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-20-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), September 10, 2020

- **Application Submission Deadline:** 11:59 p.m. ET, September 24, 2020

- **End of Application Verification Period:** 5:00 p.m. ET, September 29, 2020

- **Peer Review:** November 2020

- **Programmatic Review:** January 2021

This Program Announcement must be read in conjunction with the General Application Instructions, version 501. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

TABLE OF CONTENTS

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2020 (FY20) 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 FY19 totaled $1.82 billion. The FY20 appropriation is $110 million (M).

The PCRP seeks to promote highly innovative, groundbreaking research; high-impact research with near-term clinical relevance; the next generation of prostate cancer investigators through mentored research; and resources that will facilitate translational research.

The proposed research must be relevant to active duty Service members, Veterans, military beneficiaries, and/or the American public.

II.A.1. FY20 PCRP Overarching Challenges

The mission of the FY20 PCRP is to fund research that will lead to the elimination of death from prostate cancer and enhance the well-being of Service members, Veterans, and all the men and their families who are experiencing the impact of the disease. Within this context, the PCRP is interested in supporting research that addresses specific gaps in prostate cancer research and clinical care, with ***an emphasis on investing in research that will benefit patients diagnosed with lethal prostate cancer or improve quality of life for men diagnosed with this disease***. All applications are ***required*** to address one or more of the following FY20 PCRP Overarching Challenges:

- **Improve the quality of life for survivors of prostate cancer**

- **Develop treatments that improve outcomes for men with lethal prostate cancer**

  Applications must be directly relevant to ***lethal prostate cancer***, which includes patients with metastatic disease; treatment-resistant disease; oligo-metastases; neuroendocrine disease; high-risk localized or locoregional disease, etc.

- **Reduce lethal prostate cancer in people of African descent, Veterans, and high-risk or underserved populations**

    High-risk populations include, but are not limited to, people of African descent (including Caribbean Americans), genetically predisposed populations, Service members, and Veterans. Underserved populations include, but are not limited to, men with limited access to clinical care and resources (in both rural and urban settings), and sexual and/or gender minorities with, or at risk for, prostate cancer.

- **Define the biology of lethal prostate cancer to reduce death**

    Applications must be directly relevant to *lethal prostate cancer*, which includes patients with metastatic disease; treatment-resistant disease; oligo-metastases; neuroendocrine disease; high-risk localized or locoregional disease; etc. Applications *should not* focus on topics such as differentiation between low risk and intermediate risk prostate cancer.

II.B. Award Information

The FY20 PCRP Prostate Cancer Pathology Resource Network (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 (African Americans, African-descent, Veterans, etc.) and underserved (uninsured, rural communities, etc.) populations

- Active surveillance populations

- Longitudinal/sequential specimens

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

Applications should describe how the development of the Network biorepository will enable the prostate cancer research community to address the FY20 PCRP Overarching Challenges 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, one of which will also serve as the Coordinating Center. 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 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 (who will also be the Pathology Resource Site PI at the Coordinating Center) and two to four additional Pathology Resource Site PIs 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 their own award.

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

- **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), which will be identified from an annual survey of the prostate cancer research community.*** In addition, it is expected that at least one Pathology Resource Site will enable significant accrual of patient samples from populations that are disproportionately affected (African Americans, African-descent, Veterans, etc.) and underserved (uninsured, rural communities, etc.).

- **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.

- **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.

- **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.

- **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.

- **Organizational Structure:** The overall organizational structure of the PCPRN is *three to five* procurement Pathology Resource Sites, one of which will also serve as the Coordinating Center. The Coordinating Center organization, in addition to functioning as one of the Pathology Resource Sites, will serve as the nexus for Network information and planning, providing administrative, operational, and data management. The Coordinating Center PI will serve as the Scientific 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 Director** who will be responsible for the overall development and operation of consortium activities, including 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 Director 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 Development Command (USAMRDC) 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 USAMRDC 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.

- **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 PCRP plans to invest $9.6M in the Prostate Cancer Pathology Resource Network Award over a 3-year period. A total of $3.2M will be allocated from the FY20 budget to fund the first year of performance. Options will be included for continued performance in subsequent years with $3.2M expected from each of the FY21 and FY22 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 on receipt of sufficient Congressional appropriations to the PCRP in FY21 and FY22 and acceptable performance by the recipients.*** The anticipated direct costs budgeted for an FY20 Prostate Cancer Pathology Resource Network Award will not exceed **$2.0M per year** for a maximum of **$6.0M** for the entire 3-year performance period. Refer to [Section II.D.5, Funding Restrictions](), for detailed funding information.

