

# **Program Announcement**

**for the**

**Defense Health Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

## **Prostate Cancer Research Program**

### **Transformative Impact Award**

**Funding Opportunity Number: W81XWH-13-PCRP-TIA**

**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), June 19, 2013
- **Invitation to Submit an Application:** August 2, 2013
- **Application Submission Deadline:** 11:59 p.m. ET, October 9, 2013
- **Peer Review:** December 2013
- **Programmatic Review, Stage 1:** February 2014
- **Invitation for Oral Presentation:** February 12, 2014
- **Programmatic Review, Stage 2:** March 2014

*This Program Announcement is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.*

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

Applications to the Fiscal Year 2013 (FY13) Prostate Cancer Research Program (PCRP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The PCRP was initiated in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY12 totaled \$1.21 billion. The FY13 appropriation is \$80 million (M).

The mission of the FY13 PCRP is to find and fund research that will lead to the elimination of death from prostate cancer and enhance the well-being of men experiencing the impact of the disease. Specifically, the PCRP seeks to promote highly innovative, groundbreaking research; high-impact research with near-term clinical relevance; multidisciplinary, synergistic research; translational studies to support the fluid transfer of knowledge between bedside and bench; research on patient survivorship and quality of life; the next generation of prostate cancer investigators through mentored research; and research on disparities in the incidence and mortality of prostate cancer.

#### **PCRP Overarching Challenges** (*revised for FY13*)

Consistent with the program's mission to eliminate death from prostate cancer and enhance the well-being of men experiencing the impact of the disease, including those from disproportionately affected populations, each PCRP funding opportunity either requires or encourages (see Section I.B., Award Information below) applications to address one of the following three PCRP overarching challenges:

- Develop better tools to detect clinically relevant disease in asymptomatic men
- Distinguish aggressive from indolent disease in men newly diagnosed with prostate cancer
- Develop effective treatments and address mechanisms of resistance for men with high-risk or metastatic prostate cancer

#### **PCRP Focus Areas** (*revised for FY13*)

All applications for FY13 PCRP funding opportunities are also expected to address at least one of the following PCRP focus areas:

- **Biomarker Development:** Validation and qualification of biomarkers for early detection of clinically relevant disease or for prognosis or prediction and assessment of response to therapies
- **Genetics:** Understanding host or tumor genetics and epigenetics responsible for susceptibility, disease progression, and treatment outcomes for clinically relevant prostate cancer
- **Imaging:** Development of new anatomic, functional, and molecular imaging approaches for the detection and management of clinically relevant prostate cancer
- **Mechanisms of Resistance:** Understanding primary and acquired resistance to therapy

- **Survivorship and Palliative Care:** Improving the quality of life and well-being of prostate cancer patients and their families
- **Therapy:** Identification of new targets, pathways, and therapeutic modalities
- **Tumor and Microenvironment Biology:** Understanding the intrinsic and extrinsic mechanisms contributing to tumor development and the progression of prostate cancer

## B. Award Information

The PCRP Transformative Impact Award mechanism was first offered in FY12. Since then, 10 Transformative Impact Award applications have been received, and 3 have been recommended for funding.

The Transformative Impact Award supports prostate cancer research with near-term clinical relevance that will *transform and revolutionize* the clinical management of prostate cancer and make a major contribution to the elimination of death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease. For the purpose of this award, clinical management of prostate cancer includes the wide spectrum of screening, detection, diagnosis, prognosis, and/or treatment.

Although research that is deemed transformative must contend with potential risks, the proposed project(s) must be supported by thorough review of the literature, a sound rationale, and a well-designed research strategy. Applications must include substantive preliminary data to support the rationale and feasibility of the study. The critical components of this award mechanism are:

**Research Scope:** Since the intent of this award is to achieve near-term clinical impact for patients, the scope of the research effort is expected to include translational research, clinical research, and/or clinical trials. *All projects submitted to the Transformative Impact Award mechanism must address one of the PCRP overarching challenges and are expected to address at least one of the PCRP focus areas.*

**Transformative Impact:** Projects funded by this award will have a near-term, *revolutionary* impact on the clinical management of prostate cancer. It is the responsibility of the Principal Investigator (PI) to clearly and sufficiently describe how the proposed project(s) will transform prostate cancer clinical management in the near term.

