

Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Idea Development Award

Funding Opportunity Number: W81XWH-16-PCRP-IDA

**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), June 23, 2016
- **Invitation to Submit an Application:** late July 2016
- **Application Submission Deadline:** 11:59 p.m. ET, October 6, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, October 11, 2016
- **Peer Review:** December 2016
- **Programmatic Review:** January 2017

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 for prostate cancer, 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 PCRCP Idea Development Award mechanism was first offered in FY97. Since then, 9,087 Idea Development Award applications have been received, and 1,161 have been recommended for funding.

The Idea Development Award supports new ideas that represent innovative approaches to prostate cancer research and have the potential to make an important contribution to the PCRCP mission. Although groundbreaking research often involves a degree of risk, applications should be based on a sound scientific rationale that is established through logical reasoning and/or critical review and analysis of the literature. Due to this award's emphasis on innovation, the presentation of preliminary data relevant to prostate cancer and the proposed project is encouraged but not required. Any unpublished, preliminary data provided should originate from the laboratory of the Principal Investigator (PI) or a member(s) of the research team. Research deemed innovative may represent a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other highly creative qualities. Research that is an incremental advance upon published data is not considered innovative.

The PCRCP seeks applications from investigators from a spectrum of disciplines including, but not limited to, basic science, engineering, bioinformatics, population science, psycho-oncology, translational research, and clinical research. ***In addition, applicants are expected to address at least one of the PCRCP focus areas and are highly encouraged to address one of the PCRCP overarching challenges.*** If the proposed project does not address any of the overarching challenges, the application should describe how the project will nevertheless address a critical need in the field of prostate cancer research and/or patient care.

The Idea Development Award also emphasizes the potential impact, both short-term and long-term, of the research project on prostate cancer research and/or patient care. To maximize the potential for impact, investigators are strongly encouraged to incorporate the following components into their study design where appropriate: 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 PCRCP-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.

New Investigators: The Idea Development Award mechanism encourages applications from investigators in the early stages of their careers. The New Investigator category of this award mechanism is designed to allow applicants *early in their faculty appointments, or in the process of developing independent research careers*, to compete for funding separately from Established Investigators. PIs using the New Investigator category are strongly encouraged to strengthen their applications through collaboration with investigators experienced in prostate cancer research and/or possessing other relevant expertise as demonstrated by a record of funding and publications. It is the responsibility of the PI to describe how the collaboration(s) will augment his or her expertise to best address the research question. All New Investigator applicants must meet specific eligibility criteria as described in [Section I.C., Eligibility Information](#).

PIs employing the New Investigator category are not eligible to apply for the Partnering PI Option.

Partnering PI Option: The Idea Development Award offers a Partnering PI Option with a higher level of funding to support synergistic partnerships among *Established Investigators*. The Partnering PI Option is structured to accommodate up to a total of three PIs. One member of the team will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with the application. The other PI(s) will be referred to as the Partnering PI(s). Initiating and Partnering PIs each have different submission requirements as described in Section II; however, all PIs should contribute significantly to the development of the proposed research project. If recommended for funding, each PI will receive his or her own award. ***To justify the higher funding level, the research project must be supported by the unique expertise, experience, and abilities of each PI, and it must clearly define the synergistic components that will facilitate and accelerate progress in a way that could not be accomplished through independent efforts.*** Multidisciplinary projects are encouraged, particularly those that incorporate population science, and multi-institutional projects are allowed. Each proposed study must include a clearly stated plan for interactions among all PIs and organizations involved. The plan must include communication, coordination of research progress and results, and data transfer. Additionally, multi-institutional applications must provide an intellectual property plan to resolve potential intellectual and material property issues and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful completion of this award.

Research involving human subjects is permitted under this funding opportunity, but is restricted to studies without clinical trials. Correlative studies associated with an existing clinical trial are particularly encouraged, provided that they are determined to be no greater than minimal risk by the 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). 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 exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. PIs seeking funding for a clinical trial are encouraged to consider submitting an application to the FY16 PCRP Impact Award.

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 USAMRMC ORP, HRPO prior to research implementation. This administrative review requirement is in addition to the local 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.

