Program Announcement
for the
Department of Defense
Defense Health Program
Congressionally Directed Medical Research Programs

Prostate Cancer Research Program
Early Investigator Research Award

Funding Opportunity Number: W81XWH-16-PCRP-EIRA
Catalog of Federal Domestic Assistance Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), July 7, 2016
- **Application Submission Deadline:** 11:59 p.m. ET, July 21, 2016
- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, July 26, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, July 26, 2016
- **Peer Review:** October 2016
- **Programmatic Review:** December 2016

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 2016 (FY16) Prostate Cancer Research Program (PCRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA RDA Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). The PCRP was initiated in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY15 totaled $1.45 billion. The FY16 appropriation is $80 million (M).

The mission of the FY16 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 FY16): 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, investigators are strongly encouraged to address one or more of the following FY16 PCRP overarching challenges:

- Distinguish aggressive from indolent disease in men newly diagnosed with prostate cancer
- Develop strategies to prevent progression to lethal 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

PCRP Focus Areas: All applications for the FY16 PCRP funding opportunities are also expected to address at least one of the following FY16 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 and Response:** Understanding primary and acquired resistance as well as exceptional response to therapy

• **Survivorship and Palliative Care:** Improving the quality of life and well-being of prostate cancer patients and their families

• **Therapy:** Identification of targets and pathways, and optimization (including sequencing and combination therapies) of therapeutic modalities, including metastatic prostate cancer

• **Tumor and Microenvironment Biology:** Understanding the intrinsic and extrinsic mechanisms contributing to tumor development and the progression of prostate cancer

B. **Award Information**

The Early Investigator Research Award supports prostate cancer-focused research opportunities for individuals in the early stages of their careers, under the guidance of a designated Mentor. This opportunity allows for young investigators to develop a research project, investigate a problem or question in prostate cancer research, and further their intellectual development as a prostate cancer researcher of the future. The predoctoral or postdoctoral investigator is considered the Principal Investigator (PI) of the application, and must exhibit strong potential for, and commitment to, pursuing a career as an investigator at the forefront of prostate cancer research; however, the PI is not required to have previous prostate cancer research experience. Applications must include at least one Mentor, appropriate to the proposed research project, who has experience in prostate cancer research and mentoring as demonstrated by a record of active funding, recent publications, and successful mentorship. The selected Mentor(s) should also demonstrate a clear commitment to the development of the PI toward independence as a prostate cancer researcher.

The PI must outline an individualized, prostate cancer-focused researcher development plan. The researcher development plan should include a clearly articulated strategy for acquiring the necessary skills, competence, and expertise that will enable the PI to successfully complete the proposed research project and foster the PI’s development as an independent prostate cancer researcher. An environment appropriate to the proposed mentoring and research project must be clearly described, although any deficiencies of resources and/or mentorship at the PI’s institution can be mitigated through collaboration(s) with other institutions. If the PI will be utilizing resources at another institution to successfully complete the proposed project, then the PI is strongly encouraged to designate a co-Mentor at the collaborating institution.

*All applications for the Early Investigator Research Award are to be written by the PI, with appropriate direction from the Mentor(s).* The PCRP seeks applications from investigators from a wide spectrum of disciplines including, but not limited to, basic science, engineering, bioinformatics, population science, translational research, and clinical research. Multidisciplinary projects are encouraged. In addition, applicants are expected to address at least one of the PCRP focus areas and are highly encouraged to address one or more of the PCRP overarching challenges. If the proposed project does not address any of the overarching
challenges, the application should include a description to justify how the project will nevertheless address a critical need in the field of prostate cancer research and/or patient care. The inclusion of preliminary data relevant to prostate cancer and the proposed project is encouraged but not required. Any preliminary data provided should be from the PI, Mentor(s), or member(s) of the collaborating team.

Investigators are strongly encouraged to incorporate the following components into their study design where appropriate in order to maximize the potential impact of the proposed research project: authentication of proposed cell lines; statistical rigor of preclinical animal experiments; incorporation of experiments to assess clinical relevance and translatability of findings. As such, 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) are important resources to consider if retrospectively collected human anatomical substances or correlated data are critical to the proposed studies. Studies utilizing data derived from large patient studies that include long-term health records, biospecimen repositories, and pre-existing research and that apply state-of-the-art genomic and/or proteomic analysis, bioinformatics, and/or mathematical models to such data are also encouraged.

