Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Population-Based Research Award

Funding Opportunity Number: W81XWH-11-PCRP-PBRA
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), May 18, 2011
- Application Submission Deadline: 11:59 p.m. ET, June 8, 2011
- Scientific Peer Review: July 2011
- Programmatic Review: October 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 Population-Based Research Award mechanism was first offered as the Population-Based Idea Development Award in FY09. Since then, 51 applications have been received, and 3 have been recommended for funding.

The Population-Based Research Award mechanism supports high-impact, population-based approaches to prostate cancer research. Applications should clearly demonstrate the potential of the study to contribute significantly to the elimination of death and suffering from prostate cancer. The overall goal of this award is to generate unique information and/or tools that can only be achieved from the perspective of systematic studies of a defined patient population. A robust statistical plan is required and should be supported with requisite statistical expertise in the study team.

All applications for the Population-Based Research 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.

Applications may propose retrospective, prospective, case control, cohort, or other population-based study designs (including the use of biospecimens and data from established retrospective databases), provided the proposed 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. Applicants are expected to provide documentation demonstrating access to, and ability to recruit, the appropriate population(s) or patient samples in numbers sufficient to achieve statistical significance.

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

- Biomarkers
- Predictors of response to therapy
- Disease aggressiveness
- Epidemiology/Public Health
- 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; however, correlative studies, including studies with populations from existing clinical trials, are allowed. 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/](https://cdmrp.org/Program_Announcements_and_Forms/). Principal Investigators (PIs) seeking funding for a clinical trial should consider submitting an application for the FY11 PCRP Clinical Trial Award.

C. Eligibility Information

- The PI must be an independent investigator at or above the level of Assistant Professor (or equivalent)
- 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 4 years.
- The maximum allowable direct costs amount for the entire period of performance is $600,000 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 4 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:**
- The PI to 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
- 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

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $2.9M of the $80M FY11PCRP appropriation to fund approximately 3 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.

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-PBRA.

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/).

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.

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 – Tab 3
• **Required Files – Tab 4**

**Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. LOIs 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**

No additional documents are required.

C. **Application Submission Content and Form**

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 Population-Based Research 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 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 scientific review. Address
potential problem areas and present alternative methods and approaches. Describe the statistical/analytical plan(s) 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 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 (if applicable): 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.”
  Describe the proposed research project, including the following elements: Background, Objective/Hypothesis, Study Design and Specific Aims, 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 how 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: 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 and past successes for recruiting similar populations. Describe how the proposed sampling strategy is appropriate for the study hypotheses, design, methods, and analytical/statistical plans.

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 Department of Defense (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, 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 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 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/Analytical Plan(s)**
○ 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 sample from the proposed population.
○ To what degree the plan for recruitment is appropriate for the study’s proposed hypotheses, design, methods, and statistical/analytical plan(s).
○ Whether issues regarding ethics, information privacy, and assessment of risk versus benefit of participation have been adequately considered.

**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.

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

**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**
  ○ 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 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 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.
  • Pre-application is not submitted.
B. Modification

- 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 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 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.

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

<table>
<thead>
<tr>
<th>Grants.gov Application Components</th>
<th>Action</th>
<th>Completed</th>
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<tr>
<td>SF-424 (R&amp;R) Application for Federal Assistance Form</td>
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