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 http://www.elsevier.com/locate/09596460120000622936arrive_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

Although a PI may be eligible for both the Established Investigator and New Investigator categories, only one category may be chosen; the choice of application category is at the PI's discretion.

- **New Investigator**

By the application submission deadline date, the PI must have:

- The freedom to pursue independent research goals without formal mentorship;
- Not previously received a PCRP Idea Development Award; and
- Either completed at least 3 years of postdoctoral training or fellowship (if never held an independent faculty position) ***or*** been in an independent faculty position for less than 5 years.

New Investigators working within a laboratory team are eligible to apply for this award provided they can demonstrate that they have the freedom to pursue independent research goals without formal mentorship. Graduate students and junior postdoctoral fellows (i.e., fellows with less than 3 years postdoctoral training by the application submission deadline) are not eligible for this award.

- **Established Investigator**

The PI must be an independent investigator at or above the level of Assistant Professor (or equivalent).

- **Partnering PI Option**

Established independent investigators at or above the level of Assistant Professor (or equivalent) are eligible to submit an application as Initiating or Partnering PIs under the Partnering PI Option. ***PIs employing the New Investigator category are not eligible to apply for the Partnering PI Option.***

- 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 **3** years.
- **New Investigators:** The anticipated direct costs budgeted for the entire period of performance will not exceed **\$275,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$275,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.
- **Established Investigators:** The anticipated direct costs budgeted for the entire period of performance will not exceed **\$600,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$600,000** direct costs or use an indirect rate exceeding the organization's negotiated rate.
- **Partnering PI Option (*Established Investigators only*):**
 - The anticipated combined direct costs budgeted for the entire period of performance for the Initiating and Partnering PIs' applications will not exceed **\$1M**. The combined total direct costs of the Initiating and Partnering PIs' awards will not exceed **\$1M** direct costs. If the Initiating or Partnering PIs' budgets contain a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the Government will not exceed **\$1M** or use an indirect rate exceeding each organization's negotiated rate.
 - A separate award will be made to each PI's organization.
 - The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly, unless otherwise warranted and clearly justified.
- 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 **3** years.

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

- Salary
- Research supplies
- Equipment

- Research-related subject costs
- Clinical research costs (other than costs for clinical trials, which are not allowed)
- Support for multidisciplinary collaborations, including travel
- Travel costs for up to 1 investigator to travel to 1 scientific/technical meeting per year. ***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.***

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 \$31.5M of the \$80M FY16 PCRP appropriation to fund approximately 12 New Investigator, 14 Established Investigator, and 8 Established Investigator – Partnering PI Option Idea Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

Submission 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.

Partnering PI Option (*Established investigators*): The Idea Development Award mechanism is structured to accommodate up to a maximum of three PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as Partnering PI(s). Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute significantly to the development of the proposed research project including the Project Narrative, Statement of Work, and other required components. The Initiating PI must complete the pre-application submission process and submit the contact information for each Partnering PI. Each Partnering PI will then be notified of the pre-application submission separately by email. ***Each Partnering PI must follow the link in this email in order to associate his/her Grants.gov application package with that of the Initiating PI.*** If not previously registered, the Partnering PI must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI. Do not delay completing these steps. If they are not completed, the Partnering PI(s) will not be able to view and modify his/her application during the verification period in eBRAP.

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-IDA 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 Initiating 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 or 301-682-5507.

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

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

- Idea Development Award - **New Investigator**;
- Idea Development Award - **Established Investigator**;
- Idea Development Award - **Established Investigator with Partnering PI Option**

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**
- **Tab 2 – Application Contacts**
 - 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.
 - 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.

- 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**
 - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
 - [FY16 PCRCP 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.
 - **Partnering PI Option (*Established investigators only*):** The Initiating PI must enter the contact information for each Partnering PI (*maximum of two*) in the Partnering PI section.
 - **New Investigators:** Inclusion of a collaborator is encouraged.
 - 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>). 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 (COIs)**
 - 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**

Note: *Upload documents 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: Provide responses in the appropriate data fields for the following:

 - What is the proposed research idea to be pursued? Include background and rationale, hypothesis, and a brief description of specific aims to address the hypothesis (2,000-character limit). ***This award cannot be used to conduct clinical trials.***
 - What is the potential impact of the proposed research on one or more of the PCRCP overarching challenges or a different well-justified critical need? How does the

proposed research represent an innovative approach that will produce more than an incremental advancement? (1,000-character limit)

