

# Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

## Prostate Cancer Research Program

### Population Science Impact Award

Funding Opportunity Number: W81XWH-14-PCRP-PSIA

Catalog of Federal Domestic Assistance Number: 12.420

#### SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), July 23, 2014
- **Invitation to Submit an Application:** late August 2014
- **Application Submission Deadline:** 11:59 p.m. ET, October 29, 2014
- **End of Application Verification Period:** 5:00 p.m. ET, November 3, 2014
- **Peer Review:** December 2014
- **Programmatic Review:** February 2015

***Change for Fiscal Year 2014:*** *The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.*

***This Program Announcement/Funding Opportunity 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 2014 (FY14) 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 FY13 totaled \$1.29 billion. The FY14 appropriation is \$80 million (M).

The mission of the FY14 PCRP is to 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 FY14*)**

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.C., Award Information](#)) applications to address one of the following four PCRP overarching challenges:

- Develop better tools for early detection of clinically relevant disease
- 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
- Develop strategies to optimize the physical and mental health of men with prostate cancer

#### **FY14 PCRP Focus Areas**

All applications for the FY14 PCRP funding opportunities are also expected to address at least one of the following PCRP focus areas:

- **Biomarker Development:** Qualification and validation of biomarkers for early detection of clinically relevant disease, prognosis, and 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 prognosis and progression of prostate cancer

## **B. Award Information**

The PCRP Population Science Impact Award mechanism was first offered as the Population-Based Idea Development Award in FY09 and the Population-Based Research Award in FY10 and FY11. Since then, 62 applications have been received, and 4 have been recommended for funding.

The Population Science Impact Award mechanism supports high-impact, population science approaches to prostate cancer research. *Applications should clearly demonstrate the potential of the study to contribute significantly to the elimination of death from prostate cancer and/or enhancing the well-being of men experiencing the impact of the disease.* As such, studies should address one of the PCRP overarching challenges, or, alternatively, justify the study as addressing another critical area in prostate cancer research. In addition, studies are expected to address one or more of the PCRP focus areas; for the Population Science Impact Award, projects focused on the following are particularly encouraged: genetics/genomics and biomarkers, especially those relevant to the early detection of aggressive disease, prognosis, and treatment response; survivorship and palliative care; and health disparity.

The overall goal of this award is to generate data and/or tools that can only be achieved from the perspective of systematic studies focused on specific populations of individuals, rather than specific individuals. Such studies will be built upon the logic, concepts, and methods of one or more population sciences including but not limited to:

- Epidemiology
- Surveillance
- Health services research
- Outcomes research
- Behavioral science
- Social science
- Dissemination research

*The outcomes for research supported through this award mechanism will have the potential for substantial impact for men with or at risk for prostate cancer within, for example, epidemiologic cohorts, defined communities, or health systems.*

Applications may propose retrospective, prospective, case control, cohort, or other population science study designs (including the use of biospecimens and data from established retrospective databases), provided that the study population is of sufficient size to provide appropriate statistical power. The study should address a well-developed hypothesis that is conceptually sound and specific for prostate cancer. The epidemiologic and/or biostatistical expertise of the study team should be clearly described and evident in the study plan. Applicants are expected to provide documentation demonstrating access to, and ability to recruit, the appropriate population(s), patient samples, and/or datasets in numbers sufficient to achieve robust statistical significance.

***Research involving human subject use is permitted under this funding opportunity; however, clinical trials will be supported only if they are determined to be no greater than minimal risk*** by the local Institutional Review Board (IRB) of record and the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO). For example, a behavioral clinical trial with a prospective accrual of patients where a behavioral intervention (i.e., cohort or case-controlled study) has been designed to determine the outcome (testing instrument, study tool, hazard, etc.) with respect to exploratory information, safety, or effectiveness may be allowed if it is no greater than minimal risk as determined by the local IRB of record and HRPO. ***Clinical trials involving prospective accrual of patients to test a device, drug, biologic, or surgical procedure for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy will not be supported by this award mechanism.*** Correlative studies associated with a clinical trial testing a device, drug, biologic, or surgical procedure are permitted if it is determined to be no greater than minimal risk by the local IRB of record and HRPO. A correlative study is defined as a prospective or retrospective collection of human anatomical substances (e.g., tissue, blood, nail clippings, bone marrow, behavioral documentation, other) to be used in research to answer a question regarding the disease, injury or condition, and/or intervention. It does not include the direct assessment of the outcome of any intervention for the prevention, diagnosis, treatment, or evaluation of the quality of life of the patient. ***Human subject research qualifying as greater than minimal risk will not be supported by this award mechanism.***

**Use of Human Anatomical Substances, Human Subjects, or Human Cadavers:** All Department of Defense (DoD)-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRMC ORP, HRPO, in addition to the local IRB of record. Local IRB approval at the time of submission is ***not*** required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes. Refer to the General Application Instructions, Appendix 6, for additional information.

