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

Prostate Cancer Pathology Resource Network Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-17-PCRP-PCPRNA

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), August 24, 2017
- **Application Submission Deadline:** 11:59 p.m. ET, September 7, 2017
- **End of Application Verification Period:** 5:00 p.m. ET, September 12, 2017
- **Peer Review:** October 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."

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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 Prostate Cancer Pathology Resource Network (PCPRN or Network) Award mechanism was previously offered in FY09 and FY13. In FY14, the Prostate Cancer Biospecimen Resource Site Award was offered to add additional sites to the Network. Since then, 6 PCPRN Award applications were received for the Coordinating Center plus Pathology Resource Site, with 2 being funded, and 19 were received for Pathology/Biospecimen Resource Sites, with 5 being funded.

The anticipated direct costs budgeted for the entire period of performance for an FY17 PCRP PCPRN Award will not exceed **$3.6M**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

The FY17 PCRP PCPRN Award is intended to provide infrastructure support for the development and maintenance of a prostate cancer biorepository through a collaborative network across multiple institutions that will facilitate the collection, processing, annotation, storage, and distribution of high-quality human prostate cancer biospecimens. A major focus of the Network must be placed on the acquisition and distribution of specimens in limited supply, such as:

- Castration-resistant disease, metastatic disease, primary untreated “de novo” metastatic disease as defined by STAMPEDE or high-risk disease defined by CHAARTED, tumors of the aggressive variant phenotype
- Disproportionately affected populations, defined by ethnicity or health service access (safety net, rural, settings)
- Active surveillance populations
- Longitudinal/sequential specimens

The Network must also collect, store, and manage data derived from the distributed biospecimens, including images of the hematoxylin and eosin (H&E)-stained samples.

Applications should describe how the development of the Network biorepository will enable the prostate cancer research community to address the FY17 PCRP Overarching Challenges and FY17 PCRP Focus Areas by utilizing Network biospecimens. Applications should propose a

clearly defined mission that will guide the proposed Network's biospecimen collection, distribution, and data collection processes.

The Network will consist of three to five Pathology Resource Sites and a Coordinating Center, which will also function as one of the Pathology Resource Sites. These organizations will be jointly responsible for developing and maintaining the biorepository for prostate cancer research. The Coordinating Center and Pathology Resource Sites should together design the proposed biorepository. It is expected that the Coordinating Center will provide unique resources that may not be available at the Pathology Resource Sites and can be leveraged for the biorepository as a whole. Additionally, Pathology Resource Sites should each possess the ability to derivatize DNA, RNA, and proteins from biospecimens and utilize both standard and state-of-the-art technologies (e.g., laser capture microdissection, tissue microarrays) to provide the necessary biospecimen processing for a large range of prostate cancer research studies. Both U.S. and international organizations should be considered for inclusion in applications for this award. ***The Pathology Resource Sites should be selected for the individual contributions each can make to the biorepository; the contributions need not be equal but rather of unique value to the biorepository as a whole. If the contributions vary significantly among Pathology Resource Sites, variance in the budgets allocated to sites should be well described in the budget justification.***

The PCPRN Coordinating Center, in addition to functioning as a Pathology Resource Site, will serve as the nexus for Network information and planning, providing administrative, operational, and data management and providing support to Pathology Resource Sites in implementing Network policies and standard operating procedures (SOPs). Therefore, the Coordinating Center will have multidisciplinary expertise and extensive experience in multi-institutional collaborations in prostate cancer research. Applications from organizations with resources (such as sufficient equipment for biorepository functions, pathology and histochemistry infrastructure, and informatics and information infrastructure to support connectivity between the Coordinating Center and Pathology Resource Sites for data transfer) already in place to support the development of a biorepository are encouraged. Principal Investigators (PIs) are expected to have experience and expertise in human biospecimen procurement, annotation, storage, and distribution, and in developing and operating a biospecimen repository. PIs should have a proven track record in human pathology.