- **Partnering PI Option (*Established investigators only*):** Who will be the PIs of the project, what expertise does each bring to the project, and how will the expertise and combined efforts on the project synergize to produce an outcome greater than any that could be achieved by independent efforts? Include a description of how the combined efforts are centered on a unified objective and how the PIs will work together to achieve that objective from different perspectives. (1,000-character limit)

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

- Additional Information (optional; one page limit). Upload as “AddInfo.pdf.” One page for additional information that can be used, at the PI’s discretion, to provide supporting data or rationale for the pre-application. If no additional information will be submitted, include a page with the statement “No additional information.”
 - 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.
 - Key Personnel Biographical Sketches (five-page limit per individual) and PI Eligibility Statement. *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.
 - For all PIs, include a biographical sketch (five-page limit). Biosketches will be reviewed administratively only; they will not be included in the merit-based pre-application screening.
 - ***For New Investigators only:*** Append to the Biosketch the Eligibility Statement (one-page limit) using the Eligibility Statement template (available for download on the Full Announcement page under this funding opportunity in Grants.gov), signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met at the application submission deadline.
- **Tab 6 – Submit Pre-Application**
 - 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 based on the following criteria:

- **Innovation:** To what degree the proposed research is innovative and is likely to result in more than an incremental advance upon published data.
- **Impact:** To what degree the proposed research, if successful, could make a significant impact on prostate cancer research and/or patient care by contributing to solutions for the PCRP overarching challenges or other critical issues in prostate cancer.
- **Synergy (*Partnering PI Option only*):** How well the proposed study represents a synergistic collaboration that will produce results greater than those of the PIs working independently. To what degree it is evident that all PIs have provided appropriate levels of intellectual input into the proposed project.

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

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

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 the System for Award Management (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 or Initiating 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/>).

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.**

Partnering PI Option (*Established investigators only*): The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned a unique eBRAP log number. Each Grants.gov application package must be submitted using the unique eBRAP log number. **Note: *All associated applications (Initiating and each Partnering PI) must be submitted by the Grants.gov deadline.***

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

Application Components for the PI (for Single PI applicants) or the Initiating PI (if applying under the Partnering PI Option):
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Grants.gov application package components: For the FY16 PCRP Idea Development Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. 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 (10-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.

- **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application.
- **Hypothesis or 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 analysis.
 - Address potential problem areas and present alternative methods and approaches.
 - Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis, if applicable. If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE guidelines (http://www.elsevier.com/_data/promis_misc/622936arrive_guidelines.pdf).
 - Clearly identify the source of any proposed cell lines, and whether they were recently authenticated and/or tested for mycoplasma contamination, if applicable.
 - Describe how the clinical relevance of the anticipated findings will be determined, if applicable.
 - If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples.
This award cannot be used to conduct clinical trials.
- **New Investigators:** Collaboration is encouraged. Describe the specific contributions of the collaborator(s) to the research project.
- **Overarching Challenges and Focus Areas:** 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, describe 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 Patents: 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: 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.
 - New Investigators (if applicable): Provide a signed letter from each collaborating individual or organization that describes how he/she will support the project, to include unique expertise and/or availability of and access to research resources. If the PI is likely to change organizations during the award period of performance (e.g., New Investigators transitioning into their first independent faculty position), describe how proposed collaborations will be maintained.
 - Other: For all other investigators, provide a signed letter from each collaborating individual or organization (if applicable) that specifically describes the support to be provided.

- 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, Section K for more information about the CDMRP expectations for making data and research resources publicly available.
- 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.
- **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 do not have access to the full application and 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 objective/hypothesis.

- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design, including appropriate controls.
- 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.”** The lay 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 do not have access to the full application and therefore rely on the lay abstract for appropriate description of the project’s key aspects. Do not duplicate the technical abstract.

- Clearly describe, in a manner readily understood by readers without a background in science or medicine, the rationale, objective, and aims of the application.
- 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.”** 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 Idea Development Award mechanism, use the SOW format example titled “SOW for Basic Research.” 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.

