

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Impact Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-17-PCRP-IA

**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, 2017
- **Invitation to Submit an Application:** Early August 2017
- **Application Submission Deadline:** 11:59 p.m. ET, September 28, 2017
- **End of Application Verification Period:** 5:00 p.m. ET, October 3, 2017
- **Peer Review:** November 2017
- **Programmatic Review:** January 2018

This Program Announcement must be read in conjunction with the General Application Instructions, version 20170516. The General Applications Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”

TABLE OF CONTENTS

- I. OVERVIEW OF THE FUNDING OPPORTUNITY..... 1**
- II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY..... 3**
 - II.A. Program Description..... 3
 - II.A.1. FY17 PCRP Overarching Challenges and Focus Areas 3
 - II.B. Award Information 4
 - II.C. Eligibility Information..... 7
 - II.C.1. Eligible Applicants 7
 - II.C.2. Cost Sharing..... 8
 - II.C.3. Other 8
 - II.D. Application and Submission Information..... 8
 - II.D.1. Address to Request Application Package 9
 - II.D.2. Content and Form of the Application Submission 9
 - II.D.3. Dun and Bradstreet Universal Numbering System (DUNS) Number and System for Award Management (SAM) 27
 - II.D.4. Submission Dates and Times..... 27
 - II.D.5. Funding Restrictions..... 28
 - II.D.6. Other Submission Requirements 29
 - II.E. Application Review Information 29
 - II.E.1. Criteria 29
 - II.E.2. Application Review and Selection Process..... 33
 - II.E.3. Integrity and Performance Information..... 33
 - II.E.4. Anticipated Announcement and Federal Award Dates 34
 - II.F. Federal Award Administration Information 34
 - II.F.1. Federal Award Notices..... 34
 - II.F.2. Administrative and National Policy Requirements..... 35
 - II.F.3. Reporting..... 36
 - II.G. Federal Awarding Agency Contacts..... 36
 - II.G.1. CDMRP Help Desk 36
 - II.G.2. Grants.gov Contact Center 36
 - II.H. Other Information..... 37
 - II.H.1. Program Announcement and General Application Instructions Versions..... 37
 - II.H.2. Administrative Actions..... 37
 - II.H.3. Application Submission Checklist 40
- APPENDIX 1: ACRONYM LIST 42**

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2017 (FY17) Prostate Cancer Research Program (PCRP)) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement 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 FY16 totaled \$1.53 billion (B). The FY17 appropriation is \$90 million (M).

The mission of the FY17 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.

II.A.1. FY17 PCRP Overarching Challenges and Focus Areas

PCRP Overarching Challenges: 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 FY17 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 (*Revised for FY17!*): All applications for the FY17 PCRP funding opportunities are also expected to address at least one of the following FY17 PCRP Focus Areas:

- Data Science and Analytics
- Imaging and Targeted Radionuclide Therapy
- Population Science
- Precision Medicine, Screening, and Surveillance
- Survivorship, including Psychosocial Impact on the Patient and Family
- Therapy and Mechanisms of Resistance and Response
- Tumor and Microenvironment Biology

II.B. Award Information

The PCRP Impact Award mechanism was first offered in FY10. Since then, 213 Impact Award applications have been received, and 30 have been recommended for funding.

The anticipated direct costs budgeted for the entire period of performance for an FY17 PCRP IA award will not exceed **\$750,000** for a Single PI and will not exceed **\$2M** for a Partnering PI Option. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

The Impact Award encourages applications that support the full spectrum of research projects or ideas that specifically focus on scientific and clinical prostate cancer issues, which, if successfully addressed, have the potential to make a major impact in eliminating death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease.

The critical components of this award mechanism are:

Impact: The Impact Award is intended to support research that demonstrates the potential to have a major impact on an area of paramount importance in prostate cancer. It is the responsibility of the Principal Investigator (PI) to clearly and explicitly describe the potential impact of the proposed study on prostate cancer and to convey its level of significance. ***Applicants are highly encouraged to address one of the PCRP Overarching Challenges and are expected to address at least one of the PCRP Focus Areas.*** 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. Proposed projects may include basic, translational, or clinical research, including clinical trials, but must demonstrate clinical relevance. The potential impact of the proposed research is expected to be near-term and it must be significant and go beyond an incremental advance.