All investigators applying to FY14 PCRP funding opportunities are encouraged to consider leveraging resources available through the PCRP-funded Prostate Cancer Biorepository Network (PCBN) (<http://www.prostatebiorepository.org>) and/or the North Carolina – Louisiana Prostate Cancer Project (PCaP) (<http://www.ncla-pcap.org>) if retrospectively collected human anatomical substances or correlated data are relevant to the proposed studies.

*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 L.*

### **C. Eligibility Information**

- The PI must be an independent investigator at or above the level of Assistant Professor (or equivalent)
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. 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**

- The maximum period of performance is **4** years.
- The maximum allowable direct costs for the entire period of performance are **\$750,000** plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C.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.*

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Purchase of datasets and/or databases
- Clinical research costs (costs for clinical trials are allowed only if the trial is determined to be no greater than minimal risk)

- Travel costs of up to \$1,800 per year to attend scientific/technical meetings. ***The Government reserves the right to direct the selection of one of these meetings, should a PCRP-sponsored meeting be convened during the award period of performance.***

Intramural (DoD), other federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from federal agencies submit applications, they must submit through Grants.gov. Therefore, federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other federal agencies will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Direct transfer of funds from the recipient to a federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4. Research & Related Budget, for additional information on budget considerations for applications involving federal agencies.

***The CDMRP expects to allot approximately \$3.6M of the \$80M FY14 appropriation to fund approximately 3 Population Science Impact 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 two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

**New for FY14:** ***The CDMRP has replaced its eReceipt System with eBRAP.*** Submission remains a two-step process requiring both pre-application and application submission.

PIs must be registered in eBRAP in order to submit a pre-application and receive notification of the status of a pre-application or application. A key feature of eBRAP is that an organization's

representatives and PIs are able to view and modify the Grants.gov application submissions associated with them, but only if the organization, Business Officials, and PIs are registered and affiliated to the organization in eBRAP (see *eBRAP User Guide* at <https://ebrap.org/eBRAP/public/UserGuide.pdf>). Upon completion of an organization's registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization's business officials and PIs as they register.

**Note:** Submission of either the pre-application to eBRAP or application to Grants.gov does not require registering an organization and affiliating its Business Officials and PIs in eBRAP; however, the ability to view and modify the Grants.gov application in eBRAP is contingent upon the registration and affiliation. ***Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.*** If verification is not completed by the end of the application verification period, the application will be reviewed as submitted through Grants.gov, provided there is no cause for administrative rejection of the application (see [Section IV.A., Rejection](#)).

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-14-PCRP-PSIA.

#### **B. Pre-Application Submission and Content Form**

**New for FY14:** *In contrast with previous years, pre-applications will be screened prior to invitation to submit applications.*

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.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.

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 pre-application, the PI must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

The pre-application consists of the following components, which are organized in eBRAP 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**

- It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Collaborators and Conflicts of Interest (COI) – Tab 3**

FY14 PCRP Integration Panel (IP) members should not be involved in any preapplication or application. A list of FY14 PCRP IP members can be found at <http://cdmrp.army.mil/pcrp/panels/panel14>. 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@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

- **Required Files – Tab 4**

*Notes: Upload document(s) as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.*

**Preproposal Narrative (three-page limit):** The Preproposal Narrative page limit 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 Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should include the following:

- **Rationale:** Clearly present the ideas and reasoning behind the proposed research; include relevant literature citations. *Provide the reasoning that supports why the proposed project is considered population science research, and state the specific population of individuals upon which the proposed research will focus.*
- **Hypothesis/Objective:** State the hypothesis to be tested or the objective to be reached.
- **Research Approach:** State the project’s specific aims and briefly describe the experimental approach to accomplishing the aims. *If a clinical trial is being proposed, describe the aspects of the trial that will support its status as no greater than minimal risk.*
- **Impact:** Describe the potential short-term and long-term impact of this study on prostate cancer research and/or patient care. Briefly describe how the proposed study is responsive to one of the PCRP overarching challenges or, alternatively, provide a description to justify how the project will nevertheless address a critical need in prostate cancer clinical care.

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual documents* and 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). Upload as “References.pdf.”

- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative. Upload as “Abbreviations.pdf.”
- Key Personnel Biographical Sketches (four-page limit per individual). Upload as “Biosketches.pdf.”