**Research Involving 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 U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC 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/EC. **Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.** Refer to the General Application Instructions, Appendix 6, and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

**Clinical trials are not allowed.** A clinical trial is defined as a prospective accrual of patients where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to safety, effectiveness, and/or efficacy. PIs may participate in clinical trials as part of their research project or researcher development plan, but funding for such clinical trials must come from sources other than this award.

**Research Involving Animals:** All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. The ACURO must review and approve all animal use prior
to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies. Refer to General Application Instructions, Appendix 6, for additional information.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research. Nature 2012, 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Applicants should consult the ARRIVE (Animal Research: Reporting In Vivo Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at https://www.elsevier.com/__data/promis_misc/622936arrive_guidelines.pdf.

The CDMRP intends that information, 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

Applicants must meet the eligibility requirements for one of the following categories:

- **The Predoctoral PI must:**
  - Be enrolled full-time in an accredited doctoral program; and
  - Must have successfully completed comprehensive examinations or otherwise met predissertation requirements by March 31, 2017.

- **The Postdoctoral PI must:**
  - Have successfully defended a doctoral thesis or possess an M.D. degree (or equivalent) by March 31, 2017;
  - Be involved in an accredited training or residency program; and
  - Have 3 years or less of postdoctoral research experience (excluding clinical residency or clinical fellowship training) by March 31, 2017.

- Cost sharing/matching is not an eligibility requirement.

- Eligible investigators must apply through an organization. Organizations eligible to apply include Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.

- 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. Submissions from intramural (DoD) organizations are allowed and encouraged for this Program Announcement/Funding Opportunity. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. **If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.**

- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

**D. Funding**

- The maximum period of performance is 2 years.

Application submissions by Predoctoral PIs:

- The anticipated direct costs budgeted for the entire period of performance will not exceed $60,000. Indirect costs are to be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the Government exceeding $60,000 direct costs or using an indirect rate exceeding the organization’s negotiated rate.

Application submissions by Postdoctoral PIs:

- The anticipated direct costs budgeted for the entire period of performance will not exceed $125,000. Indirect costs are to be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the Government exceeding $125,000 direct costs or using an indirect rate exceeding the organization’s negotiated rate.

- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.

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

- PI salary or stipend
- Research supplies
- Workshop costs
- Publication costs
- Support for collaborations between institutions, including travel
- Travel costs for up to one investigator to travel to one scientific/technical meeting per year.

Shall not be requested for:

- Mentor or other salary
- Equipment
- Clinical trial costs

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural (DoD) agencies and other Federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process); or DD Form 1144 Support Agreement). Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.

The CDMRP expects to allot approximately $5.96M of the $80M FY16 PCRP appropriation to fund approximately 10 Predoctoral and 25 Postdoctoral Early Investigator Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

Submission 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(s).

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/). Refer to the General Application Instructions, Section II.A., for registration and submission requirements for eBRAP and Grants.gov.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. 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.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization’s representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant’s responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.
The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application deadline.

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. Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

A. Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-16-PCRP-EIRA in Grants.gov (http://www.grants.gov/).

B. Pre-Application Submission Content

The pre-application process should be started early to avoid missing deadlines. There are no grace periods. During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the application process on Grants.gov.

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

PIs, Mentors, 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 or 301-682-5507.

When starting the pre-application, PIs should ensure that they have selected the appropriate application category and option (if applicable):

- Early Investigator Research Award - Predoctoral;
- Early Investigator Research Award - Postdoctoral

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):

- Tab 1 – Application Information

DoD FY16 Prostate Cancer Early Investigator Research Award
• Tab 2 – Application Contacts
  o Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
  o Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on “Add Organizations to this Pre-application.” The organization(s) must either be selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.
  o It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

• Tab 3 – Collaborators and Key Personnel
  o Enter the name, organization, and role of all collaborators and key personnel associated with the application.
  o FY16 PCRP Programmatic Panel members should not be involved in any pre-application or application. For questions related to Panel members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.
  o To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in application preparation, research, or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess.shtml). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.

• Tab 4 – Conflicts of Interest
  o List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). Refer to Appendix 1, Section C of the General Application Instructions for further information regarding COIs.

• Tab 5 – Pre-Application Files
  Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. LOIs are used for program planning purposes only (e.g., reviewer
recruitment) and will not be reviewed during either the peer or programmatic review sessions.