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. 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 Scope: 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, including clinical trials. Only small-scale (i.e., up to and including Phase II or equivalent) clinical trials are allowed. Investigators proposing a clinical trial are highly encouraged to consider leveraging the PCRCP Prostate Cancer Clinical Trials Consortium (PCCTC) (<http://pcctc.org/>) to facilitate the rapid initiation and completion of the trial. Projects that incorporate population science-based approaches are particularly encouraged. Applications must include preliminary data to support feasibility of the study. Any unpublished, preliminary data provided should originate from the laboratory of the PI or a member(s) of the research team.

Partnering PI Option: The Impact Award mechanism offers a Partnering PI Option with a higher level of funding to support synergistic partnerships. The Partnering PI Option is structured to accommodate up to 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 a Partnering PI(s). Initiating and Partnering PIs each have different submission requirements, as described in [Section II.D.2, Content and Form of the Application Submission](#); 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.

While the Partnering PI Option places primary focus on the synergy between established investigators, it is also important that younger investigators be integrated into the research project to help foster their future in prostate cancer research; therefore, all applications submitted under the Partnering PI Option ***must include support for at least one postdoctoral fellow, who is expected to be integrally involved in the project.*** Involvement of the postdoctoral fellow is expected to include (but not be limited to) data acquisition and interpretation, as well as dissemination of the research findings through conference presentations and preparation of manuscripts.

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.*** When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application. Submission to HRPO of protocols covering more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol as DoD-supported research and may include extensive modifications to meet DoD human subjects protection requirements. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

A clinical trial is defined as a prospective accrual of patients (human subjects) in whom an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction.

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 the General Application Instructions, Appendix 1, 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/_data/promis_misc/622936arrive_guidelines.pdf.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. This information should be provided as the Data and Research Resources Sharing Plan as described in [Section II.D.2.b, Full Application Submission Content](#) of this Program Announcement. For additional guidance, refer to the General Application Instructions, Appendix 2, Section K.

Awards will be made no later than September 30, 2018. For additional information refer to [Section II.F.1, Federal Award Notices](#).

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including international organizations, are eligible to apply.

Government Agencies within the United States: Local, state, and Federal Government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this Program Announcement may be submitted by extramural and intramural organizations, these terms are defined below.

Extramural Organization: An eligible non-DoD organization. Examples of extramural organizations include academia, biotechnology companies, foundations, Government, and research institutes. *Extramural Submission: Application submitted by a non-DoD organization to Grants.gov.*

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center. *Intramural Submission: Application submitted by a DoD organization for an intramural investigator who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility or in a DoD activity embedded within a civilian medical center.*

Note: Applications from an intramural organization or from an extramural non-DoD Federal organization may be submitted through a research foundation.

The USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

- Independent investigators at or above the level of Assistant Professor (or equivalent) are eligible to submit an application.
- **Partnering PI Option**
 - 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.

An eligible Principal Investigator, regardless of ethnicity, nationality, or citizenship status, must be employed by, or affiliated with, an eligible organization.

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at <http://orcid.org/>.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Extramural organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

There are no limitations on the number of applications for which an investigator may be named as a PI within the category selected for application (i.e., Single PI or Partnering PI Option).

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to [Section II.H.2, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this Program Announcement.

II.D. Application and 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).

Extramural Submission is defined as an application submitted by a non-DoD organization to Grants.gov.

Intramural Submission is defined as an application submission by a DoD organization for an intramural investigator, who is a DoD military or civilian employee working within a DoD

laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center.

II.D.1. Address to Request Application Package

Submitting Extramural and Intramural Organizations: Pre-application content and forms can be accessed at eBRAP (<https://eBRAP.org>).

Submitting Extramural Organizations: Full application packages can be accessed at Grants.gov.

Submitting Intramural DoD Organizations: Full application packages can be accessed at eBRAP.org.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in [Section II.G, Federal Awarding Agency Contacts](#).

II.D.2. Content and Form of the Application Submission

Submission is a two-step process requiring both ***pre-application*** and ***full application*** as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (<https://eBRAP.org/>).

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.

Full Application Submission: Full applications must be submitted through the online portals as described below.