- **Submit Pre-Application – Tab 5**

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

### **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:

- **Intent of the Award Mechanism:** Whether the proposed research will generate data and/or tools that can only be achieved from the perspective of systematic studies focused on specific populations of individuals, rather than specific individuals.
- **Research Approach:** To what degree the experimental approach for accomplishing the specific aims is based on a sound rationale, is feasible, addresses the objectives, and appropriately leverages existing resources, if applicable.
- **Impact:** To what degree the proposed study could, whether short-term or long-term, make a significant impact on prostate cancer research and/or patient care, including its potential contribution to the elimination of death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease.

- **Notification of Pre-Application Screening Results**

Following the pre-application screening, 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 Forms**

*Applications will not be accepted unless the 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/>).

**New for FY14: Applications submitted through and validated by Grants.gov will be retrieved and processed by eBRAP to allow for review, modification, and verification.** The PI and organizational representatives will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing files (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the verification period.

**Note: Changes to either the Project Narrative or Budget are not allowed in eBRAP;** if such changes are required, the entire application package must be submitted through Grants.gov as a “Changed/Corrected Application” with the Previous Grants.gov Tracking ID *prior to the application submission deadline (which occurs earlier than the end of the application verification period).*

**Grants.gov application package components:** For the Population Science 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 (15-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. *The inclusion of preliminary data to support the study feasibility is required.* Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team.

- **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application, including examples of previous successful collaborations (if applicable).
- **Hypothesis/Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims. If this application is part of a larger study, present only tasks that this award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for scientific review. Address potential problem areas and present alternative methods and approaches.

Describe the statistical/analytical plan(s) for the research proposed. *If a clinical trial is being proposed, describe the aspects of the trial that will support its status as no greater than minimal risk.*

- **Overarching Challenges and Focus Areas:** Describe how the proposed study is responsive to one of the PCRP overarching challenges. If the proposed project does not address any of the overarching challenges, provide a description to justify how the project will nevertheless significantly address a critical need in the field of prostate cancer research and/or patient care. In addition, state at least one of the PCRP focus areas to which the proposed study is responsive.
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *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.
  - **Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work, to include:
    - Unique expertise,
    - Availability of and access to research resources, and/or
    - Availability of and access to appropriate prostate cancer populations.

- Intellectual Property
  - Background and Proprietary Information: All software and data first produced under the award are subject to a federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the federal purpose license.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about the CDMRP expectations for making data and research resources publicly available.
- Transition Plan: Describe the methods/practices that will be used to facilitate the adoption or utilization of the outcomes from the proposed project to make advancements in prostate cancer research and/or clinical care.

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

The technical abstract is used by all reviewers. Of particular importance, programmatic reviewers typically 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.
- Hypothesis/Objective: State the hypothesis to be tested or the objective to be reached. Provide evidence or rationale that supports the hypothesis/objective.
- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design.
- Impact: Summarize the impact of the proposed research, if successful, on the PCRP overarching challenges or other critical issues in 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 and rationale for the proposed project in a manner that will be *readily understood by readers without a background in science or medicine*.
- Describe the ultimate applicability of the research.
  - What types of patients will it help, and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected time it may take to achieve a patient-related outcome?
- If the research is too basic for clinical applicability, describe the interim outcomes.
- What are the likely contributions of this study to advancing the field of prostate cancer research?
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Program Announcement and Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Population Science Impact Award mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching.

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

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

***Describe the short-term impact:*** Detail the anticipated outcome(s)/product(s) that will be directly attributed to the results of the proposed research.

***Describe the long-term impact:*** Explain the anticipated long-term gains from the proposed research, including the advantages that the new understanding may contribute to the goal of elimination of death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease.

***PCRP overarching challenges:*** Summarize how the proposed project addresses one of the PCRP overarching challenges. If the proposed project does not address any of the overarching challenges, provide a description to justify how the project will nevertheless significantly address a critical need in the field of prostate cancer research and/or patient care.

- **Attachment 7: Human Subject and Statistical Plan (two-page limit):** Upload as “SubjectPlan.pdf.”
  - Describe how the proposed study population is appropriate to study the hypotheses. Include potential issues regarding ethics, information privacy, and assessment of risk versus benefit of participation, and other regulatory considerations.

- Describe the availability of this population, whether the PI and/or research team currently have access to this population, and how access to potential participants/tissues/data will be coordinated.
  - If applicable, outline the recruitment strategy and past successes for recruiting similar populations.
  - Describe how the proposed sampling strategy is appropriate for the study hypotheses, design, methods, and analytical/statistical plans, including evidence that the study will be appropriately powered.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.3., 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.”
  - Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4., 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.5., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6., for detailed information.

#### **D. Verification of Grants.gov Application in eBRAP**

For FY14, a new process has been initiated whereby organizational representatives and PIs can view their applications as submitted through Grants.gov and prior to peer review of the application. This will enable applicants to make modifications prior to scientific and programmatic evaluation of applications, provided the modifications are made by either the end of the application verification period or, for changes to the Project Narrative or Budget, by the application submission deadline.