Awards will be made no later than September 30, 2021. For additional information refer to [Section II.F.1, Federal Award Notices](#).

The CDMRP expects to allot approximately $3.2M of FY20 PCRP Congressional funds to fund the initial 12-month performance period for one Prostate Cancer Pathology Resource Network Award application. Funding of applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the Government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY20 funding opportunity will be funded with FY20 funds, which will expire for use on September 30, 2026.

The types of awards made under the Program Announcement will be assistance agreements. An assistance 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. The level of involvement on the part of the Department of Defense (DoD) during project performance is the key factor in determining whether to award 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), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, 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.

Use of DoD or Department of Veterans Affairs (VA) Resources: If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

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

Extramural Organization: An eligible non-DoD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, Federal Government organization other than the DoD, and research institutes.

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

USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

Each investigator may be named on only one FY20 PCRP PCPRN Award application as Initiating PI or Partnering PI.

PIs must be independent investigators with a faculty-level appointment (or equivalent) with access to the 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 https://orcid.org/.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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.

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:

- Pre-application content and forms must be accessed and submitted at electronic Biomedical Research Application Portal (eBRAP) eBRAP.org.

- Full application packages must be accessed and submitted at Grants.gov.

Intramural DoD Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.

- Full application packages must be accessed and submitted at eBRAP.org.

Note: Applications from an intramural DoD organization or from an extramural Federal Government organization may be submitted to Grants.gov through a research foundation.

II.D.1. Address to Request Application Package

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.

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* (eBRAP.org) and *full application* (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to Table 1. Full Application Guidelines).

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 full 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 submission deadline.

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

During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required 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 will delay 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 to request a change in designation.

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

The applicant organization and associated PIs 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 applicant must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

PIs with an ORCID identifier should enter that information in the appropriate field in the "My Profile" tab in the "Account Information" section of eBRAP.

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**

  Submission of application information includes assignment of primary and secondary research classification codes, which may be found at https://ebrap.org/eBRAP/public/Program.htm. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **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 Research & Related 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 Research & Related 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 applicants 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.

  FY20 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 the Pathology Resource Site PIs (Partnering PIs) in the Partnering PI section.

- **Tab 4 – Conflicts of Interest**

  List all individuals other than collaborators and key personnel who may have a conflict of interest in the review of the application (including those with whom the PI has a personal or professional relationship).

- **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

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 must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission.

Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the *same version* of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the "Apply For Grants" page of Grants.gov (https://www.grants.gov/web/grants/applicants/apply-for-grants.html) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

Do not password protect any files of the application package, including the Project Narrative.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-20-PCRP-PCPRNA from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-20-PCRP-PCPRNA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related 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 • Research & Related Subaward Budget Attachment(s) Form	**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

Extramural Submissions	Intramural DoD Submissions
	date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission. **Note:** If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID *prior to* the application submission deadline. *Do not password protect any files of the application package, including the Project Narrative.*	**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 next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. *Do not password protect any files of the application package, including the Project Narrative.*
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 may be modified *with the exception of the Project Narrative and Research & Related Budget Form*.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official and PIs will receive 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 may be modified *with the exception of the Project Narrative and Research & Related Budget Form*. Your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.

Extramural Submissions	Intramural DoD Submissions
Further Information	
Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission. 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 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 Research & Related 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 have 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. *It is important to include the attachment name as a header on each page of the attachment files.*

○ **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," [http://biospecimens.cancer.gov/global/pdfs/NCI_Best_Practices_060507.pdf] as applicable. All items should be addressed for both the Coordinating Center and Pathology Network Sites.

Personnel Experience and Expertise in Multi-Institutional Collaboration and Biorepository Development

– Describe each applicant's previous experience, accomplishments, and success in multi-institutional collaborations including past performance of a PCRP PCPRN Award, if applicable.

– Describe Coordinating Center PI's, Pathology Resource Site PIs', and other key personnel's expertise, experience, and accomplishments that will enable the successful development, administration, and fiscal management of a biorepository.

– Describe previous experience of the named Network Director and Pathology Resource Site Coordinators in coordinating Network activities across all Sites and expediting protocols through regulatory approval processes, and expediting the review, evaluation, selection, and prioritization of specimen distribution.

– Describe previous experience of the named Data Management Specialist and Data Quality Control Specialist in informatics, data management, and procedure implementation to enable successful data management and quality control within the Network.