Submitting Extramural Organizations: Full applications from extramural organizations must be submitted through Grants.gov. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions.

Submitting Intramural DoD Organizations: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in [Section II.C.1, Eligible Applicants](#).

eBRAP allows intramural organizations to submit full applications following pre-application submission.

For both Extramural and Intramural applicants: A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Program Announcement 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.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and application submission process. Inconsistencies may delay application processing and limit or negate 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.

Partnering PI Option: The Impact 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 full application package with that of the Initiating PI. After following the link, each Partnering PI must verify their contact information, organization, and designation as an extramural or intramural submission within eBRAP.*** 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.

II.D.2.a. Step 1: Pre-Application Submission Content

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 full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type may result in delays in processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

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.

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 be either 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 be either 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.

[FY17 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 II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

Partnering PI Option: The Initiating PI must enter the contact information for each Partnering PI (*maximum of two*) in the Partnering PI section.

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 pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY17, 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>). Pre-applications or 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 Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- **Tab 4 – Conflicts of Interest**

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 the General Application Instructions, Appendix 3, Section C, 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 (three-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should include the following:

- **Background/Rationale:** Present the ideas and reasoning behind the proposed research, to include relevant literature citations.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Research Approach:** State the project’s specific aims and briefly describe the experimental approach to accomplishing the aims. Describe the preliminary power analysis that reflects sample size projections that will address the hypothesis and/or objective(s) of the proposed project (if applicable). Describe the availability of the necessary research resources as determined by the preliminary power analysis, and a

- brief summary of the plan for acquiring these research resources. Describe how the clinical relevance of the study will be determined; if the proposed research includes a clinical trial, briefly state the clinical intervention, subject populations(s), and phase of the clinical trial.
- **Research Team:** Describe the composition, expertise, and organization of the research team and each team member’s role in the project(s). Briefly describe how these features will facilitate the success of the key aspects the project(s). Include evidence of sufficient clinical and/or statistical expertise, if applicable.
 - **Partnering PI Option (if applicable):** Identify the Initiating and Partnering PI(s) and describe the expertise each will bring to the project. Describe how the combined expertise and efforts will provide synergy and enhance the research effort 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.
 - **Impact:** Describe the intended outcome of the proposed research and how it will make a *near-term, major impact* in eliminating death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease. Also, state how the project is responsive to at least one of the PCRP Overarching Challenges and at least one of the PCRP Focus Areas. 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.
- **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 the following:
 - References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
 - Key Personnel Biographical Sketches (five-page limit per individual). *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.
 - **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.

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 PCR, pre-applications will be screened based on the following criteria:

- **Intent of the Award Mechanism:** To what degree the proposed research project will make a near-term, major impact in eliminating death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease.
- **Research Approach:** How well the rationale and specific aims support the project's objective(s). How the necessary research resources, as determined by the preliminary power analysis, are available to and accessible by the PI(s).
- **Research Team:** To what degree the research team's background is appropriate with respect to its ability to successfully complete the proposed work, including whether there is evidence of sufficient clinical and/or statistical expertise, if applicable.
- **Synergy (*Partnering PI Option only*):** How well the proposed study represents a synergistic collaboration that will produce results greater than what could be accomplished through individual efforts. 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 time frame for notification of invitation to submit an application is indicated in [Section I, Overview of the Funding Opportunity](#). Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

II.D.2.b. Step 2: Full Application Submission Content

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. Refer to the General Application Instructions, Section III, 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 full application package for this Program Announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<http://www.grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Application Guidelines

Extramural organizations, including non-DoD Federal agencies, must submit full applications through Grants.gov. Submissions of extramural applications through eBRAP may be withdrawn.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-17-PCRP-IA from Grants.gov (https://www.grants.gov/).	Download application package components for W81XWH-17-PCRP-IA from eBRAP (https://ebrap.org/).
Full Application Package Components	
SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	Tab 1 – Summary: Provide a summary of the application information. Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: <ul style="list-style-type: none"> • Attachments • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • R&R Subaward Budget Attachment(s) Form (if applicable) 	Tab 3 – Full Application Files: Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites Tab 4 – Application and Budget Data: Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.