Partnering PI Option (*Established investigators only*): Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task. For investigators applying under this option, PIs are encouraged to use the SOW format example titled “SOW for Collaborative PI projects.”

- **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, including any clinically relevant results.
- ***Describe the long-term impact:*** Explain the anticipated long-term gains from the proposed research, including the anticipated 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 and focus areas:*** Summarize how the proposed project addresses one of the PCRP overarching challenges and at least one of the focus areas. If the project does not address any 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 7: Innovation Statement (one-page limit): Upload as “Innovation.pdf.”**

Describe how the proposed work is innovative. Research that represents an incremental advancement on published data is not considered innovative.

The following examples of ways in which the proposed work may be innovative, although not all-inclusive, are intended to help the PIs frame the innovative features of their application:

- Study concept: Investigation of a novel idea and/or research questions.
 - Research method or technology: Use of novel research methods or new technologies, including technology development, to address a research question.
 - Novel method or technology: Development of a novel method or technology for prevention, detection, diagnosis, or treatment.
 - Existing methods or technologies: Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.
- **Attachment 8: Synergy Statement (one-page limit): Upload as “Synergy.pdf.”** (*Attachment 8 is only applicable and required for applications submitted under the Partnering PI Option.*)
 - Discuss in detail the advantages of addressing the research problem through the combined expertise of the PIs and how this contributes to the synergy of the application. Include each PI’s history of synergistic and collaborative study with one another and/or with other investigators.
 - Describe the elements of interdependence in the proposed work and the contributions of each PI to the overall synergy of the project. Describe how the combined efforts of the PIs will result in a level of productivity that is greater than that achievable by each PI working independently.

- Describe plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all PIs and organizations participating in the project.
 - **Attachment 9: (Only applicable and required for applications submitted under the New Investigator category): Statement of Independence (one-page limit): Upload as “Independence.pdf.”**
 - For investigators not yet in an independent faculty position, complete and sign the Statement of Independence template (available for download on the Full Announcement page under this funding opportunity in Grants.gov). The Statement of Independence must also be signed by the investigator’s current mentor/supervisor.
 - **Attachment 10: 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 biographical sketches for the Partnering PI(s), if applying under the Established Investigator - Partnering PI Option.

- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
 - Include previous/current/pending support for the Partnering PI(s), if applying under the Established Investigator - Partnering PI Option.
- 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.
 - **Partnering PI Option (*Established investigators only*):** Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for Partnering PI(s), even if they are located within the same organization. The anticipated combined direct costs budgeted for the entire period of performance for the Initiating and Partnering PIs’ applications will not exceed **\$1M**. The combined total direct costs of Initiating and Partnering PIs’ awards will not exceed **\$1M** direct costs. If the Initiating or Partnering PIs’ budgets contain a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate. The combined budgeted direct costs approved by the Government will not exceed **\$1M** or using an indirect rate exceeding each organization’s negotiated rate.
- 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 10, 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.

<p>Application Components for the Partnering PI(s):</p>
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Each Partnering PI must follow the link in the email from eBRAP and, if not registered in eBRAP, complete the registration process prior to the application submission deadline in order to associate his/her Grants.gov application package with that of the Initiating PI.

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

1. SF424 (R&R) Application for Federal Assistance Form

2. Attachments Form

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C.2., for detailed information on completing the SOW. *Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task.*

3. 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.”**
- **Partnering PI Option (Established investigators only):** Initiating and Partnering PIs must each submit a budget and justification specific to his/her own portion of the efforts as part of his/her separate Grants.gov application packages. The Research & Related Budget for the Partnering PI(s) should not include budget information for the Initiating PI, even if they are at the same organization. The anticipated combined direct costs budgeted for the entire period of performance for the Initiating and Partnering PIs’ applications will not exceed **\$1M**. The combined total direct costs of the Initiating and Partnering PIs’ awards will not exceed **\$1M** direct costs. If the Initiating or Partnering PIs’ budgets contain a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate. The combined budgeted direct costs approved by the Government will not exceed **\$1M** or using an indirect rate exceeding each organization’s negotiated rate.

4. Project/Performance Site Location(s) Form: Refer to the General Application Instructions, Section II.C.5., for detailed information.

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

Collaborating DoD Military Facilities Form: Refer to the General Application Instructions, Section II.C.7., for detailed information. The costs per year should be included on the Grants.Gov Research and Related Budget form under subaward costs.