– 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.

Organizational Structure: Describe the organizational structure that will enable the development and implementation of the biorepository at each institution, 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, including decision-making, allocation of resources, coordination of Network functions, and conflict resolution among all participating PIs and institutions.

– 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 submissions and approvals at participating Sites, including how any regulatory issues will be resolved.

– 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 one or more of the FY20 PCRP Overarching Challenges.

– 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 in order to provide sufficient oversight and guidance for the success of the biorepository.

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 commitment, support, resources, and facilities for the development of a biospecimen repository and its operation in the context of a cooperative network of organizations. Include evidence of the institution's track record of sharing biospecimens.

– Provide evidence of institutional commitment to allow specimens collected at Pathology Resource Sites to be shared with 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 disproportionately affected (African Americans, African-descent, Veterans, etc.) and underserved (uninsured, rural communities, etc.) populations.

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 Director** at the Coordinating Center who will be responsible for the overall development and operation of consortium activities, including interacting with a **named 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 biospecimen distribution to the prostate cancer research community that includes processing, evaluating, and prioritizing requests for biospecimens from Network members and other investigators, including potential restrictions governing

use of biospecimens by commercial entities. The plan should include a description of how operational capabilities could be streamlined or maximized to allow the network to scale up management operations.

– 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, including patients from disproportionately affected (African Americans, African-descent, Veterans, etc.) and underserved (uninsured, rural communities, etc.) 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.

Biospecimen Management, Quality Assurance, and Distribution: Describe the plans for biospecimen management, quality assurance, and distribution to support the PIs' capabilities in obtaining high-quality biospecimens; include the following key features:

– The model to be used for biospecimen collection, annotation, processing, storage, and distribution; include how CDEs 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. The plan should include clearly described benchmarks for effective utilization of the Network's resources that would be addressed through revised advertising/marketing strategies if not adequately met.

Informatics and Data Management: Describe the plan for data management, including a common informational (informatics) system to manage the biorepository resources and provide for ongoing data transfer, security, and integrity. The data management plan should include the following:

– Describe the common informational (informatics) 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. Research data that are collected and stored should include molecular data, digital images, and blood-based germline assessments generated by Network and non-Network investigators.

– 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, and ensure quality control and quality assurance.

- Describe the overall planned approach to data collection, management, and ongoing data transfers; include details regarding how security, confidentiality, and integrity will be maintained while providing appropriate access to the data.

- 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 of data between the Pathology Resource Sites, and between the Network and the prostate cancer research community, including all molecular data, digital images, blood-based germline assessments, and any other data derived from internal and external studies of the biorepository specimens.

- 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.

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 and plans for addressing associated regulatory issues.

- 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.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative 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 articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- Letters of Organizational Support: Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.

- Letters of Collaboration: Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- 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 biospecimens, datasets 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.

- Use of DoD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military populations and/or DoD resources or databases.

- Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

- ○ **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 (African Americans, African-descent, Veterans, etc.) and/or underserved (uninsured, rural communities, etc.) 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 time of submission. Leave Attachment 4 space blank.

- **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** The suggested Statement of Work (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 PCPRN 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.

  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. Detail the anticipated outcome(s)/product(s) generated in the short term that will be directly attributed to the development of the biorepository. Explain the anticipated long-term gains from the proposed project, including how the efforts of the biorepository will make a major impact on the field of prostate cancer research. Describe how the proposed project will enable investigators to conduct meaningful studies addressing the FY20 PCRP Overarching Challenges, and ultimately contribute to the goal of eliminating death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease.

  ○ **Attachment 7: Representations, if applicable (extramural submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

  ○ **Attachment 8: Suggested Collaborating DoD Military Facility Budget Format, if applicable: Upload as "MFBudget.pdf".** If a military facility (Military Health System facility, research laboratory, medical 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 a separate budget, using "Suggested Collaborating DoD Military Facility Budget Format," 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 & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

  To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 et seq.), the DoD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

Research & Related Personal Data: 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.

Research & Related Senior/Key Person Profile (Expanded): 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.

- ○ 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 (NIH) Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

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

- ○ Key Personnel Biographical Sketches (five-page limit each): Upload as "Biosketch_LastName.pdf".

  - – Include biographical sketches for Pathology Resource Site PIs, all co-investigators, Network Director, Pathology Resource Site Coordinator, 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.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

Budget Justification (no page limit): Upload as "BudgetJustification.pdf". The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PIs 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.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

  Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.7, for detailed information.