After application submission to Grants.gov, eBRAP will retrieve and validate the application submission. eBRAP will notify the organizational representatives and PI via email and instruct them to log into eBRAP to review, modify, and verify the application. Files that fail eBRAP validation will be noted in both the email and in the Full Application Files tab. eBRAP does not

validate the accuracy or completeness of content in the files. PIs are strongly encouraged to review all application components. If either the Project Narrative or the Budget fail eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov prior to the application submission deadline, which occurs earlier than the end of the application verification period. ***The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.***

#### **E. 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 either of these deadlines will result in application rejection.

#### **F. 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 DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the 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 applicants are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is 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 (a) technical merit and (b) the relevance to the mission of the DHP and PCRCP and to 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 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 Process**

**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 proposed study could, if successful and *whether short-term or long-term*, make a substantial impact for men at risk for prostate cancer and/or men with prostate cancer and ultimately contribute to the elimination of prostate cancer death and enhancing the well-being of men experiencing the impact of the disease.
- How the proposed research addresses at least one of the PCRP focus areas and one of the PCRP overarching challenges or is otherwise justified as significantly addressing another critical issue in prostate cancer research and patient care.

- **Research Strategy and Feasibility**

- How the scientific rationale supports the research project and its feasibility as demonstrated by a critical review and analysis of the literature, prostate cancer-relevant preliminary data, and/or logical reasoning.
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
- How the data analysis plan is consistent with the study objectives.
- How well the PI acknowledges potential problems and addresses alternative approaches.

- **Human Subject and Statistical Plan**

- How well the selected population is described and whether it is appropriate for the proposed project.
- How well the PI has demonstrated sufficient availability of and access to the appropriate prostate cancer population(s).
- Whether an appropriate statistical plan, including sample size projections and power analysis, is present and adequate for the study.
- To what extent the PI has supported the feasibility of accruing a statistically significant sample from the proposed population.
- If applicable, to what degree the plan for recruitment is appropriate for the study's proposed hypotheses, design, methods, and statistical/analytical plan(s).
- Whether issues regarding ethics, information privacy, and assessment of risk versus benefit of participation, and other regulatory considerations, have been adequately considered.

- **Personnel**

- Whether the PI meets the eligibility requirements for this mechanism.
- How the research team's background and prostate cancer-related expertise are appropriate with respect to its ability to perform the proposed work, including whether there is evidence of sufficient epidemiologic and/or biostatistical expertise to support the project.
- To what degree the levels of effort are appropriate for successful conduct of the proposed work.

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

- **Environment**

- To what extent the scientific environment is appropriate for the proposed research.
- How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
- To what extent the quality and extent of organizational support are appropriate for the proposed research.
- If applicable, to what degree the intellectual and material property plan is appropriate.

- **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 influence 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 FY14 PCRP, as evidenced by the following:**

- Adherence to the intent of the award mechanism
- Program portfolio composition
- Programmatic relevance in relation to the PCRP overarching challenges and focus areas
- Relative impact

### **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 email notification of posting of the funding recommendation in eBRAP. Each PI will receive a 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 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.

### **B. Modification**

- Pages exceeding the specific 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 application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing documents (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These

modifications must be completed by the end of the application verification period; otherwise, the application will be reviewed as submitted.

### **C. Withdrawal**

The following may result in administrative withdrawal of the pre-application or application:

- A FY14 PCRIP 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 documentation. A list of the FY14 PCRIP IP members can be found at <http://cdmrp.army.mil/pcrp/panels/panel14>.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- 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 proposed research is, or requests funding for, a clinical trial that is determined to be greater than minimal risk.
- The PI does not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.
- The invited application does not propose the same research project described in the pre-application.

### **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, 2015. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

### **B. Administrative Requirements**

Refer to the General Application Instructions, Appendix 4 for general information regarding administrative requirements.

### **C. National Policy Requirements**

Refer to the General Application Instructions, Appendix 5 for general information regarding national policy requirements.

### **D. Reporting**

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

### **E. Award Transfers**

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

## **VI. AGENCY CONTACTS**

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

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through eBRAP 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@eBRAP.org](mailto:help@eBRAP.org)

### **B. Grants.gov Contact Center**

Questions related to application submission through 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

<b>Grants.gov Application Components</b>	<b>Action</b>	<b>Completed</b>
SF-424 (R&R) Application for Federal Assistance	Complete form as instructed.	
Attachments Form	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	Human Subject and Statistical Plan: Upload as Attachment 7 with file name "SubjectPlan.pdf."	
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_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.	