**Implementation Plan:** The project(s) must be supported by a detailed plan that identifies critical milestones, outlines the knowledge, expertise, and technical innovations that the investigative team will utilize to achieve the milestones and explains how the outcomes of the project(s) will be translated to patients. The application must include information demonstrating accessibility and availability of human subjects and/or human anatomical samples, substances, and/or data necessary for the study so that the project(s) can commence immediately after an award is made. PIs whose study design(s) require human anatomical substances are encouraged to collaborate with personnel affiliated with established prostate cancer biorepositories (e.g., Prostate Cancer Biorepository Network [PCBN] [<http://www.prostatebiorepository.org>] and/or the North Carolina – Louisiana Prostate Cancer Project [PCaP] [<http://www.ncla-pcap.org>]). A robust statistical plan and statistical expertise should be included where appropriate in proposed investigation(s).

**Research Team:** It is expected that the proposed research team will include an exceptionally skilled group of individuals (e.g., scientists, clinicians, consumer advocates, etc.) well positioned to achieve the goals, with leadership from multiple collaborators. The PI(s) should possess a track record of success in leading large, focused projects with clinical impact. The PI(s) also should demonstrate a strong commitment to the project and to the research team, and develop a communications plan that fosters consistent and intensive interactions by all team members to accelerate translation of the project's outcomes to patients and/or for clinical use. The inclusion of scientific advisors, external to the conduct of the research, is encouraged. ***The PCRP Science Officer assigned to any resulting award must be invited to participate in periodic research team meetings. The plan for such meetings should be noted in the application.***

**Partnering PI Option:** The Transformative Impact Award mechanism encourages multi-institutional applications. The Partnering PI Option under this award mechanism is structured to accommodate up to three PIs, each of whom will receive a separate award. One partner is identified as the Initiating PI and additional PIs are identified as Partnering PIs. The Initiating and Partnering PIs have different application submission requirements; however, each PI should contribute to the preparation of each of the application components. The PIs may have expertise in similar or disparate scientific disciplines. It is the responsibility of the collaborating investigators to describe how their efforts will combine and synergize to maximize the project's outcomes.

**Oral Presentation:** An oral presentation to the PCRP Integration Panel (IP) is a requirement for application review as described below:

- ***Programmatic Review, Stage 2:*** A PI or Initiating PI whose application is selected for final consideration in Stage 2 of the Programmatic Review will be required to give an oral presentation that will be held in the National Capital Area in March 2014.

**Use of Human Subjects and Human Anatomical Substances:** All Department of Defense (DoD)-funded research involving new and ongoing research with human subjects and human anatomical substances must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB approval at the time of submission is NOT required. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is supported by the DoD. These laws and directives require information in addition to that supplied to the local IRB. Allow a minimum of 2-3 months for regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

***The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.***

### **C. Eligibility Information**

- The PI (or each of the Initiating and Partnering PIs) must be an independent investigator at or above the level of Assistant Professor (or equivalent).

- Cost sharing/matching is not an eligibility requirement.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

#### **D. Funding**

***Applications with a single PI or using the Partnering PI Option have the same funding level.***

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance are **\$5M** plus indirect costs. For applications employing the Partnering PI Option, the ***combined*** direct costs of all PIs may not exceed **\$5M**.
- 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(s) may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.
- Regardless of the period of performance proposed, the applicant(s) 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.4., for budget regulations and instructions for the Research & Related Budget. ***For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.***