  - ○ **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

  - ○ **Intramural DoD Collaborator(s):** Complete the "Suggested Collaborating DoD Military Facility Budget Format" and upload to Grants.gov attachment form as Attachment 8. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DoD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

  Suggested DoD Military Budget Format: 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. *Note:* Applicants should complete a separate military budget using "Suggested Collaborating DoD Military Facility Budget Format" (available for download on the eBRAP "Funding Opportunities & Forms" web page [https://ebrap.org/eBRAP/public/Program.htm]) (Attachment 8) 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.8, 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 their full application package with that of the Initiating PI.

For each Partnering PI, the Initiating PI must identify if each Partnering PI will be named on 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 their contact information and mode of submission within eBRAP to ensure proper submission of their application.

The application submission process for each Partnering PI uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications**

  Attachments:

  - ○ **Attachment 5: Statement of Work (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 each Partnering PI should be noted for each task.

○ **Attachment 7: Representations (extramural submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

○ **Attachment 8: Suggested Collaborating DoD Military Facility Budget Format: Upload as "MFBudget.pdf".** Refer to the General Application Instructions, Section IV.A.4, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.

Research & Related Personal Data: 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.

Research & Related Senior/Key Person Profile (Expanded): 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.

○ PI Biographical Sketch (5-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 NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.

○ PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

○ Key Personnel Biographical Sketches (5-page limit each): Upload as "Biosketch_LastName.pdf".

– Include biographical sketches for all co-investigators, Pathology Resource Site Coordinator, and other key personnel.

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

Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section III.A.5, and for intramural submissions, refer to the General Application Instructions, Section IV.A.4, 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 or eBRAP application packages. The Research & Related Budget for each Partnering PI 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.6, and for intramural submissions (via eBRAP), refer to General Application Instructions, Section IV.A.5, 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.7, for detailed information.)

    ○ **Intramural DoD Collaborator(s):** Complete a separate DoD military budget, using "Suggested Collaborating DoD Military Facility Budget Format" (available for download on the eBRAP "Funding Opportunities & Forms" web page [https://ebrap.org/eBRAP/public/Program.htm]), and upload to Grants.gov attachment form as Attachment 8. (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

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

Applicant organizations and all sub-recipient 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 organization's Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at 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.

Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI): Through December 2020, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

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

For Both Extramural and Intramural Applicants: eBRAP allows an organization's representatives and PIs to view and modify the full application submissions associated with them. 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 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. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. 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 Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Extramural Submission: 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.

Intramural DoD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PIs will receive email notification of the 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. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

For All Submissions: Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

II.D.5. Funding Restrictions

The PCRP plans to invest a total of $9.6M in the FY20 PCRP PCPRN Award over a 3-year period. Approximately $3.2M will be allocated from the FY20 PCRP budget to fund the first year of performance. Options will be included for continued performance in subsequent years with $3.2M expected from each of the FY21 and FY22 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 FY21 and FY22 and acceptable performance by the recipient.*

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

The anticipated combined direct costs budgeted for the Initiating PI and each Partnering PI's applications will not exceed **$2.0M per year** for a maximum of **$6.0M** for the entire 3-year performance period. 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 **$6.0M** 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 each PI to attend a 1-day meeting held in the National Capital Area once 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 their individual budget.*

May be requested for (not all-inclusive):

- 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

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 funds 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.

Refer to the General Application Instructions, Section III.A.5, 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.5.***

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 applicants have demonstrated previous experience, accomplishments, and success in multi-institutional collaborations including past performance of a PCRP PCPRN Award, if applicable.

  ○ To what degree the previous experience of the named Network Director and Pathology Resource Site Coordinators is sufficient to coordinate Network activities across all Sites and expedite protocols through regulatory approval processes, and expedite the review, evaluation, selection, and prioritization of specimen distribution.

  ○ To what degree the named Data Management Specialist and Data Quality Control Specialist possess sufficient experience in informatics, data management, and procedure implementation to enable successful data management and quality control within the

Network.

- ○ Whether there are sufficient levels of effort for key personnel to enable 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 capabilities and strengths 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 plans for administration and day-to-day management of Network operations are appropriate with respect to decision-making, allocation of resources, coordination of Network functions, 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 and could be reasonably scaled up.

  - ○ 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 evaluate 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 timely publication and other public dissemination of data generated by the Network.

- ○ To what degree the proposed advertising/marketing plan for obtaining and distributing biospecimens to the prostate cancer research community will facilitate the success of the biorepository, and whether the benchmarks for effective utilization are adequate to help the Network revise the plan as needed.