**List of Individuals Providing Confidential Letters of Recommendation:** Enter contact information for the individuals who will provide letters of recommendation. Each individual will receive an email generated from eBRAP containing specific instructions on how to upload his/her letter. The three letters of recommendation must include one from the mentor and at least one from the co-Mentor (if applicable) or other independent researcher who has had scientific knowledge and interaction with the PI. *The total number of letters must not exceed three.*

**Biospecimen Resource Statement (one page limit):** Provide a brief statement regarding whether the proposed research will require the use of prostate cancer biospecimens, and if so, whether the resources available through the PCRP-funded Prostate Cancer Biorepository Network (PCBN) (http://www.prostatebiorepository.org) were considered as a source of samples for the proposed study.

- **Tab 6 – Submit Pre-Application**
  - This tab must be completed for the pre-application to be accepted and processed.

**C. Full Application Submission Content**

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of the applicant’s organization’s Entity registration in SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the General Application Instructions, Section II, for additional information.

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

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. See Section II.C. of the General Application Instructions for details on compatible Adobe software.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each application submission must include the completed Grants.gov application package for this Program Announcement/Funding Opportunity. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (http://www.grants.gov). For the Early Investigator Research Award, additional application components are also required and should be submitted as directed below.

*Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline.*
If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application submission deadline.

The Grants.gov application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

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

1. **SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

2. **Attachments Form**

   Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

   • **Attachment 1: Project Narrative (six-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 may result in administrative withdrawal of the application.

   Describe the proposed project in detail using the outline below. The Project Narrative must be written by the PI while also showing evidence of appropriate direction from the Mentor(s).

   ○ **Principal Investigator:** The PI should describe his/her career goals and how the proposed research project and mentoring experience will promote his/her development toward becoming an independent prostate cancer researcher. The PI should discuss his/her research plans and career plans after the completion of this award.

   ○ **Mentor(s):** For each Mentor or co-Mentor, describe his/her background and experience in prostate cancer research. Explain how he/she will assist the PI throughout the period of performance in developing toward independence in prostate cancer research. Provide details on the amount and types of
interactions between the Mentor(s) and the PI. Describe the track record of each Mentor for mentoring young investigators in prostate cancer research.

- **Research Project:** Describe the proposed research project, including the background, hypothesis/purpose and rationale, broad objectives and specific aims, and methods (including appropriate controls). Address potential problem areas and present alternative methods and approaches. Include a statistical analysis of the proposed research, if applicable. Explain how cell line authentication and/or statistical rigor of preclinical experiments have been incorporated into the study design, if applicable.

- **Overarching Challenges and Focus Areas:** Briefly describe how the proposed research is relevant to at least one of the PCRP focus areas and responsive to one or more 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 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 will result in the removal of those items or may result in 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 a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may 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 support not requested in the Program Announcement/Funding
Opportunity, such as those from members of Congress, do not impact application review or funding decisions.

○ 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.

○ Intellectual Property
  – Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
    ▪ Clearly identify all such property;
    ▪ Identify the cost to the Federal government for use or license of such property; or
    ▪ Provide a statement that no property meeting this definition will be used on this project.

  – Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

  – Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

○ Transcripts: Include a copy of the PI’s transcripts from both undergraduate and graduate institutions, if applicable. All foreign-language transcripts must be accompanied by a certified English translation. The Government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts. If an institution does not provide academic transcripts (i.e., a record of courses completed, grades and credit hours earned, and indication of completion of degree), complete and include the Academic Statement (available for download on the Full Announcement page in Grants.gov) in place of the transcript.

• Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.” The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. Do not include proprietary or confidential information. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.
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:

○ **Research Plan**
  - Background: Present the ideas and reasoning behind the proposed work.
  - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
  - Specific Aims: State the specific aims of the study.
  - Study Design: Briefly describe the study design including appropriate controls.

○ **Personnel**
  - The PI should describe his/her career goals and potential for a career at the forefront of prostate cancer research.
  - The PI should describe the strategy for acquiring necessary skills, competence, and expertise to successfully complete the proposed research project. Describe the Mentor’s (and co-Mentor’s, if applicable) background and experience in prostate cancer research and contribution to the career development of the PI.
  - The PI should describe how the proposed research project will prepare him/her to make valuable contributions to the understanding and management of prostate cancer.