Extramural Submissions	Intramural DoD Submissions
Application Package Submission	
<p>Submit package components to Grants.gov (https://www.grants.gov).</p> <p>If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget need 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.</p>	<p>Submit package components to eBRAP (https://ebrap.org).</p> <p>Tab 5 – Submit/Request Approval Full Application: After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller or equivalent Business Official by email to log into eBRAP to review and to approve prior to the application submission deadline.</p>
<u>Application Verification Period</u>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, <i>with the exception of the Project Narrative and Budget Form</i>, may be modified.</p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller or equivalent Business Official and PI(s) will receive an email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, <i>with the exception of the Project Narrative and Budget Form</i>, may be modified.</p>
Further Information	
<p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

The organization’s Business Official or Authorized Organization Representative (or Resource Manager/Comptroller) should approve/verify the full application submission prior to the application verification deadline.

Application viewing, modification, and verification in eBRAP are 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.

Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.

Partnering PI Option The CDMRP requires separate full 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 full application package must be submitted using the unique eBRAP log number. *Note: All associated applications (Initiating and each Partnering PI's) must be submitted by the full application submission deadline.*

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

II.D.2.b.ii. Full Application Submission Components:

Application Components for the PI (for Single PI applicants) or the Initiating PI (if applying under the Partnering PI Option):
--

- **Extramural Applications Only –**

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

- **Extramural and Intramural Applications –**

Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are 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, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire full application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (15-page limit):** Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) 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/Rationale:** Briefly describe the ideas and reasoning on which the proposed work is based. Provide sufficient preliminary data to support the feasibility of work proposed. Demonstrate logical reasoning and provide a sound scientific rationale for the proposed project as established through a critical review and analysis of published literature. If proposing translational or clinical research, it is important to describe the studies showing proof of concept and clinical relevance.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project's specific aims to be funded by this award.
- **Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls and endpoints to be tested (if applicable) in sufficient detail for analysis.
 - Explain how this research strategy will meet the research goals and milestones. Address potential pitfalls and problem areas and present alternative methods and approaches.
 - Clearly identify the source of any proposed cell lines, and whether they were recently authenticated and/or tested for mycoplasma contamination, if applicable.
 - If the methodology is new or unusual, provide sufficient details for evaluation.
 - Describe the availability of the necessary resources, including human subjects or human anatomical samples; include a detailed plan for the recruitment of subjects or the acquisition of samples. Address any potential ethical concerns. Outline how approvals from local IRBs will be obtained and how the informed consent process will be initiated, as applicable.
 - Describe the statistical plan including power analysis that reflects sample size projections that will address the hypothesis and/or the objectives of the project. 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).
 - If the study does not include a clinical trial, describe how the clinical relevance of the anticipated findings will be determined.
 - **Partnering PI Option only:** Describe the integral role of the postdoctoral researcher(s) in the proposed research project, and how that involvement will promote his/her/their career development in prostate cancer research.

- Provide an overall strategic plan for completing the proposed project. If the entire project will not be completed during the performance period of the award (i.e., requires longitudinal follow up), provide evidence that sufficient funds will be available to complete the project.
- **Research Team:** Discuss the qualifications of the research team, each individual's specific contributions to the project, including how the appropriate expertise is incorporated to address the research question and enable the success of the proposed project. If prospective clinical studies are included, the PI(s) or research team must demonstrate appropriate expertise in conducting clinical studies.
- **Clinical Trial (if applicable):** *Only small-scale (i.e., up to and including Phase II or equivalent) clinical trials are allowed.* Provide detailed plans for initiating the clinical study within the first year and conducting the clinical trial during the course of this award. As appropriate, outline a plan for applying for and obtaining Investigational New Drug/Investigational Device Exemption (IND/IDE) status (or other U.S. Food and Drug Administration [FDA] approvals). Describe the rationale for the trial and summarize the previous work that led to the development of the proposed clinical trial. Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.
 - Identify the intervention to be tested and describe the projected outcomes.
 - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
 - Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random). Provide information on the inclusion and exclusion criteria, the availability of and access to the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects for the clinical trial.
 - Describe any ethical issues (e.g., informed consent, information privacy, assessment of risk versus benefit of participation) raised by the proposed study, and provide a detailed plan for how the ethical issues will be addressed.
 - Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
 - Describe the statistical model and data analysis plan with respect to the study objectives. Specify the number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at

each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.

