

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Population-Based Research Award

Funding Opportunity Number: W81XWH-10-PCRP-PBRA

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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 and 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; and
- Promote research into prostate cancer health disparities.

New for FY10: PCRP Overarching Challenges

The overarching goals of the FY10 PCRP are aimed towards eliminating death and suffering from prostate cancer. All applications for the PCRP Population-Based Research Award must address at least one of the PCRP overarching challenges:

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

PCRP Focus Areas (*revised for FY10*)

Applications for the PCRP Population-Based Research Award must 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 impacts 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 Population-Based Research Award mechanism was first offered as the Population-Based Idea Development Award in FY09. Thirty-one applications were received, and none were recommended for funding. The award mechanism has been modified for FY10.

The FY10 Population-Based Research Award mechanism supports high-impact, population-based approaches to prostate cancer research. These studies, if successful, should contribute significantly to the elimination of death and suffering from prostate cancer. Proposed research must be responsive to at least one of the FY10 PCRP overarching challenges and at least one of the focus areas. The overall goal of this award is to generate unique information and/or tools that can only be achieved from the perspective of statistical analysis of a defined patient population.

Applications may propose retrospective, prospective, case control, cohort, or other population-based study designs, provided the population sample is of sufficient size to demonstrate statistical significance. The study should address a well developed hypothesis that is conceptually sound and specific for prostate cancer. The statistical expertise of the study team should be clearly described and evident in the study plan. It is expected that investigators will demonstrate appropriate access to the population(s) needed for the study.

Research proposed under the Population-Based Research Award may include the following areas:

- Biomarkers
- Predictors of response to therapy
- Disease aggressiveness
- Epidemiology
- Genomics (germline or somatic)
- Health disparity
- Molecular genetics
- Risk prediction

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 Principal Investigator (PI) to clearly and explicitly articulate how the project addresses the following important aspects of the Population-Based Research Award:

- 1. Impact:** Research that has high impact will, if successful, significantly accelerate the elimination of death and suffering from prostate cancer.
- 2. Statistical plan:** A robust statistical plan is required and should be supported with requisite statistical expertise in the study team.

3. Human subject plan: Applicants should provide documentation demonstrating access to, and ability to recruit, the appropriate population(s) or patient samples in numbers sufficient to achieve statistical significance.

4. Preliminary data: The presentation of preliminary data to support the study feasibility is required. Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team.

5. Responsiveness to PCRP 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.

C. Eligibility

Applicants must be independent investigators 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 **4** years.
- The maximum allowable funding for the entire period of performance is **\$600,000** in direct costs.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 4-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
- Purchase of datasets and/or databases
- 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 the PI to travel to one 3½-day PCRP IMPaCT (Innovative Minds in Prostate Cancer Today) Meeting.

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$2.9M of the \$80M FY10 PCRFP appropriation to fund approximately three Population-Based Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

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), May 5, 2010**
- **Application Submission Deadline: 11:59 p.m. ET, May 26, 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/>).

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.**

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 – Tab 3**
- **Required Files – Tab 4**

Letter of Intent (LOI) Narrative (one-page limit): Provide a brief description of the research to be conducted. LOI Narratives are used for program planning purposes only (e.g., reviewer recruitment) and *will not be reviewed* during either the peer or programmatic review sessions.

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

B. Step 2 – Application Components

Applications will not be accepted unless the pre-application process is completed by the pre-application deadline. 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 (10-page limit):** Upload as “ProjectNarrative.pdf.”
Describe the proposed project in detail using the outline below. The inclusion of preliminary data to support the study feasibility is 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 examples of previous successful collaborations (if applicable). Provide reasoning to support why the project is considered population-based research.
 - **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. Describe the statistical plan for the research proposed. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples, including ethical and regulatory considerations. *This award may not be used to conduct clinical trials.*
- **Overarching Challenges and Focus Areas:** Describe (a) how the proposed research addresses at least one of the PCRCP overarching challenges, and (b) how the proposal is responsive to at least one of PCRCP 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 collaborator that describes how he/she will support the project, to include:
 - Unique expertise,
 - Availability of and access to research resources, and/or
 - Availability of and access to appropriate prostate cancer populations.
 - **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.
 - Impact: Summarize how the proposed project will have an impact on the elimination of death and suffering from prostate cancer.
 - Human subject plan: Briefly describe the accessible population(s) for the study.
 - 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.

- **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.”
State explicitly how the proposed work, if successful, will contribute to the goal of eliminating death and suffering from prostate cancer by having a significant impact on prostate cancer research and/or clinical care.
- **Attachment 9: Human Subject Plan (one-page limit):** Upload as “SubjectPlan.pdf.”
Describe how the proposed study population is appropriate to study the hypotheses. Include potential issues regarding ethics, information privacy, and assessment of risk versus benefit of participation. Describe the availability of this population, whether the PI and/or research team currently have access to this population, and how access to potential participants will be coordinated. Outline the recruitment strategy, past successes for recruiting similar populations, and how the sample size will achieve statistical power.

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>

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. Of these, Impact, Research Strategy and Feasibility and Statistical Plan are equally the most important, with the remaining criteria listed in decreasing order of importance.

- **Impact**
 - To what degree the project, if successful, will contribute to the goal of eliminating death and suffering from prostate cancer by having a significant impact on prostate cancer research and/or clinical care.
- **Research Strategy and Feasibility**
 - How well the scientific rationale supports the research 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 and integrated into the project.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
- **Statistical Plan**
 - Whether an appropriate statistical plan, including sample size projections and power analysis, is adequate for the study.
 - The consistency of the data analysis plan with the study objectives.
- **Human Subject Plan**
 - How well the selected population is described and whether it is appropriate for the proposed project.
 - How well the PI has demonstrated sufficient availability of and access to the appropriate prostate cancer population(s).
 - To what extent the PI has supported the feasibility of accruing a statistically significant population sample size.
- **Personnel**
 - Whether the PI meets the eligibility requirements for this mechanism.
 - To what extent the research team's background and prostate cancer-related

expertise are appropriate with respect to its ability to perform the proposed work, including whether there is evidence of sufficient biostatistical expertise to support the project.

- 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 Area(s)**
 - Whether the proposed research project responds to at least one of the PCRCP overarching challenges and at least one of the PCRCP focus areas, toward the goal of eliminating death and suffering from prostate cancer.
- **Ethics and/or Regulatory Issues**
 - Whether issues regarding ethics, information privacy, and assessment of risk versus benefit of participation have been adequately considered.
- **Environment**
 - To what extent 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 extent the quality and extent of organizational 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 criteria are used by programmatic reviewers to make funding recommendations.

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

V. ADMINISTRATIVE ACTIONS

After receipt of applications from Grants.gov, the following administrative actions may occur:

A. Rejection

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).
- 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 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 proposed research 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 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 Human Subject Plan (SubjectPlan.pdf) as Attachment 9	
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	