In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel for the PI and up to two additional members of the research team to attend a 1-day meeting to be held in the National Capital Area during the award period of performance. This meeting will be held to provide a presentation on progress. Costs associated with travel to this meeting, up to \$1,800 per person, should be included in Year 2 of the budget. ***If the Partnering PI Option is employed, travel costs should be requested only for each of the PIs on their separate budgets.***
- Travel for the PI and up to two additional members of the research team to attend one DoD PCRP Innovative Minds in Prostate Cancer Today (IMPACT) meeting, which is held to disseminate the results of PCRP-sponsored research. Costs associated with travel to this meeting, up to \$1,800 per person, should be included in Year 2 of the budget. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings. ***If the Partnering PI Option is employed, travel costs should be requested only for each of the PIs on their separate budgets.***

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Research-related subject costs
- Clinical research costs
- Purchase of datasets and/or databases
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year per person for three individuals among the PI(s) and the key personnel to attend scientific/technical meetings in addition to the required meeting described above. *If the Partnering PI Option is employed, these costs can be requested on each of the PIs' separate budgets.*

*The CDMRP expects to allot approximately \$8M of the \$80M FY13 PCRP appropriation to fund approximately 1 Transformative Impact Award application, 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 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/>).

**Partnering PI Option:** The Transformative Impact Award mechanism is structured to accommodate up to three PIs. One partner will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as the Partnering PI(s). Initiating and Partnering PIs each have different submission requirements; however, each PI should contribute significantly to the development of the proposed research project including the Project Narrative, Statement of Work (SOW), and other required components. The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PI(s). The Partnering PI(s) will then be notified separately by email. Please note that each Partnering PI must follow the link in this email and register with CDMRP eReceipt in order to associate his/her grant application package with that of the Initiating PI. If an application is invited, only the Initiating PI will receive a letter of invitation via email from the CDMRP. The letter will provide the information necessary to begin application submission through Grants.gov.

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application.

## 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-13-PCRP-TIA.

## B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI or the Initiating PI through the CDMRP eReceipt System (<https://cdmrp.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

**Partnering PI Option:** *The Initiating PI is responsible for submission of all pre-application components.*

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the preapplication, the PI or Initiating PI must contact the CDMRP Help Desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507. A change in PI or organization after submission of the pre-application will be allowed only at the discretion of the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer.

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 (COI) – Tab 3**

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

FY13 PCRP IP members should not be involved in any pre-application or application. A list of FY13 PCRP IP members can be found at <http://cdmrp.army.mil/pcrp/panels/panel13>. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.

- **Required Files – Tab 4**

**Preproposal Narrative (three-page limit):** The Preproposal Narrative page limit applies to text and any non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the proposed project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application. *Note: At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.*



The Preproposal Narrative should describe the proposed project(s) using the outline below:

- **Background/Rationale:** Clearly present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe the problem or question in prostate cancer that will be the focus of the proposed project(s). Describe the approach to develop a solution for the problem or question.
- **Hypothesis or Objective:** State the hypothesis(es) to be tested or the objective(s) to be reached. Clearly describe how the research questions address one of the PCRP overarching challenges.
- **Impact:** Describe the intended outcome of the proposed project(s) on the clinical management of prostate cancer and how the impact would be highly transformative in the near term.
- **Research Approach:** State the project's specific aims and concisely describe the experimental approach for accomplishing the aims.
- **Research Team:** Briefly describe the composition, expertise and organization of the research team and each team member's role in the project(s), with additional emphasis on the leadership role(s) of the PI(s). Briefly describe how these features will facilitate the success of the key aspects the project(s).

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application are limited to:

- References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal 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 used in the Preproposal Narrative.
- PI and Key Personnel Biographical Sketches (four-page limit per individual)
- **Submit Pre-Application – Tab 5**

This tab *must* be completed for the pre-application to be accepted and processed by CDMRP.

- **Other Documents Tab**

No additional documents are required.

## Pre-Application Screening

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the PCRP, pre-applications will be screened by the PCRP IP based on the following criteria, which are of equal importance:

- **Intent of the Award Mechanism:** To what degree the proposed research, if successful, will make a highly *transformative* impact on eliminating death from prostate cancer and enhancing the well-being of men experiencing the impact of the

disease through major improvements to prostate cancer clinical management in the near term.