- Describe the composition of the clinical trial team. Provide details on how the team (including investigator(s), study coordinator, statistician) possesses the appropriate expertise in conducting clinical trial
- **Attachment 2: Supporting Documentation:** Combine and upload as a single file named “Support.pdf.” Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application.

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, 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. 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.
- Intellectual Property: Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), “Intangible Property.”
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
- **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.

- Background: Present the ideas and reasoning behind the proposed work.
- Objective/Hypothesis: State the objective to be reached or the 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.
- Impact: Summarize the near-term 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.

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.

- 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?
 - What is the likely impact of this study on addressing a central question or problem in prostate cancer?
- **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 Impact Award mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

Include the name(s) of the key personnel and contact information for each study site/subaward site.

Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.

Briefly state the methods to be used.

For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.

If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the FDA or other Government agency.

Partnering PI Option: Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and each Partnering PI should be noted for each task. Contributions of the key postdoctoral investigator(s) should also be noted for the relevant tasks. 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 near-term impact:*** Detail the anticipated outcome(s)/product(s) that will be directly attributed to the results of the proposed research. Explain how these results/outcome(s)/product(s) will have a ***major impact*** on the goal of elimination of death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease, and how rapidly they will be successfully translated to patients.
 - ***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: Synergy Statement (one-page limit): Upload as “Synergy.pdf.”** (*Attachment 7 is only applicable and required for applications submitted under the Partnering PI Option.*)
 - Discuss in detail the advantages of addressing this 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.

- Describe how the partnering team of PIs will expand the synergy to include the required postdoctoral fellow (or fellows), and how the involvement of the postdoc (or postdocs) in the project will help foster his/her/their future career in prostate cancer research.
- **Attachment 8: Transition Plan (one-page limit): Upload as “Transition.pdf.”**
Provide information on potential methods and strategies to move the project’s findings to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award (e.g., specific potential industry partners; specific funding opportunities to apply for). In addition, provide a plan to distribute the findings or intervention to the prostate cancer community.
- **Attachment 9: DoD Military 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 DoD Military 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 III.A.7, for detailed information.
- **Extramural and Intramural Applications –**
 - Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, 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 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.
 - **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) and required postdoc, if applying under the Partnering PI Option.

- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
 - Include previous/current/pending support for the Partnering PI(s), if applying under the Partnering PI Option.

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, 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.

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 or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s), even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.

Project/Performance Site Location(s) Form): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only –**

R&R Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.6, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.)
- **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov as Attachment 9. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

DoD Military Budget Form: A military facility collaborating in the performance of the project (but not participating as a Partnering PI) 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 DoD Military Budget Form (Attachment 9) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.7, for detailed information.

Application Components for the Partnering PI(s)

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 full application package with that of the Initiating PI.

For each Partnering PI, the Initiating PI must state whether that Partnering PI will be submitting an extramural or intramural application (in accordance with the guidelines in [Section II.C.1.a, Organization](#)) and the appropriate mode of submission (Grants.gov for extramural and eBRAP for intramural). Each Partnering PI must verify his/her contact information and mode of submission within eBRAP to ensure proper submission of his/her application.

The application submission process for the Partnering PI(s) uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications –**

Attachments:

- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf.”** Refer to the General Application Instructions, Section III.A.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.
- **Attachment 9: DoD Military Budget Form: Upload as “MFBudget.pdf.”** Refer to the General Application Instructions, Section III.A.7, for detailed information. The costs per year should be included on the Grants.Gov Research and Related Budget form under subaward costs.

Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section III.A.4, and for intramural submissions refer to the General Application Instructions, Section IV.A.3, for detailed information.

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

Partnering PI Option: 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 Partnering PI(s) should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only –**

R&R Subaward Budget Attachment(s) Form.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.)
- **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov as Attachment 9. (Refer to the General Application Instructions, Section IV.A.3, for detailed information.)

II.D.3. Dun and Bradstreet Universal Numbering System (DUNS) Number and System for Award Management (SAM)

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. 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. If an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application 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 a submitted application. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate retrieved files against the specific Program Announcement 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. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

II.D.5. Funding Restrictions

Application submissions with a single PI:

The maximum period of performance is **3** years.