- **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.

  - ○ Whether the plans for data sharing between the Pathology Resource Sites and with the prostate cancer research community, including all molecular data, digital images, blood-based germline assessments, and any other 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 through appropriate coordination and oversight of privacy and confidentiality of patient data.

  - ○ Whether the plans for data collection and management 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, tiered patient 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 (African Americans, African-descent, Veterans, etc.) and underserved (uninsured, rural communities, etc.) 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 FY20 PCRP Overarching Challenges.

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

- **Budget**

- ○ Whether the **direct** costs exceed the allowable direct costs as published in the Program Announcement.

- ○ Whether the budget is appropriate for the proposed research.

- **Environment**

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

- **Application Presentation**

- ○ To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers

- Relevance to the mission of the DHP and FY20 PCRP, as evidenced by the following:

- ○ Adherence to the intent of the award mechanism

- ○ Programmatic relevance to the FY20 PCRP Overarching Challenges

- ○ Program portfolio composition

- ○ Relative impact

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**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC, on behalf of the DHA and the OASD(HA). ***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 https://cdmrp.army.mil/about/2tierRevProcess. An information paper describing the funding recommendations and review process for the award mechanisms for the PCRP will be provided to the PIs and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring 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 and approval 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 and approval 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, as defined in 2 CFR 200.88, 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 organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization 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 (DoDGARs), Section 22.415.

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

All application review dates and times are indicated in <u>Section I, Overview of the Funding Opportunity</u>.

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 supported with FY20 funds are anticipated to be made no later than September 30, 2021. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

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

Pre-Award Costs: An institution of higher education, hospital, or other non-profit organization may, at its own risk and without the Government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Application Instructions, Section III.B.

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 document.**

Federal Government Organizations: Funding made 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 Manager/Task Area Manager/Comptroller or equivalent Business Official.

II.F.1.a. PI Changes and 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.

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

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

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

At the Government's discretion, the PIs and other key personnel may be requested to participate in a pre-award meeting at the Government's expense.

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, 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 latest [DoD R&D General Terms and Conditions](#); the [General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions](#); 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. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Annual progress reports as well as a final progress report will be required. Each PI, whether Initiating or Partnering, must submit individual annual progress reports as required by their individual assistance agreement, as well as a final progress report.

The Award Terms and Conditions will specify if more frequent reporting is required.

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 Representations (see General Application Instructions, Appendix 5, Section B).

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 501e. The Program Announcement numeric version code will match the General Application Instructions version code 501.

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.

- More than one application is received naming the same investigator as Initiating PI or Partnering PI. Only the first application received will be accepted; additional applications will be administratively rejected.

- 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 application:

- An FY20 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 FY20 PCRP Programmatic Panel members can be found at https://cdmrp.army.mil/pcrp/panels/panel20.*

- The application fails to conform to this Program Announcement description.

- 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 FY20, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval 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.

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

- Submission of the same research project to different funding opportunities within the same program and fiscal year.

II.H.2.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

II.H.3. Application Submission Checklist

Application Components	Action	Initiating PI Completed	Partnering PI Completed
SF424 Research & Related Application for Federal Assistance **(extramural submissions only)**	Complete form as instructed		
Summary (Tab 1) and Application Contacts (Tab 2) **(intramural submissions only)**	Complete 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"		
	Representations (extramural submissions only): Upload as Attachment 7 with file name "RequiredReps.pdf" if applicable		
	Suggested Collaborating DoD Military Facility Budget Format: Upload as Attachment 8 with file name "MFBudget.pdf" if applicable		
Research & Related Personal Data	Complete form as instructed		

Application Components	Action	Initiating PI Completed	Partnering PI Completed
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field		
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field		
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field		
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field		
Research & Related Budget **(extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field		
Budget **(intramural submissions only)**	Complete the Suggested DoD Military Budget Format, including justification		
Project/Performance Site Location(s) Form	Complete form as instructed		
Research & Related Subaward Budget Attachment(s) Form	Complete form as instructed		

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
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
DoDGARs	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
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
NCI	National Cancer Institute
NIH	National Institutes of Health
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PCRP	Prostate Cancer Research Program
PCPRN	Prostate Cancer Pathology Resource Network
PI	Principal Investigator
PSA	Prostate-Specific Antigen
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOPs	Standard Operating Procedures
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics

TNM	Tumor Node Metastasis
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs