

# Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Exploration – Hypothesis Development Award

Funding Opportunity Number: W81XWH-10-PCRP-EHDA

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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 Fiscal Year 1997 (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; and
- 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 Exploration – Hypothesis 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 Exploration – Hypothesis 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 Exploration – Hypothesis Development Award was introduced in FY03. Since then, 665 applications have been received, and 115 have been recommended for funding.

The Exploration – Hypothesis Development Award supports the exploration of highly innovative, untested, high-risk/high-gain concepts, theories, paradigms, and/or methods that address an important problem in prostate cancer. Results of studies conducted through this award may provide the scientific rationale upon which a new hypothesis can be based, or initial proof-of-principle of an innovative hypothesis. This award is designed to provide investigators the opportunity to pursue serendipitous observations that may reveal entirely new avenues for investigation. ***Presentation of preliminary data is not allowed.*** However, logical reasoning and a sound scientific rationale for the proposed work must be provided.

Because these awards are designed for preliminary investigations, projects involving human subjects or specimens will not be supported unless they are exempt under 32 CFR 219.101(b) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110). Additional information on the protection of human subjects and exempt or expedited review status may be found at [https://www.bids.tswg.gov/TSWG/bids.nsf/5DD5E2BA50F02C18852572B1005F5B8B/\\$file/Title\\_32\\_CFR\\_Part\\_219.pdf](https://www.bids.tswg.gov/TSWG/bids.nsf/5DD5E2BA50F02C18852572B1005F5B8B/$file/Title_32_CFR_Part_219.pdf). ***Applications proposing studies that do not qualify for exempt or expedited review status will be administratively withdrawn.***

## C. Eligibility

All investigators at or above the level of postdoctoral fellow (or equivalent) are eligible to apply for this award. Refer to General Application Instructions, Appendix 1, for general eligibility information.

## D. Funding

- The maximum period of performance is **1** year.
- The maximum allowable funding for the entire period of performance is **\$75,000** in direct costs.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 1-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
- Clinical research costs
- 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

*The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$2.4M of the \$80M FY10 PCRP appropriation to fund approximately 20 Exploration – Hypothesis Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.*

#### **E. Award Administration**

Changes in organization are discouraged and will be allowed only at the discretion of the Grants Officer. 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 10, 2010**
- **Application Submission Deadline: 11:59 p.m. ET, March 31, 2010**
- **Scientific Peer Review: April/May 2010**
- **Programmatic Review: July 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](mailto: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 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

**Reviewers will be blinded to the identity of the PI, collaborators, and their organizations.** Due to the blinded nature of the review process, identifying or making references to the PI, collaborators, or their organizations within the Project Narrative or List of Acronyms and Symbols is prohibited and will result in administrative rejection of the application. The use of “I,” “our,” “this organization,” or similar wording in phrases that refer to the PI, collaborators, and/or their organizations through the references listed will result in administrative rejection of the application.

- **Attachment 1: Project Narrative (one-page limit):** Upload as “ProjectNarrative.pdf.”

Describe the proposed project in detail using the outline below.

- **Innovation:** Innovation should be the primary feature of the proposed study. Concisely state how the proposed project represents the exploration of a shift in paradigms, a new line of questioning, or an innovative methodological approach to an important problem in prostate cancer.
- **Relevance to the PCRP Goals:** Briefly describe how the proposed research addresses at least one of the PCRP overarching challenges and at least one of the PCRP focus areas.
- **Rationale:** State the rationale for the proposed research. *The presentation of preliminary data is not allowed.*
- **Objectives:** State concisely the specific aims and research strategy of the study.
- **Methods:** Describe the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation. *This award may not be used to conduct clinical trials or studies that are not exempt under 32 CFR 219.101(b) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110).*

The one-page limit of the Project Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, or cartoons to support the proposed study. *The Project Narrative will be available for both peer and programmatic review.*

- **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 (five-citation limit):** 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).
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”  
A technical abstract is not required for applications to the PCRP Exploration – Hypothesis Development Award. Leave Attachment 3 blank in the Grants.gov Attachments Form.

- **Attachment 4: Public Abstract (one-page limit):** Upload as “PublicAbs.pdf.”  
A public abstract is not required for applications to the PCRP Exploration – Hypothesis Development Award. Leave Attachment 4 blank in the Grants.gov Attachments Form.
- **Attachment 5: Statement of Work (SOW) (one-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.

**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.

Although requested, the Statement of Work, Detailed Budget and Justification, Subaward Detailed Budget and Justification (if applicable), Research & Related Senior/Key Person Profile (Expanded) Form, Biographical Sketch(es), Current/Pending Support, and Project/Performance Site Location(s) Form will not be forwarded for review due to the blinded nature of review for this award. These documents will be used for administrative purposes only.

## **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> *Reviewers will be blinded to the identity of the PI, collaborators, and their organizations.*

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).

## **B. Review Criteria**

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

- **Innovation**
  - To what degree the proposed concept is innovative.
    - Whether the project proposes new paradigms, challenges existing paradigms, or otherwise represents the exploration of a new line of questioning or an innovative methodological approach to an important problem in prostate cancer.
    - How the proposed research represents more than an incremental advance beyond ongoing or published research.
  - Whether the concept is untested (preliminary data are not allowed).
- **Relevance of the Concept**
  - To what degree the proposed research is relevant and potentially important to eliminating death and suffering from prostate cancer.
  - Whether the proposed research addresses at least one of the PCRP overarching challenges, and at least one of the PCRP focus areas.
- **Research Strategy**
  - To what degree the proposed research is supported by a sound scientific rationale.



- To what degree the experimental design and methodology are appropriate to address the stated objectives.

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

- **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 PCRFP overarching challenges and focus areas
- Ratings and evaluations of the peer reviewers
- Relative innovation
- Program portfolio composition

*Approximately 4 weeks after programmatic review, each PI will receive notification of the status of his/her application. However, PIs will not receive access to a scientific peer review summary statement or other feedback on the strengths and weaknesses of the application.*

## 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).
- PI's or collaborator's name or organizations is included in the Project Narrative or List of Acronyms and Symbols.
- Use of "I," "our," "this organization," or similar phrases in the Project Narrative that refer to the PI, collaborators, and/or organizations in the references listed.
- 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.
- Inclusion of studies that do not qualify for exempt status under Title 32, Code of Federal Regulations, Part 219, Section 101(b) (32 CFR 219.101[b]) or expedited review (32 CFR 219.110 or 21 CFR 56.110).

## **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](mailto: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](mailto: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](mailto: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

| <b>Grants.gov<br/>Application Components</b>            | <b>Action</b>  | <b>Completed</b>     |
|---|--|----------------------|
| 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  | Not applicable (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                           |                      |
| 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  |                      |