- **Research Approach:** Whether the research approach is based on a sound rationale and appears feasible and appropriately designed to accomplish the aims of the project(s).
- **Research Team:** To what degree the background and prostate cancer-related expertise of the PI(s) and key personnel are appropriate with respect to their abilities to successfully complete the proposed work and the extent to which the PI(s) is/are well prepared and committed to lead the proposed project(s) toward clinical impact.
- **Notification of Pre-Application Screening Results**

Following the pre-application screening, PIs or Initiating PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

### C. Application Submission Content and Form

*Applications will not be accepted unless the PI or Initiating PI has received notification of invitation.*

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 through the Grants.gov portal (<http://www.grants.gov/>). For the Transformative Impact Award, additional application components are also required and should be submitted as directed below.

*Partnering PI Option: The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and the Partnering PI(s). Initiating and Partnering PIs will each be assigned unique log numbers by the CDMRP eReceipt System. Each Grants.gov application package must be submitted using the unique log number.*

#### **Application Components for Single PIs or for Initiating PIs under the Partnering PI Option:**

**Grants.gov application package components:** For the Transformative Impact 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 (25-page limit):** Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and

non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below. Throughout the Project Narrative, clearly convey how the proposed research, if successful, would transform the clinical management of prostate cancer and/or change clinical practice, and ultimately advance the goal of eliminating death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease.

- **Background:** Present the ideas and reasoning behind the proposed research and include a literature review and preliminary studies and/or preclinical data that led to the development of the proposed project(s); unpublished preliminary data should originate from the laboratory of the PI(s) or members of the research team named on this application.
- **Hypothesis or Objective:** State the hypothesis(es) to be tested or the objective(s) to be reached.
- **Specific Aims:** State the specific aims of the project(s).
- **Research Strategy:** Describe the experimental design, methods, and analyses. Include a description of appropriate controls and endpoints to be tested, if applicable. Address potential problem areas and present alternative methods and approaches. Statistical analyses appropriate to the type of study (e.g., power analysis for population-based studies) should be well described in sufficient detail for evaluation.

If a prospective clinical study is proposed, provide a properly powered statistical plan and information demonstrating how a sufficient number of human subjects or human anatomical substances will be accrued to the proposed study during the award period. ***Include a clear and detailed description of the potential ethical issues raised by the proposed study and provide a detailed plan for how the ethical issues will be addressed.*** The study personnel must demonstrate appropriate expertise in conducting clinical studies.

- **Implementation Plan:** Provide an overall strategic plan for completing the proposed project(s) that identifies critical milestones; outlines the knowledge, expertise, and technical innovations that the investigative team will utilize to make decisions, allocate resources, and accomplish the milestones; and explains how the outcomes of the project(s) will be translated to patients. Describe and/or provide evidence that the research can be initiated without delay once the award is made.
- **Research Team and Environment:** Describe how the PI's or PIs' research experience, leadership skills, and commitment to making a revolutionary impact for prostate cancer patients provide substantial qualifications to coordinate this collaborative effort. Discuss the qualifications of the full research team, their specific contributions to the project(s), and how the appropriate expertise is necessary to address the research question and enable the success of the

proposed project(s). Describe the research environment(s) and how the facilities and resources will support the research requirements and the collaborative project(s). Present an overall management plan to facilitate consistent and intensive interactions by all team members in the project(s), including aspects such as communications, data sharing, adherence to regulatory requirements, administrative support, and oversight to accelerate translation of the project's outcomes to patients and/or for clinical use.

- **Overarching Challenges and Focus Areas:** Describe how the proposed research is relevant to one or more of the PCRP focus areas and responsive to one of the PCRP overarching challenges.
- **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. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.***
  - **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 award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award 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 a copy/copies of the published manuscript(s) must be included in Attachment 2. 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, confirming the laboratory space, equipment, and other resources available for the project(s). ***If the project is multi-institutional, a letter for each site should be provided.***
  - **Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual or organization that describes how he/she will support the project(s), to include:
    - Unique expertise