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>.

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, of which Innovation, Impact, and Synergy are equally the most important, with the remaining criteria listed in decreasing order of importance.
 - **Innovation**
 - How the research proposes new paradigms or challenges existing paradigms, or is otherwise highly creative.
 - To what degree the proposed research represents more than an incremental advance upon published data.
 - **Impact**
 - To what degree the proposed research, whether in the short term or long term, would make a major impact toward the elimination of death from prostate cancer and enhance the well-being of men experiencing the impact of the disease.
 - How well the proposed research addresses one of the PCRP overarching challenges and at least one of the PCRP focus areas. If the project does not address any 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.
 - **Synergy (Partnering PI Option only)**
 - How the proposed partnership among the PIs is likely to result in a level of productivity that is greater than that achievable by each PI working independently.
 - To what degree the contributions of each PI to the project are appropriate and balanced.
 - How well the application addresses processes for ongoing communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all participating PIs and organizations.

- **Research Strategy and Feasibility**
 - How well the scientific rationale supports the research and its feasibility, as demonstrated by a critical review and analysis of the literature, the presentation of preliminary data (if applicable), and logical reasoning.
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
 - Whether the application includes an appropriate statistical plan with power analysis (if applicable).
 - Whether the PI has provided sufficient evidence to support availability of and access to the populations/samples required for the study, and whether the plan for acquiring the necessary research resources is sufficient for the proposed research project (if applicable).
 - As applicable, how well the PI has included components to increase the impact of the project, including cell line authentication, proper design of animal studies to achieve reproducible and rigorous results, and/or experiments to address clinical relevance.
- **Personnel**
 - To what degree the research team's background is appropriate with respect to its ability to perform the proposed work, including whether there is evidence of sufficient clinical and/or statistical expertise (if applicable).
 - How the levels of effort are appropriate for successful conduct of the proposed work.
 - ***New Investigators only:***
 - How the PI's record of accomplishment demonstrates his/her potential for contributing to the prostate cancer research field and completing the proposed work.
 - If applicable, how well the proposed contributions of collaborators will complement the New Investigator's ability to perform the proposed work.

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

- **Environment**
 - To what degree the scientific environment is appropriate for the proposed research.
 - How well the research requirements are supported by the availability of and access to facilities and resources (including patient populations, samples, and collaborative arrangements).

- To what degree the quality and extent of institutional support are appropriate for the proposed research.
- If applicable, to what degree the intellectual and material property plan is appropriate.
- **Data and Resource Sharing**
 - To what degree the plan for sharing of project data and research resources is appropriate and reasonable to facilitate use by the wider prostate cancer research community.
- **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 and innovation
 - 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 pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

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

- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.
- Partnering PI Option: All associated [Initiating and Partnering PI(s)] applications are not submitted by the deadline.

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 pre-application or 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>.*
- 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>). 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.
- The invited application does not propose the same research project described in the preapplication.
- 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.

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

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.

To assist New Investigators who are transitioning into their first independent faculty position, the submitting organization must agree to relinquish the award if the PI obtains an independent faculty position, or equivalent, at another institution prior to the last year of the (original) period of performance so that it can be transferred to the new institution.

Partnering PI Option: An organizational transfer of an award supporting the Initiating or Partnering PI(s) is discouraged and will be evaluated on a case-by-case basis and only allowed 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.

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

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.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Initiating PI Completed	Partnering PI Completed
SF424 (R&R) Application for Federal Assistance		Complete form as instructed.		
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."		
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."		
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."		
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."		
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."		
	6	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."		
	7	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf."		
	8	<i>(Partnering PI Option Only)</i> Synergy Statement: Upload as Attachment 8 with file name "Synergy.pdf," if applicable.		
	9	<i>(New Investigators Only)</i> Statement of Independence: Upload as Attachment 9 with file name "Independence.pdf," if applicable.		
	10	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 10 with file name "MFBudget.pdf," if applicable.		
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.		

Grants.gov Application Components	Upload Order	Action	Initiating PI Completed	Partnering PI Completed
Research & Related Budget		Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.		
Project/Performance Site Location(s) Form		Complete form as instructed.		
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.		