○ **Impact:** Summarize how the proposed research will have an impact on progress toward the elimination of death from prostate cancer and/or enhancing the well-being of men experiencing the impact of the disease.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.” The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publically. *Do not include proprietary or confidential information.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The lay abstract 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.*
o 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 near term clinical applicability, describe the interim outcomes.

o Describe the PI’s career goals in prostate cancer research.
  – How does the research plan support the PI in achieving these goals?
  – How does the mentorship and researcher development plan support the PI in achieving these goals?

o 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.” The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm). For the Early Investigator Research Award mechanism, use the SOW format example titled “SOW for Basic Research (Training Section optional).” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

• Attachment 6: Researcher Development Plan (one-page limit): Upload as “ResearchDev.pdf.”
  o Clearly articulate a strategy for acquiring the necessary skills, competence, and expertise to successfully complete the proposed research project.
  o Indicate how the individualized researcher development plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in the field of prostate cancer, and effectively prepare him/her for a career as an independent prostate cancer researcher.
  o Describe how the researcher development plan is supported by the environment and mentorship, including a description of ongoing prostate cancer research at the institution. Include a description of the environment of any collaborating institutions that will augment the lack of specific resources at the PI’s primary institution (if applicable). Include information on collaborations with other investigators, seminars, workshops, and other opportunities to interact with leaders in the prostate cancer field. Do not reference or include members of the FY16 PCRP Programmatic Panel.

• Attachment 7: Impact Statement (one-page limit): Upload as “Impact.pdf.” State explicitly how the proposed research project will have an impact on prostate cancer research and/or patient care, including its contribution to the goal of
eliminating death from prostate cancer and/or enhancing the well-being of men experiencing the impact of the disease. Describe how the proposed research addresses at least one of the PCRP Focus Areas and one or more of the PCRP overarching challenges. If the proposed project does not address at least one of the overarching challenges, describe how the project will nevertheless significantly address a critical need in the field of prostate cancer research and/or patient care.

- **Attachment 8: Eligibility Statement (one-page limit):** Upload as “Eligibility.pdf.” Use the Eligibility Statement template (available for download on the Full Announcement page under this Funding Opportunity on Grants.gov) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met.

- **Attachment 9: Collaborating DoD Military Facility Budget Form(s), if applicable:** Upload as “MFBudget.pdf.” If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form, available for download on the eBRAP “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information.

   - **PI Biographical Sketch (five-page limit):** Upload as “Biosketch_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The five-page National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.

   Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

   - **PI Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf.”

   - **Key Personnel Biographical Sketches (five-page limit each):** Upload as “Biosketch_LastName.pdf.”
     - Include the Mentor’s (and co-Mentor’s, if applicable) biographical sketch.

   - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf.”
     - Include Mentor’s (and co-Mentor’s, if applicable) previous/current/pending support.
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.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

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.

   Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.Gov R & R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 9, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.

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### Additional Application Components:

In addition to the complete Grants.gov application package of forms and attachments, Early Investigator Research Award applications require submission of confidential letters of recommendation to support the PI. The letters of recommendation should be provided on letterhead, signed, and uploaded as PDF files to eBRAP by 5:00 p.m. ET on the last day of the verification period. The PI should monitor whether the letters have been received in eBRAP by viewing the status in the “Pre-Application Files” tab of the pre-application; however, the PI will not be able to view these letters.

The confidential letters should include the following (2 pages per letter recommended):

- **A confidential letter of recommendation from each Mentor**, describing his/her commitment to the PI’s career development and mentorship in prostate cancer research. Mentor letters should address the following:
  - The PI’s potential to become a successful and independent prostate cancer researcher;
  - The commitment of the Mentor to the career development and mentorship of the PI, including details of the proposed interactions of the Mentor with the PI during the PI’s research project;
  - The mentoring environment, including ongoing prostate cancer research in the Mentor’s laboratory and in the organization as a whole, resources available, and how this environment will promote the development of the PI as a prostate cancer researcher;
• The degree to which the PI participated in the project development and application preparation, and the degree to which the PI will participate in the execution of the application if funded.