- Availability and access to research resources, and/or
- Availability of and access to appropriate populations (and/or access to available samples/data or database[s]) (if applicable)
- Intellectual and Material Property Plan: Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”  
The technical abstract is used by all reviewers. Programmatic reviewers do not typically have access to the full application and therefore rely on the technical abstract for appropriate description of the project’s key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.  
Describe the proposed research project including the following elements:
  - Background: Present the ideas and reasoning behind the proposed project(s).
  - Objective/Hypothesis: State the hypothesis to be studied and/or the objectives to be reached.
  - Specific Aims: State the specific aims of the study.
  - Study Design: Briefly describe the study design including appropriate controls.
  - Clinical Impact: Briefly summarize how the proposed project(s) may lead to a near-term, transformative impact on the clinical management of prostate cancer.
- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.”  
Lay abstracts should be written using the outline below. ***Do not duplicate the technical abstract.*** Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.
  - Describe the scientific objective(s) and rationale for the proposed project(s) 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?
- **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, including guidance on appropriate SOW formats.  
***For the Partnering PI Option: Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should***

*be noted for each task.* An example of this type of SOW is available at [https://cdmrp.org/Program Announcements and Forms/](https://cdmrp.org/Program_Announcements_and_Forms/).

- **Attachment 6: Impact Statement (one-page limit):** Upload as “Impact.pdf.”

Explain in detail how the proposed research project is important, as follows:

***Describe the near-term impact:*** Detail the anticipated results/outcome(s)/ product(s) that will be directly attributed to the results of the proposed research. Explain how these results/outcome(s)/ product(s) will be transformative on the clinical management of prostate cancer. Describe the benefits to be realized and how rapidly they will be successfully translated to prostate cancer patients.

***Describe the long-term impact:*** Although the expectation is that projects supported by the Transformative Impact Award will result in near-term benefits for patients, additional/ongoing benefits over time are also expected. Explain the anticipated long-term gains from the proposed research, including how the outcomes or products will ultimately contribute to eliminating death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease.

***PCRP overarching challenges:*** Summarize how the proposed research addresses one of the PCRP overarching challenges.

- **Attachment 7: Transition Plan (one-page limit):** Upload as “Transition.pdf.”

Provide information on the methods and strategies proposed to move the outcomes of the project to clinical use. The transition plan should include the components listed below.

- A description of the expected outcome(s) that will result after completion of the proposed research project. Outcomes should be specific, measurable, and should include a definition of the end user.
- Details of the funding strategy that will be used to bring the outcomes to delivery to market (e.g., specific potential industry partners, specific funding opportunities to be applied for, etc.).
- A description of collaborations and other resources that will be used to provide continuity of development.
- A brief schedule and milestones for bringing the outcome(s) to delivery to market.

- **Attachment 8: Data- and Research Resource-Sharing Plan (one-page limit):** Upload as “Sharing.pdf.”

Describe how unique and/or final research data will be shared with the wider prostate cancer research community, along with any resulting research resources. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the proposed project. If there are limitations associated with a preexisting agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data- and/or research resource-sharing plan.

Refer to the General Application Instructions, Appendix 4, Section K, for additional information.

In preparing requested budgets, applicants may include anticipated costs associated with data- and research resource-sharing (i.e., making a large dataset available to the public or developing an important resource for the scientific community).

- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information. *Note: Some of the items in this attachment may be made available for programmatic review.*
  - PI Biographical Sketch (four-page limit): Upload as “Biosketch\_LastName.pdf.”
  - PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
  - Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch\_LastName.pdf.”
    - *Include biographical sketches for the Partnering PI(s), if applying under the Partnering PI Option.*
  - Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
    - *Include previous/current/pending support for the Partnering PI(s), if applying under the Partnering PI Option.*
- 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.”

*For the Partnering PI Option: Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for the Partnering PI(s), even if they are at the same organization. The combined total direct costs for the Initiating and Partnering PIs’ budgets cannot exceed \$5M.*
- 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.

**Application Components for the Partnering PI, if applying under the Partnering PI Option:**

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

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

**1. SF 424 (R&R) Application for Federal Assistance Form**

**2. 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 on completing the SOW. *Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task.* An example of this type of SOW is available at [https://cdmrp.org/Program\\_Announcements\\_and\\_Forms/](https://cdmrp.org/Program_Announcements_and_Forms/).

**3. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.

- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”

*Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget for the Partnering PI(s) should not include budget information for the Initiating PI, even if they are at the same organization. The combined total direct costs for the Initiating and Partnering PIs’ budgets cannot exceed \$5M.*

**4. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

**5. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

**Additional Application Components:** In addition to the completed Grants.gov application package of forms and attachments, Transformative Impact Award applications also require the following component:

**Oral Presentation:** PIs or Initiating PIs whose applications are selected during Programmatic Review, Stage 1, for final consideration in Programmatic Review, Stage 2, will be required to give an oral presentation that will be held in the National Capital Area in March 2014.

Each presentation will include a 10-minute talk by the PI or Initiating PI, followed by a 20-minute question and answer session with IP members. The oral presentation should not be used to reiterate the technical/scientific details of the project(s) already described in the written application. Rather, the following questions will be the topics for discussion during the PI’s or Initiating PI’s talk and the question and answer session. A PI who is invited must prepare a five-slide presentation that specifically addresses these questions:

- Without addressing the specific technical/scientific aspects of your project, what do you consider to be the most critical barriers to be overcome in the clinical management of prostate cancer, and how do the goals of your proposed effort relate to current broader efforts to overcome these barriers?
- Without addressing the specific technical/scientific aspects of your project, how do you envision transitioning the results from your efforts into a near-term, major advancement



from the current standard of care for the management of prostate cancer and, in addition, ultimately contribute significantly to the elimination of death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease?

- Without addressing the specific technical/scientific aspects of your project, what leadership skills will you use in your research team's efforts to move the project quickly and effectively toward completion of the objectives?

#### **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 will 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. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an "Active" status 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 makes recommendations for funding to the Commanding General, USAMRMC, based on technical merit, the relevance to the mission of the DHP and PCRP, 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. Panel members sign a non-disclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations 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 panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 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:

- **Impact**

- To what degree the potential gains of the proposed project(s):
  - Will be near term and
  - Will be transformative in the clinical management of prostate cancer.
- How and to what degree the transformative outcomes of the proposed research will contribute to the elimination of death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease.
- How well the project(s) addresses one or more of the PCRP overarching challenges.

- **Research Strategy and Feasibility**

- How well the scientific rationale supports the research and its feasibility, as demonstrated by a critical review and analysis of the literature, the presentation of preliminary data, and logical reasoning.
- How well the hypothesis(es) or objective(s), aims, clinical and other appropriate endpoints (as applicable), experimental design, methods, and analyses are developed and integrated into the project(s).
- How well potential problems are acknowledged and alternative approaches addressed.
- Whether the application includes an appropriate statistical plan with power analysis (if applicable).
- Whether there is sufficient evidence to support availability and accessibility of the populations/samples required for the study (if applicable).

- **Implementation Plan**

- How the proposed project(s) is supported by a detailed plan that identifies critical milestones and explains how these milestones will be achieved.
- Whether the proposed plan is appropriate with respect to plans for decision-making, allocation of resources, consistent interaction and coordination of personnel and collaborations, including regulatory approval processes, management of intellectual and material property aspects, and conflict resolution among all participating PIs and institutions.

- **Research Team**

- To what degree convincing evidence has been provided to substantiate the PI's or PIs' abilities and commitment to successfully lead the research team in achieving the outcome of transformative, revolutionary impact from the proposed project(s).

- To what degree the research team’s background and expertise are appropriate with respect to its ability to perform the proposed work, including whether there is evidence of sufficient expertise for all aspects of the work and whether there is evidence of strong commitment to the project(s).
- To what degree the levels of effort are appropriate for successful conduct of the proposed work.
- **Environment**
  - To what degree the scientific environment(s) is appropriate for the proposed research.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including patient populations, samples, and collaborative arrangements).
  - To what degree the quality and extent of organizational support are appropriate for the proposed research.

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

- **Ethical and/or Regulatory Issues**
  - If applicable, whether there is evidence that a plan to address potential ethical issues (e.g., informed consent, information privacy, assessment of risk versus benefit of participation) raised by the proposed study has been appropriately considered and developed.
- **Data and Resource Sharing**
  - To what degree the plan for sharing of project data and research resources is appropriate and reasonable to facilitate use by the wider prostate cancer research and consumer communities.
- **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 make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

- a. Ratings and evaluations of the peer reviewers**
- b. Relevance to the mission of the DHP and FY13 PCRP, as evidenced by the following:**
  - **Stage 1:** During the first stage of programmatic review, applications will be selected for the second stage using the following criteria:

- Adherence to the intent of the award mechanism
- Programmatic relevance in relation to the PCRCP overarching challenges and focus areas
- Relative impact
- Program portfolio composition
- **Stage 2:** During the second stage of programmatic review, the following criteria will be used:
  - Understanding of critical issues/barriers in prostate cancer clinical management and selection of projects best suited to address the issues/barriers in the context of the current landscape of prostate cancer research
  - Articulation of a vision for achieving a readily translatable, transformative impact for prostate cancer patients
  - Capability to lead and synergize the research team's efforts effectively accomplish the aims of the project

### **C. Recipient Qualification**

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

### **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. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

## **IV. ADMINISTRATIVE ACTIONS**

After receipt of pre-applications from the CDMRP eReceipt System or applications from Grants.gov, the following administrative actions may occur:

### **A. Rejection**

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.

- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- **Partnering PI Option:** All associated (Initiating and Partnering PI) applications are not submitted by the application submission deadline.

## **B. Modification**

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI or Initiating PI 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 pre-application or application:

- A FY13 PCRP IP member is named as being involved in the research proposed or is found to have assisted in the pre-application 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 FY13 PCRP IP members can be found at <http://cdmrp.army.mil/pcrp/panels/panel13>.
- 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 & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The PI or, if applicable, the Initiating PI and Partnering PI(s) do not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.
- The proposed project does not address one of the PCRP overarching challenges.

## **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 USAMRAA 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, 2014. 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 D, for general information regarding administrative and national policy requirements.

### **C. Reporting**

Recipients of this award will be required to present an update on progress toward accomplishing the goals of the project(s) at a 1-day meeting to be held in the National Capital Area during the award period of performance.

If employing the Partnering PI Option, each PI, whether the Initiating or a Partnering PI, must submit individual progress reports as required by his/her individual assistance agreement.

For all awards including prospective accrual of human subjects, quarterly technical progress reports will be required.

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

### **D. Award Transfers**

Changes in any personnel designated as PI, Initiating PI, or Partnering PI are strongly discouraged and will be allowed only under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

The institutional transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 4, Section F, for general information on organization or PI changes.

## **E. Pre-Award Meeting**

At the Government's discretion, the PI(s) and key personnel may be requested to participate in a pre-award meeting at the Government's expense.

## **VI. AGENCY CONTACTS**

### **A. CDMRP Help Desk**

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as 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: 301-682-5507

Email: [help@cdmrp.org](mailto: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: 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 or by responding to the prompt provided by Grants.gov when first downloading the application package. 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	Single or Initiating PI Completed	Partnering PI Completed (if applicable)
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 Lay Abstract (LayAbs.pdf) as Attachment 4.		
	Upload Statement of Work (SOW.pdf) as Attachment 5.		
	Upload Impact Statement (Impact.pdf) as Attachment 6.		
	Upload Transition Plan (Transition.pdf) as Attachment 7.		
	Upload Data- and Research Resource-Sharing Plan (Sharing.pdf) as Attachment 8.		
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
	Attach PI Previous/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 Previous/Current/Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.		
Research & Related Budget	Complete 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.		
Additional Application Components	Action	Single or Initiating PI Completed	Partnering PI Completed (if applicable)
Oral Presentation	Confirm availability to give an oral presentation in the National Capital Area in March 2014 (if selected for Programmatic Review, Stage 2).		