The PCPRN Award mechanism requires a multi-PI partnership between one Coordinating Center PI and three to five Pathology Resource Site PIs (one of whom will also be the Coordinating Center PI) who will be jointly responsible for development of the biospecimen repository. Each partner in the Network will be recognized as a PI and submit a separate application. The Coordinating Center PI will be the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. Pathology Resource Site PIs at organizations other than that of the Coordinating Center will be the Partnering PIs. Initiating and Partnering PIs each have different submission requirements, as described in Section II.D, Application and Submission Information; however, all PIs should contribute significantly to the preparation of each of the application components. If recommended for funding, each PI will receive his or her own award.

The principal areas of responsibility for the Prostate Cancer Pathology Resource Network are as follows:

1. **Biospecimens:** The biorepository will collect, process, annotate, store, and distribute high-quality human prostate cancer biospecimens and matched or unmatched normal tissues and other non-anatomic pathologic samples to include blood, urine, prostatic fluids, and other source genomic and proteomic material. ***Prospective collection of high-quality prostate cancer biospecimens is required; however, the inclusion of previously collected high-quality biospecimens for distribution by the biorepository is encouraged.*** The Coordinating Center will be responsible for developing and maintaining Network SOPs for biospecimen collection methods, post-collection processing, and quality assurance of specimens.

   The Network must focus significant attention on the collection and distribution of biospecimens currently in limited supply for research (e.g., castration-resistant disease, metastatic disease, primary untreated "de novo" metastatic disease as defined by STAMPEDE and high-risk disease as defined by CHAARTED, tumors of the aggressive variant phenotype, disproportionately affected populations), which will be identified from an annual survey of the prostate cancer research community.

2. **Clinical Annotation of Biospecimens and Data Quality Assurance:** Within the framework of the data management plan, the Network must establish and maintain common data elements (CDEs) and standardized language to annotate tissue specimens collected for the biorepository. The extent of the clinical annotation should include data on (1) patient history and demography, (2) characterization of individual pathological cases to include grade, Tumor Node Metastasis (TNM) staging, zonal origin of tumor, biospecimen size, storage conditions, the existence of case-matched normal biospecimens, and other standard parameters, (3) patient treatment to include adjuvant or neoadjuvant therapeutic interventions, including attention to interventions resulting from participation in clinical trials, and (4) outcome such as disease progression, recurrence, and/or prostate-specific antigen (PSA) levels or other biochemical status. ***Given the importance of clinical annotation, the PCPRN must provide for regular updating of annotated data in the repository.*** To ensure the quality of the biospecimens and the consistency and accuracy of data in the repository, the Network is expected to develop quality assurance measures for clinical and pathological data and data transmission by establishing policies for appropriate quality control and quality assurance.

3. **Informatics and Data Management:** It is expected that the Network will develop and maintain a comprehensive data management plan that includes a common informatics system to manage the biorepository resources and provide for ongoing data transfer, security, and integrity. The system should remain current and responsive to the prostate cancer research community so that data can be both retrieved and deposited into the system. ***Costs associated with developing the common informatics system are allowable and, if necessary, should be included in the proposed budget.***

   PIs must provide a plan to deposit all data generated from the use of biospecimens obtained from the funded biorepository into a common information grid. ***Investigators utilizing the Network biospecimens must agree to share the resulting data after publication and as***

prescribed by the Network and in accordance with journal policies. The data-sharing plan must include steps for sharing the data with the prostate cancer research community through an internet-accessible source administered by the Coordinating Center. In addition, in order to maximize the impact of the biorepository, protocols and other methods used to derive tests, assays, and associated data from the biorepository specimens must be available to the entire prostate cancer research community via an open source system such as public websites.

4. **Informed Consent:** Applications for the PCPRN Award are expected to demonstrate plans for establishing and managing procedures to ensure requests for use of biospecimens are in compliance with the local institutional review boards (IRBs) for the conduct of research and the protection of human subjects. Assurances should be made for appropriate acquisition of patient-informed consent, with tiers as appropriate, to include clinicians, surgeons, or other personnel necessary for the consent process, and disassociation of patient identities from biospecimens. PIs should also address how informed consent will be handled beyond consent obtained for surgical procedures. This includes specimens collected during routine medical care that will be used for future research purposes.