- **Additional confidential letters of recommendation (one is required; maximum of two).** Additional letters should describe the PI’s unique qualifications and accomplishments that highlight his/her potential for success in pursuing a career in prostate cancer research. Specifically, each letter should offer the writer’s perspective on:
  o The PI’s qualifications, characteristics, and achievements;
  o The PI’s potential for productivity and desire for establishing a successful and independent career in prostate cancer research;
  o The relevance of the proposed research project to developing the PI’s career in prostate cancer research; and
  o The suitability of the Mentor(s) and the research environment for providing the PI with a solid foundation to support an independent career in prostate cancer research.

D. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. **If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application submission deadline.** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

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 submission rejection.

F. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All extramural 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, Section II.A., for information on Grants.gov registration requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and PCRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section III.B.2., Programmatic Review. Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.shtml.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a 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:

   - Principal Investigator
     - How the PI’s achievements (as reflected by academic performance, awards, honors, and/or previous publications and funding) indicate the potential for a successful career as a prostate cancer researcher.
     - To what extent the PI’s stated career goals demonstrate a strong personal commitment to pursuing an independent career as a leader in prostate cancer research.
To what extent the letters of recommendation from the Mentor(s) and others support the PI’s potential for a highly productive career as a prostate cancer researcher.

Whether the PI’s proposed level of effort, if not 100%, is appropriate for successful completion of the proposed work.

**Mentor(s)**

- Whether there is at least one Mentor who is an established prostate cancer researcher, as evidenced by a demonstrated record of active funding and recent publications in prostate cancer research.
- How the Mentor’s (and co-Mentor’s, if applicable) own experience indicates the potential of the Mentor(s) to supervise the PI’s research project.
- To what extent the track record(s) of the Mentor(s) in training previously mentored young investigators indicate the potential for successful mentoring of the PI in prostate cancer research.
- Whether the Mentor letter(s) indicate a high level of commitment to the PI’s development as a prostate cancer researcher.
- Whether the quality of the application suggests that the Mentor(s) provided appropriate guidance in its preparation.

**Research Project**

- How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, prostate cancer-relevant preliminary data (if included), and/or logical reasoning.
- Whether the experimental design and the statistical plan, if applicable, are appropriate for the research proposed.
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
- How well the PI acknowledges potential problems and addresses alternative approaches.
- If applicable, to what degree the intellectual and material property plan is appropriate.

**Researcher Development Plan and Environment**

- How well the PI has outlined an individualized plan that will enable him/her to acquire the necessary skills, competence, and expertise to successfully complete the proposed research project.
- How well the individualized researcher development plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in prostate cancer research, and effectively prepare him/her for a career as an independent prostate cancer researcher.
○ To what extent the scientific environment at the primary institution (and collaboration institution, if applicable) is appropriate for the proposed research and career development activities, including professional interaction with established prostate cancer researchers.

○ To what extent the research requirements are adequately supported by the availability and accessibility of facilities and resources (including collaborative arrangements and/or intellectual property plans as applicable).

- Impact

○ To what degree the expected results of the project will impact prostate cancer research and/or patient care, and contribute to the goal of eliminating death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease.

○ To what degree the proposed research project and mentoring experience will bring the PI to the forefront of prostate cancer research.

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

- Responsiveness to Overarching Challenges and Focus Areas

○ How well the proposed research addresses at least one of the PCRP focus areas and one or more of the PCRP overarching challenges, or is otherwise justified as significantly addressing another critical issue in prostate cancer research and/or patient care.

- 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 and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

a. Ratings and evaluations of the peer reviewers

b. Relevance to the mission of the DHP and FY16 PCRP, as evidenced by the following:

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

- Pre-application was not submitted.
- 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 Project Narrative.
- Documents not requested will be removed.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- An FY16 PCRP Programmatic Panel 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 FY16 PCRP Programmatic Panel members can be found at http://cdmrp.army.mil/pcrp/panels/panel16.shtml.
• The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.

• 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)

• To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess.shtml). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, 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.

• An application submitted by a PI who does not meet the eligibility criteria will be withdrawn.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization 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, 2017. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD’s implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards” (2 CFR part 200).
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 H, for general information on reporting requirements.

E. Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

VI. VERSION CODES AND AGENCY CONTACTS

A. Program Announcement/Funding Opportunity and General Application Instructions Version

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code [20160210i]. The Program Announcement/Funding Opportunity numeric version code will match the General Applications Instructions version code [20160210].

B. 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
C. 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; International 1-606-545-5035
Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.
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<td>Supporting Documentation: Upload as Attachment 2 with file name “Support.pdf.”</td>
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