The anticipated direct costs budgeted for the entire period of performance will not exceed **\$750,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$750,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

All direct and indirect costs of any subaward or contract 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 applications submitted under the Partnering PI Option:

Partnering PI: The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI and each Partnering PI's applications will not exceed **\$2M**. The combined total direct costs of Initiating PI and all Partnering PIs' awards will not exceed **\$2M** direct costs. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. 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 **\$2M** or use an indirect cost 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.

For this award mechanism, direct costs must be requested for:

- ***For Partnering PI Option only:*** Salary support for at least one postdoctoral fellow. This can be included in either the Initiating and/or Partnering PI(s) budget(s).

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Research-related subject costs

- Clinical research costs
- Support for multidisciplinary collaborations, including travel
- Travel costs for one investigator to travel to one 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.***
- ***For Partnering PI Option only:*** Travel costs for the required postdoctoral fellow to travel to one scientific/technical meeting per year.

Extramural (non-Federal) awards will consist solely of assistance agreements (Cooperative Agreements and Grants). For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intragovernmental only funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators. Application packages from associated extramural partners will be funded through assistance agreements.

Refer to the General Application Instructions, Section III.A.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 the General Application Instructions, Section III.A.4.***

The CDMRP expects to allot approximately \$17.6M of the \$90M FY17 PCRP appropriation to fund approximately 8 Impact Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program.

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

- **Impact**

- To what degree the proposed research would make a near-term, 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, or is otherwise justified as significantly addressing another critical issue in prostate cancer research and/or patient care.

- **Research Strategy and Feasibility**

- How well the scientific rationale supports the research and its feasibility, as demonstrated by a critical review and analysis of the literature, the presentation of preliminary data, and logical reasoning.
- How well the 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).
- How well the animal study (or studies) is designed to achieve the objectives and generate reproducible and rigorous results (if applicable).
- Whether experiments to address the clinical relevance of the anticipated findings have been incorporated into the study design (if applicable).
- Whether appropriate measures have been taken or are in place to authenticate proposed cell lines and/or test for mycoplasma contamination (if applicable).
- Whether the PI has provided sufficient evidence that resources will be available to complete longitudinal follow-up beyond the period of performance (if applicable).
- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.

- **Clinical Strategy (for applications with a clinical trial)**

- How the type of clinical trial (e.g., prospective, randomized, controlled) proposed is appropriate to meet the project's objectives.

- How the clinical trial is designed with appropriate study variables, controls, and endpoints.
- How the application demonstrates the availability of and access to the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects.
- Whether the clinical trial design, methods, and analysis plan meet the requirements for applying for and obtaining IND/IDE status (or other FDA approvals), if appropriate.
- Whether the PI has sufficiently demonstrated that the clinical trial can be initiated in the first year of the award.
- Whether potential challenges and alternative strategies are appropriately identified.
- **Transition Plan**
 - How the application demonstrates feasible methods and strategies to move the project's findings to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award.
- **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.
- **Synergy (*Partnering PI Option only*)**
 - How the proposed partnership between 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.
 - How well the required postdoctoral fellow (or fellows) has been integrated into the project, and how well their involvement will foster the postdoctoral fellow's future career in prostate cancer research.

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

- **Ethics and/or Regulatory Issues**
 - Whether potential problems regarding ethics, information privacy, and assessment of risk versus benefit of participation have been adequately considered (if applicable).
- **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 **direct** maximum costs are equal to or less than the allowable direct maximum costs as published in the Program Announcement.
 - Whether the budget is appropriate for the proposed research.
- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. 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:

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY17 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

II.E.2. 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 Commanding General, USAMRMC, on behalf of the DHA 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. 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 II.E.1.b, 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 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold (currently \$150,000) over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant, at its option, may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about itself that a Federal awarding agency previously entered and is currently available in FAPIIS.

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the

applicant's integrity, business ethics and record of performance under Federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGAR), Section 22.415.

II.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

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.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

Awards are made to organizations, not to individual PIs. The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

Extramural Organizations: An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a "thing of value," to a "state, local government," or "other recipient," to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the USAMRAA will contact the business official authorized to negotiate on behalf of the PI's organization.

