.

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

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

- Adherence to the intent of the award mechanism
- Programmatic relevance in relation to the PCRP overarching challenges and focus areas
- Ratings and evaluations of the peer reviewers
- Relative synergy, innovation and impact
- Program portfolio composition

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.
- Initiating or Partnering PI(s) application is not submitted by the deadline.

B. Modifications

- Pages exceeding the specified limits will be removed 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 PCRP Integration Panel (IP) member(s) 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 FY10 PCRP IP members may be found at http://cdmrp.army.mil/pcrp/panel10
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the detailed budget form exceed maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- The application includes a clinical trial.
- One of the PIs 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	Initiating PI Completed	Each Partnering PI Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed		
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1		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 Synergy Statement (Synergy.pdf) as Attachment 10		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