5. **Intellectual Property and Material Transfer Agreements:** Since the biospecimen repository will be a collaborative network of institutions, the Network PIs will work together with the Coordinating Center to resolve potential intellectual and material property issues and remove any institutional barriers that might interfere with achieving the high levels of cooperation necessary for the success of the biorepository Network. Applications for the PCPRN Award must provide documented evidence of institutional commitment to allowing specimens collected at Pathology Resource Sites to be sent to investigators at non-Network institutions for the purpose of conducting prostate cancer research.

6. **Organizational Structure:** The overall organizational structure of the PCPRN is ***three to five*** procurement Pathology Resource Sites and one Coordinating Center. The Coordinating Center organization will function as one of the Pathology Resource Sites, in addition to serving as the nexus for Network information and planning, providing administrative, operational, and data management. The Coordinating Center PI will serve as the Director of the Network and the Chair of the Steering Committee. In addition to the Coordinating Center PI and the Pathology Resource Site PIs and collaborators, other key personnel in the Network include:

    - A Coordinating Center **Network Manager** who will assist with daily operations of the Coordinating Center;

    - A Coordinating Center **Data Management Specialist** who will interact and oversee all informatics and data management within the Network;

    - A Coordinating Center **Data Quality Control Specialist** who will be responsible for implementing established operational procedures to ensure the quality of biospecimens and biospecimen data across the Network and the shared information grid; and

- **Pathology Resource Site Coordinators** (one for each Site) who will work with the Coordinating Center Network Manager on Network-wide functions in addition to Pathology Resource Site-specific functions.

- A **Steering Committee** composed of Coordinating Center PI (Chair), Pathology Resource Site PIs and/or co-PIs, and other personnel with key expertise will assume the role of the governing body with responsibility for operation of the biorepository Network. This committee will also be responsible for establishing polices that govern SOPs (in accordance with the National Cancer Institute's [NCI's] "Best Practices for Biospecimen Resources" (http://biospecimens.cancer.gov/global/pdfs/NCI_Best_Practices_060507.pdf)). Representatives of the PCRP, CDMRP, and/or U.S. Army Medical Research and Materiel Command (USAMRMC) must be invited to participate as members of the Steering Committee.

- **External Advisory Board:** To ensure optimal conduct and oversight of Network activities, the Network will propose and develop an External Advisory Board (EAB). Applications must include a description of the proposed EAB members, the role of each member (e.g., scientific, business, or other type of review), evidence of agreement to serve, and plans for interaction between the EAB and Network members, which should, at a minimum, include meetings (whether in person or by other means) no less than twice yearly. Support for this interaction must be included in the proposed budget. In selecting EAB members, the types of samples to be collected should be considered, as well as the importance of having external expertise in pathology, biobanking, and current advancements in biospecimen science.

  The Government reserves the right to require augmentation of the EAB membership prior to or during the award performance period. In addition, representatives of the PCRP, CDMRP, and/or USAMRMC must be invited to participate in meetings involving the EAB. The Government reserves the right to direct the location of any in-person meeting. Costs for Government participation should not be included in the proposed budget.

Overall, the Coordinating Center will be responsible for the establishment and management of a communications plan and an ongoing communications system to maintain optimal operation of all Network components.

7. **Performance Metrics:** The PCPRN Award recipients will be accountable to the following performance metrics, upon which continued funding will be contingent after the first 12 months of the award:

   - Development of SOPs for prospective biospecimen collection methods and post-collection processing. Following EAB review of the SOPs, the Coordinating Center must provide documentation of these SOPs to the Government no later than the end of the first year of performance.

   - Annual evaluation of the current biospecimen needs of the prostate cancer research community through the annual distribution and collection of information through a

survey. Any new findings indicating a new disease state(s) should be noted and such specimens should be collected.

- Evaluation of the services provided by the Network to previous biospecimen recipients through the distribution and collection of information through a survey, to be conducted no less than once per year, and demonstration of efforts to improve access of samples to investigators by improving internal processes for sample requests, review, and approval.

- Demonstration of ongoing documentation of Letters of Intent for utilization of specimens, to include the number of requests received, approved, or rejected and the types and timeliness of specimens distributed.

- Demonstration of the impact of the biospecimens distributed through tracking of the number of publications involving the use of Network biospecimens.

- Demonstration of sufficient data quality control and assurance through documentation that SOPs are being followed for biospecimen annotation (e.g., patient history and demographic data, clinical history, treatment, pathology, and outcome such as disease progression, recurrence, and PSA levels and/or other biochemical statuses). This may include an online portal for communication and submission of required data, increase in the amount of information provided for samples (such as additional clinical data and/or patient follow-up data), and audits of unacceptable data (record, clinical, pathological) returned to Pathology Resource Sites for review and correction for data quality assurance.

- Each Pathology Resource Site must contribute prospectively collected biospecimens from a minimum of 50 patients per year with the expectation that biospecimen contribution will exceed the minimum requirement. A minimum of 50% of the samples collected across the entire Network must be in limited supply and documented to be the most needed by the prostate cancer research community, as determined by the required annual survey.

- Submission of quality data and reports in a timely manner as outlined by the Coordinating Center. This includes, but is not limited to, requests for biospecimens, entry of data upon sample acquisition, and all subsequent information updates.

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. 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-Department of Defense (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:

PIs must be independent investigators at or above the level of an Assistant Professor (or equivalent) with access to appropriate facilities. Eligibility is not affected by previous receipt of a PCRP PCPRN Award.

An eligible PI, 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.

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 the electronic Biomedical Research Application Portal (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.

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 **Coordinating Center PI** (Initiating PI) through eBRAP (https://eBRAP.org/).

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.

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.

The Initiating PI must enter the contact information for each Partnering PI 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**

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

- **Tab 6 – Submit Pre-Application**

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

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

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 (https://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-PCPRNA from Grants.gov (https://www.grants.gov).	Download application package components for W81XWH-17-PCRP-PCPRNA 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: • 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: • 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	
Submit package components to Grants.gov (https://www.grants.gov). 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.	**Submit package components to eBRAP (https://ebrap.org).** **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.
Application Verification Period	
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, ***with the exception of the Project Narrative and Budget Form,*** may be modified.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller or equivalent Business Official and PIs 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, ***with the exception of the Project Narrative and Budget Form,*** may be modified.
Further Information	
Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

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.

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:

- **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 (40-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, with consideration of NCI's "Best Practices for Biospecimen Resources," as applicable. All items should be addressed for both the Coordinating Center and Pathology Network Sites.

(1) Experience and Expertise in Multi-Institutional Collaboration and Biorepository Development

- Describe previous experience and accomplishments in multi-institutional collaboration.
- Describe expertise, experience, and accomplishments related to the development, administration, and fiscal management of a biorepository.
- Describe previous experience with establishing communications systems and data management resources for multi-institutional projects.
- Reference relevant publications.

If any of the institutions is a previous recipient of a PCRP PCPRN Award, whether as Coordinating Center or Pathology Resource Site, a description of the performance of that award must be included.

(2) Organizational Structure: Describe the organizational structure, including the following key features:

- The structure of interaction among the Coordinating Center and Pathology Resource Sites (a chart format for this information is encouraged).
- Plans for administration and day-to-day management of Network operations.
- Communication and Network Interaction: Describe the communication plan between the Coordinating Center and Pathology Resource Sites, including methods for information distribution within the Network, information technologies that will be used to facilitate routine multi-institutional communication, and ongoing communication and data sharing.
- Standardized operations across institutions.
- Coordination and development of protocols, equipment, and training of personnel.
- Coordination of regulatory issues.
- Coordination and oversight of privacy and confidentiality of patient data.
- Procedures for ensuring that research projects with requests for use of biospecimens are in compliance with local IRB approvals for the conduct of research and the protection of human subjects.
- Management and monitoring of biospecimen processing, annotation, storage, and distribution.

- Procedures for developing SOPs for collection, processing, annotation using standardized language, storage, and distribution of prostate cancer and normal biospecimens.

- Network committees that will be responsible for approval of all SOPs and laboratory protocols, and prioritization of biospecimen distribution to prostate cancer investigators to ensure appropriate and efficient distribution of samples and attention to studies that address PCRP Focus Areas.

- Oversight by an EAB for scientific review, data monitoring, and evaluation. Include a description of the proposed EAB members, the role of each member (e.g., scientific, business, or other type of review), evidence of agreement to serve, and plans for interaction between the EAB and Network members, which should, at a minimum, include meetings (whether in person or by other means) no less than twice yearly.

(3) Institutional Resources: Describe the institutional resources, including the following aspects:

- The unique capabilities and strengths of each institution to serve as a member of the Network.

- Provide evidence of institutional support, resources, and facilities for the development of a biospecimen repository and its operation in the context of a cooperative network of organizations.

- Provide evidence of institutional commitment to allow specimens collected at Pathology Resource Sites to be sent to investigators at non-Network institutions for the purpose of conducting prostate cancer research.

- Provide a plan for resolving intellectual and material property issues among participating institutions and how material transfer agreements will be established.

- Describe the unique capabilities and strengths of the institutions selected to serve as Pathology Resource Sites.

- Document access to patient populations: Describe the available patient populations. Provide documentation of access to the populations (and families, where appropriate) and ability to recruit patients and/or patient specimens identified as being in limited supply and from ethnically diverse and disproportionately affected populations.

(4) Operational Management

- Provide evidence of the expertise of all key personnel that will be involved in the Coordinating Center and the Pathology Resource Sites, respectively. Describe their expected roles as they relate to the collection, processing, annotation, storage, and distribution of human prostate biospecimens. Key personnel must

include a **named Network Manager** at the Coordinating Center who will interact with and coordinate activities across all Sites, including interacting with a Pathology Resource Site Coordinator at each site to expedite protocols through regulatory approval processes, expedite review, evaluation, selection, and prioritization of specimen distribution, develop protocols, coordinate personnel training, and coordinate patient participation and other biorepository activities across all institutions.

- Include a **named Data Quality Control Specialist** at the Coordinating Center who will interact with all Pathology Resource Sites and oversee implementation of established operational procedures to ensure the quality of biospecimens and biospecimen data across the Network and shared information grid.

- Describe plans for collecting and ensuring the quality of pathological and clinical biospecimen data and research data analyses.

- Include a plan for sharing biospecimens across the Network.

- Include a plan for processing, evaluating, and prioritizing requests for biospecimens from Network members and other investigators, including potential restrictions governing use of biospecimens by commercial entities.

- Outline a plan for ensuring rapid publication and other public dissemination of data generated by Network investigators, and procedures for timely release of data obtained from use of biospecimens following publication of significant findings by non-Network investigators.

- Provide a plan for the development and management of procedures for biospecimen inventory control, quality assurance, and quality control measures across institutions, including:

  - A plan for regular monitoring of biospecimen quality, biospecimen clinical and pathological data, and data transmission across the Network as described in the **Clinical Annotation of Biospecimens and Data Quality Assurance** section above;

  - Registration, tracking, and reporting of patient participation and biospecimens;

  - Timely review and assessment of biospecimen data, deposited clinical annotated data and deposited research data for consistency and accuracy; and,

  - Development, implementation, and periodic evaluation of quality assurance and control procedures.

- Development and implementation of comprehensive data collection and data management systems to manage biorepository resources and provide for ongoing

needs of all Sites in terms of access to data, data transfer, data security, and data integrity.

- Development and implementation of procedures for the timely release of all data obtained from use of biospecimens following publication of significant findings.

- Plans for contribution by each Pathology Resource Site of biospecimens from at least the minimum number of 50 patients per year (to include patients from disproportionately affected populations).

- Plans for evaluation of the biospecimen needs of the prostate cancer research community through annual surveys (and other methods if desired) and how the Network will adapt to meet the changing needs of the research community.

- Development and implementation of procedures for the timely publication of research results.

(5) Biospecimen Management, Quality Assurance, and Distribution: Describe the plans for biospecimen management, quality assurance, and distribution, including the following key features:

- The model to be used for biospecimen collection, annotation, processing, storage, and distribution; include how common data elements will be developed and methods/applications for data collection and transmission.

- Methods for biospecimen collection, tracking, storage, transport, distribution, and security.

- Plans for quality assurance, quality control, and monitoring of biospecimens to avoid sample variability, ensure specimen integrity (e.g., RNA, DNA, protein), and maximize efficiency.

- Plans for biospecimen management, to include methods for biospecimen collection, tracking, storage, integrity, transport distribution, and security.

- Descriptions of quality control measures for biospecimens, data, and monitoring to avoid sample variability.

- Plans for collecting and ensuring the quality of pathological and clinical biospecimen data and research data analyses.

- Include plans for advertising/marketing for both obtaining and distributing the biospecimens to the prostate cancer research community.

(6) Informatics and Data Management

- Describe the common informational system to be used in the Network. Include database design, operation, and maintenance; inventory control system(s); access; and searchable functions for biospecimen information and research data.
- Include a named Data Management Specialist at the Coordinating Center who will interact with all Pathology Resource Site Coordinators to optimize informatics and data management within the Network.
- Describe the overall planned approach to data collection and management.
- Describe the plan for ongoing data transfer, security, and integrity.
- Describe the plan for managing the resources of the Network and the Pathology Resource Sites while remaining current and responsive to non-Network prostate cancer investigators.
- Include the plan for sharing all data derived from Network biorepository specimens, whether generated by Network or non-Network investigators.
- Provide evidence of adequate resources for ongoing data transfer, and expertise for data management and maintenance of data security/ confidentiality.
- Describe the information technologies that will be used to facilitate routine communication and information and data sharing with the Coordinating Center and other Pathology Network Sites.

(7) Legal, Ethical, and Human Subject Issues

- Outline the ethical and legal procedures and policies that will be followed for collection and use of biospecimens in research.
- Include a description of the methods for obtaining informed, tiered patient consent, how patient identities will be disassociated from biospecimens provided to investigators, and how research results from the biospecimens will be made available to clinicians of patient participants.
- Describe the process through which all Sites in the Network will adhere to a common policy governing legal, ethical, and human subject issues.
- Describe procedures for ensuring compliance with ethical and legal involvement of human subjects, and issues involved in the collection and use of biospecimens in research.

- **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 Network PIs 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.

- If applicable: Provide a signed letter from each collaborating individual or institution that will demonstrate that the PI has the resources necessary for the proposed project, including but not limited to:

  - Availability of and access to high-quality specimens, data sets or databases that are necessary for the success of the project.

  - Availability of and access to appropriate prostate cancer patient populations and/or families.

- 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.

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

- 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.

  - ***Expertise:*** Summarize the key personnel's (including the PIs and other key personnel) commitment to and expertise in prostate cancer research and pathology.

  - ***Coordinating Center Organizational Structure and Operational Management:*** Briefly outline the overall organizational structure, administration, and model for SOPs.

  - ***Biospecimen Management and Quality Assurance, Control, and Distribution:*** Briefly describe the model to be used for biospecimen collection, processing, annotation, storage, and distribution. State concisely how quality assurance and quality control will be managed to ensure specimen integrity and avoid sample variability.

- ***Informatics and Data Management:*** Describe the plan for data management, including a common informational (informatics) system to manage the biorepository resources, provide for ongoing data transfer, security, and integrity. State briefly how this system will be used to facilitate communication and Network interactions between the Pathology Resource Sites and the Coordinating Center.

- ***Institutional Resources:*** Summarize the unique capabilities and strengths of the institutions serving as Coordinating Center and Pathology Resource Sites. Include available resources, facilities, and prior experience in multi-institutional collaborations.

- ***Prostate Cancer Populations:*** Describe the accessible prostate cancer populations that will be recruited for biospecimen acquisition and/or the accessible patient specimens. Include a description of any disproportionately affected populations to be included.

- ***Impact:*** Describe how the proposed Network will have a significant impact on prostate cancer and/or prostate cancer research.

- **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.

  Not required at this time. Leave Attachment 4 space blank.

- **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 Prostate Cancer Pathology Resource Network Award mechanism, use the SOW format example titled "SOW for Collaborative PI Projects." 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 U.S. Food and Drug Administration or other Government agency.

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.

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

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

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

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

  - ***PCRP Overarching Challenges and Focus Areas:*** Describe how the proposed project will facilitate research that addresses one or more of the FY17 PCRP Overarching Challenges and one or more of the FY17 PCRP Focus Areas.

- **Attachment 7: 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 the Pathology Resource Site PIs, all co-investigators, Network Manager, Pathology Resource Site Coordinators, Data Management Specialist, Data Quality Control Specialist, and other key personnel.

- Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

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 PI 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), even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

Note: Budget amounts for the Pathology Network Sites should reflect the resources to be contributed; however, if the budgets differ significantly among Pathology Resource Sites, the differences must be well-justified in the budget justification.

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 7. (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 7) 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 PIs

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 identify if 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 PIs 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 7: 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."

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 PIs 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 7. (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

The PCRP plans to invest a total of $5.8M in the FY17 PCRP PCPRN Award over a 3-year period. Approximately $1.9M will be allocated from the FY17 PCRP budget to fund the first year of performance. Options will be included for continued performance in subsequent years with $1.9M expected from each of the FY18 and FY19 PCRP budgets to fund the options. The initial performance period of the award and each option period will be for 12 months. ***Exercise of the options for continued performance is contingent upon meeting the performance metrics and acceptable performance by the recipient and upon receipt of sufficient Congressional appropriations for the PCRP in FY18 and FY19 and acceptable performance by the recipient.***

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

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 **$3.6M**. The combined total direct costs of Initiating PI and all Partnering PIs' awards will not exceed **$3.6M** 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 **$3.6M** or use an indirect cost rate exceeding each organization's negotiated rate.

A separate award will be made to each PI's organization.

All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.

For this award mechanism, direct costs for the **Coordinating Center and Pathology Resource Sites** must be requested for:

- Travel for attendance at in-person EAB review meetings (including costs for all appropriate personnel), to be held a minimum of two times per year. Costs should also be included for conducting these meetings.

- Travel costs for the PI to attend a 1-day meeting held in the National Capital Area **each year** during the award period of performance. This meeting will be held to provide a presentation on progress. ***Travel costs for each PI should be requested on his/her individual budget.***

May be requested for (not all-inclusive):

- Salary

- Development of software, databases, inventory systems, websites, and/or other information technology

- Purchase of equipment, including computers (equipment purchases should not exceed $50,000 total)

- Advertising/marketing costs for the Network

- Other costs associated with planning and developing Network collaborations and resources

- Network meetings including travel among Network PIs and staff

- Planning and travel costs for Network symposia or workshops

- Travel costs for up to two investigators to travel to two scientific/technical meetings 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***.

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 $1.9M of the $90M FY17 PCRP appropriation to fund approximately one PCPRN Award application, 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:

- **Personnel**
    - How well the Coordinating Center PI, Pathology Resource Site PIs, and other key personnel have demonstrated the expertise, experience, and accomplishments to enable successful development, administration, and fiscal management of a biorepository.
    - How the Coordinating Center PI, Pathology Resource Site PIs, and other key personnel have demonstrated previous success in multi-institutional collaborations including past performance of a PCRP PCPRN Award, if applicable.
    - To what degree the named Network Manager and Pathology Resource Site Coordinators possess the appropriate expertise to coordinate Network activities across all Sites and expedite protocols through regulatory approval processes.
    - To what degree the named Data Management Specialist and Data Quality Control Specialist possess sufficient expertise in informatics and data management.
    - Whether there are sufficient levels of effort for the successful conduct of the proposed work at each of the institutions involved.
- **Institutional Resources and Commitment**
    - Whether there is evidence of strong commitment from the Coordinating Center and each Pathology Resource Site institution to provide the necessary resources and facilities for the development of a biospecimen repository, its operation in the context of a cooperative network, and allow biospecimens to be shared with investigators outside the Network.
    - Whether each institution to be involved in the proposed work has unique resources that will benefit the biorepository Network as a whole.

- To what degree the institutions have a demonstrated track record of sharing biospecimens and/or suitable plans to do so.

- Whether the willingness and abilities of the institutions to resolve intellectual and material property issues among all participating institutions are demonstrated.

- **Organizational Structure**

  - To what degree the strategies for the development and implementation of the biorepository at each institution involved are well demonstrated and will facilitate its success.

  - Whether the proposed organizational management plan is appropriate with respect to decision making, allocation of resources, coordination of Network functions including regulatory approval processes, and conflict resolution among all participating PIs and institutions.

  - Whether there are appropriate plans for oversight by an EAB with qualifications to provide sufficient oversight and guidance for the success of the biorepository.

- **Operational Management**

  - Whether the proposed plan for coordinating ongoing communication across the Network is appropriately robust.

  - Whether appropriate plans for biospecimen distribution to the prostate cancer research community, including evaluation and prioritization of requests for biospecimens, have been included.

  - To what extent the plans for sharing of data between the Network and with the prostate cancer research community, including all data derived from internal and external studies of the biorepository specimens are sufficient.

  - Whether there are adequate plans to assess the biospecimen needs of the prostate cancer research community through surveys (and other methods, if applicable), and how well the Network plans to adapt to meet the changing needs of the research community.

  - Whether there are appropriate plans for rapid publication and other public dissemination of data generated by the Network.

  - The degree to which the proposed plan for obtaining and marketing biospecimens to the prostate cancer research community will facilitate the success of the biorepository.

- **Data Management**

  - Whether the proposed plan for data management will provide appropriate access to data, data security and confidentiality, and data integrity.

- Whether the proposed data management plan is appropriate with respect to quality control and quality assurance.

- The degree to which the proposed informatics structure and data management plans will successfully facilitate prostate cancer research.

- Whether the plans for data sharing between the Pathology Resource Sites and with the prostate cancer research community, including all data derived from internal and external studies of the biorepository specimens, are sufficient.

- **Legal, Ethical, and/or Regulatory Issues**

  - Whether there are appropriate plans for addressing regulatory issues associated with the legal and ethical protection of human subjects and the use of human biospecimens in research.

  - Whether all relevant privacy issues have been addressed appropriately.

  - Whether the plans for data acquisition and storage will sufficiently maintain patient confidentiality.

  - Whether there are appropriate plans for the coordination of regulatory submissions and approvals at participating Sites.

  - Whether the plans for ensuring informed consent are sufficiently developed.

- **Participant Access and Recruitment**

  - To what degree the PI has demonstrated enhanced access to patient specimens that are in limited supply for prostate cancer research.

  - Whether there is sufficient evidence of access to and ability to recruit patients from disproportionately affected populations.

  - How well the PI has demonstrated excellent capabilities in obtaining high-quality biospecimens.

- **Impact**

  - The extent to which the biorepository as proposed will, if successful, make a major impact on the field of prostate cancer research and enable investigators to conduct meaningful studies addressing the FY17 PCRP Overarching Challenges and FY17 PCRP Focus Areas.

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

- **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.
- **Environment**
    - If applicable, to what degree the intellectual and material property plan is appropriate.

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 to the FY17 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

The transfer of a PCPRN Award to another institution is not allowed.

Unless otherwise restricted, changes in PI will be allowed at the discretion of the USAMRAA Grants Officer, provided that the intent of the award mechanism is met. Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

II.F.1.b. Pre-Award Meeting

At the Government's discretion, the PI and Clinical Study Coordinator or other personnel may be requested to participate in a pre-award meeting at the Government's expense.

II.F.2. Administrative and National Policy Requirements

Attendance is required at a 1-day meeting to be held in the National Capital Area each year for the purpose of reporting on progress.

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.

Biannual technical progress reports will be required, where PIs will be required to report on progress towards meeting the Performance Metrics as outlined in Section II.B, Award Information.

Each PI, whether Initiating or Partnering, must submit individual annual progress reports as required by his or her individual assistance agreement, as well as a final progress report.

In addition to written progress reports, Annual Award Charts will be required. For the PCPRNA 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 applications, the following administrative actions may occur:

II.H.2.a. Rejection

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

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.

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

- All associated (Initiating PI and Partnering PI) applications are not submitted by the deadline.

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."		
	DoD Military Budget Form(s): Upload as Attachment 7 with file name "MFBudget.pdf," as 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
CDE	Common Data Elements
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
EAB	External Advisory Board
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FY	Fiscal Year
H&E	Hematoxylin and Eosin
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
NCI	National Cancer Institute
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PCPRN	Prostate Cancer Pathology Resource Network
PCRP	Prostate Cancer Research Program
PI	Principal Investigator
PSA	Prostate-Specific Antigen
RDT&E	Research, Development, Test, and Evaluation
RM	Resource Manager
SAM	System for Award Management

SOPs	Standard operating procedures
SOW	Statement of Work
TNM	Tumor Node Metastasis
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code