Only an appointed USAMRAA Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. The award document signed by the Grants Officer is the official authorizing documents.

Intramural Organizations: Awards to Federal Government organizations (to include intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request

(MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers (RM).

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the CDMRP will contact the business official authorized to negotiate on behalf of the PI's organization.

II.F.1.a. 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.

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

Single PI Option: An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Partnering PI Option: An organizational transfer of an award supporting the Initiating or Partnering PI 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 2, Section B, for general information on organization or PI changes.

II.F.2. Administrative and National Policy Requirements

In-person presentations may be requested.

Applicable requirements in the DoDGAR found in 32 CFR, Chapter 1, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

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

Refer to full text of the [USAMRAA General Research Terms and Conditions for Institutions of Higher Education, Hospitals, and Non-Profit Organizations](#) and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. Annual progress reports as well as a final progress report will be required.

If employing the Partnering PI Option, each PI, whether Initiating or Partnering, must submit individual annual progress reports as required by the individual award agreement, as well as a final progress report.

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

In addition to written progress reports, Annual Award Charts will be required. For the IA mechanism, use the format example titled, “Generic Award Charts,” available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>).

Awards resulting from this Program Announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose semiannually information about criminal, civil, and administrative proceedings as specified in the applicable Terms and Conditions. The applicable Terms and Conditions for institutions of higher education, hospitals, and nonprofit organizations is available in OAR Article I, Section B, in the [July 2016 R&D General Terms and Conditions](#). The applicable Terms and Conditions for for-profit organizations is available in Section 34 of the [February 2017 USAMRAA General Research Terms and Conditions with For-Profit Organizations](#).

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to Program Announcement content or submission requirements as well as questions related to the pre-application or intramural application submission 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

II.G.2. Grants.gov Contact Center

Questions related to extramural 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 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.

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 20170516b. The Program Announcement numeric version code will match the General Applications Instructions version code 20170516.

II.H.2. Administrative Actions

After receipt of pre-applications or applications, the following administrative actions may occur:

II.H.2.a. Rejection

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

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

The following will result in administrative rejection of the application:

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

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.

- Documents not requested will be removed.

II.H.2.c. Withdrawal

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

- An FY17 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 FY17 PCRP Programmatic Panel members can be found at <http://cdmrp.army.mil/pcrp/panels/panel17>.*
- The application fails to conform to this Program Announcement 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 FY17, 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 Grants Officer. Refer to the General Application Instructions, Appendix 3, 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.
- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- The invited application does not propose the same research project described in the pre-application.
- An application for which the PI does not meet the eligibility criteria will be withdrawn.
- Partnering PI Option: All associated (Initiating and Partnering PI) applications are not submitted by the deadline.

- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.

II.H.2.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.

II.H.3. Application Submission Checklist

Application Components	Action	Initiating PI Completed	Partnering PI Completed
SF424 (R&R) Application for Federal Assistance (Extramural submissions only)	Complete form as instructed.		
Summary (Tab 1) and Application Contacts (Tab 2) (Intramural submissions only)	Complete these tabs as instructed.		
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."		
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."		
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."		
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."		
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."		
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."		
	<i>(Partnering PI Option Only)</i> Synergy Statement: Upload as Attachment 7 with file name "Synergy.pdf," if applicable.		
	Transition Plan: Upload as Attachment 8 with file name "Transition.pdf."		
	DoD Military Budget Form(s): Upload as Attachment 9 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.		

Application Components	Action	Initiating PI Completed	Partnering PI Completed
Research & Related Budget (Extramural submissions only)	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.		
Budget (Intramural submissions only)	Complete the DoD Military Budget Form and Justification.		
Project/Performance Site Location(s) Form	Complete form as instructed.		
R&R Subaward Budget Attachment(s) Form	Complete form as instructed.		

APPENDIX 1: ACRONYM LIST

ACURO	Animal Care and Use Review Office
B	Billion
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGAR	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
M	Million
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OMB	Office of Management and Budget
ORP	Office of Research Protections
PCRP	Prostate Cancer Research Program
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
RM	Resource Manager
SAM	System for Award Management
SOW	Statement of Work
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code