Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Exploration – Hypothesis Development Award

Funding Opportunity Number: W81XWH-11-PCRP-EHDA

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 Exploration – Hypothesis Development Award mechanism was first offered in FY03. Since then, 1,056 Exploration – Hypothesis Development Award applications have been received, and 142 have been recommended for funding.

The Exploration – Hypothesis Development Award supports the exploration of highly innovative, untested, potentially 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 strongly discouraged.*** However, logical reasoning and a sound scientific rationale for the proposed work must be provided.

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

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/. Also, for more information on clinical research, a Human Subject Resource Document is provided at https://cdmrp.org/Program_Announcements_and_Forms/. ***Applications proposing studies that do not qualify for exempt or expedited review status will be administratively withdrawn.***

C.   Eligibility Information

- All investigators at or above the level of postdoctoral fellow (or equivalent) are eligible to apply for this award.
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D.   Funding

- The maximum period of performance is **1** year.
- The maximum allowable direct costs amount for the entire period of performance is **$75,000** 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 **1** year.
- 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:

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Clinical research costs
- 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 $3.6M of the $80M FY11 PCRP appropriation to fund approximately 30 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.

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-EHDA.

B.   Pre-Application Submission Content and Form

All pre-application components must be submitted by the Principal Investigator (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/).

Reviewers will be blinded to the identity of the PI, collaborators, and their organization(s). Due to the blinded nature of the review process, identifying or making references to the PI, collaborators, or their organization(s) in the Project Narrative or List of Abbreviations, Acronyms, and Symbols is prohibited and will result in administrative rejection of the proposal. In addition, the use of "I," "our," "this organization," or similar phrases that refer to the PI, collaborators, or their organization(s) through the references listed will result in administrative rejection of the proposal.

Due to the blinded nature of the review process, the requested Statement of Work, Research & Related Senior/Key Person Profile (Expanded), Biographical Sketch(es), Current/Pending Support, Research & Related Budget form and Budget Justification, Project/Performance Site Location(s) Form, and R & R Subaward Budget Attachments(s) Form (if applicable) will not be forwarded for peer or programmatic review. These documents will be used for administrative purposes only.

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

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

2. **Attachments Form**

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

     Describe the proposed project using the outline below.

     o **Innovation:** Innovation should be the primary feature of the proposed study. Concisely state how the proposed project represents the exploration of a shift in paradigm, a new line of questioning, or an innovative methodological approach to an important problem in prostate cancer.

     o **Relevance to the PCRP Goals:** Briefly describe how the proposed research addresses one of the PCRP overarching challenges. If the proposed project does not address one of the overarching challenges, provide a description to justify how the project will nevertheless address a critical need in the field of prostate cancer research and/or patient care. In addition, state how the research addresses at least one of the PCRP focus areas.

     o **Hypothesis/Rationale/Purpose**: State the rationale for the proposed research. *The inclusion of preliminary data is strongly discouraged.*

     o **Objectives:** State concisely the specific aims and research strategy of the study.

     o **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).*

   - **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 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). The inclusion of Internet URLs to references is encouraged; *however, to comply*

> ***with blinded review, do not include URLs that incorporate the name or abbreviation of the organization(s) of the PI or collaborator.***

- ○ List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols. ***Do not include information that will identify the organization(s) of the PI or collaborator.***

- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf."

  A technical abstract is not required at this time for applications to the PCRP Exploration – Hypothesis Development Award. Leave Attachment 3 space blank in the Grants.gov Attachments Form.

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

  A public abstract is not required at this time for applications to the PCRP Exploration – Hypothesis Development Award. Leave Attachment 4 space blank in the Grants.gov Attachments Form.

- **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.

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, US Army Medical Research and Materiel Command (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. *Reviewers will be blinded to the identity of the PI, collaborators, and their organization(s).*

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, which are 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.

  o Whether the concept is untested (e.g., no preliminary data).

- **Relevance of the Concept**

  o To what degree the proposed research is relevant and potentially important to eliminating death and suffering from prostate cancer.

  o To what degree the proposed research addresses one of the PCRP overarching challenges or, alternatively, provides adequate justification for addressing a different critical need in prostate cancer research and/or patient care.

- **Research Strategy**

  o To what degree the proposed research is supported by a sound scientific rationale.

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

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

- **Application Presentation**

  o To what extent the writing, clarity, and presentation of the application components influenced the review.

2. **Programmatic Review:** To determine the application's relevance to the mission of the DOD and CDMRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

- Adherence to the intent of the award mechanism

- Programmatic relevance

- Ratings and evaluations of the peer reviewers

- Relative innovation

- 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.
- PI's or collaborator's name or organizations is included in the Project Narrative or List of Abbreviations, 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.   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).

- 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).

- The PI does not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

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

B. Administrative and National Policy Requirements

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

C. Reporting

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

D. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section E, for general information on organization or PI changes. Changes in organization are discouraged and will be allowed only at the discretion of the Grants Officer.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

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

    Phone: 1-301-682-5507

    Email: help@cdmrp.org

B. Grants.gov Contact Center

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

    Phone: 1-800-518-4726

    Email: support@grants.gov

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

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	The Technical Abstract is not required with application submission. Leave Attachment 3 space blank.	
	The Public Abstract is not required with application submission. Leave Attachment 4 space blank.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	