Program Announcement for the Department of Defense
Defense Health Program

Prostate Cancer Research Program Clinical Consortium Award

Funding Opportunity Number: HT942525PCRPCCA

Pre-Application Due: August 11, 2025

Application Due: September 2, 2025

This program announcement must be read in conjunction with the General Application Instructions, version CD25_01.

Content

Before You Begin

- **Active SAM.gov, eBRAP.org, and Grants.gov registrations are required for application submission.** User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- **Read the funding opportunity announcement in the order it is written before beginning to prepare application materials.** It is the responsibility of the applicant to determine whether the proposed research meets the intent of the funding opportunity and that all parties meet eligibility requirements.

Who to Contact for Support

eBRAP Help Desk

301-682-5507
help@eBRAP.org

Questions regarding funding opportunity submission requirements, as well as technical assistance related to pre-application or intramural application submission.

Grants.gov Contact Center

800-518-4726
International: 1-606-545-5035
support@grants.gov

Questions regarding Grants.gov registration and Workspace.

This document uses internal links; you can go back to where you were by pressing Alt + left arrow key (Windows) or command + left arrow key (Macintosh) on your keyboard.

1. Basic Information About the Funding Opportunity

Summary: The fiscal year 2025 (FY25) Prostate Cancer Research Program (PCRP) Clinical Consortium Award (CCA) provides support to develop, maintain, and enhance the necessary collaborations and resources to rapidly execute phase 2 and/or phase 2-linked phase 1 (phase1/2) prostate cancer clinical trials. The primary intent of the PCRP Clinical Consortium Award is to combine the efforts of leading investigators across multiple institutions to expedite the clinical advancement of novel therapeutic interventions in prostate cancer to decrease the impact of the disease.

Distinctive Features:

- This award mechanism ***does not*** support the development of clinical protocols.
- **Coordinating Center:** This award mechanism supports one coordinating center, which will be responsible for development and maintenance of the consortium organizational structure, and also function as a Clinical Research Site.
- **Clinical Research Sites:** This award mechanism supports multiple clinical research sites, which will be responsible for clinical trial introduction and selection, patient accrual for consortium studies, data collection and timely submissions, meeting attendance, and adherence to the consortium's operating procedures.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $10.5 million (M) to fund approximately 1 Clinical Consortium Award – Coordinating Center application with a total cost cap of $10.5M. The maximum period of performance is 4 years. The CDMRP expects to allot approximately $22.0M to fund approximately 11 Clinical Consortium – Clinical Research Site applications with total cost caps of $2.0M. The maximum period of performance is 4 years. It is anticipated that awards made from this FY25 funding opportunity will be funded with FY25 funds, which will expire for use on September 30, 2031. Awards supported with FY25 funds will be made no later than September 30, 2026.

Submission and Review Dates and Times

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern Time (ET), August 11, 2025
- **Application Submission Deadline:** 11:59 p.m. ET, September 2, 2025
- **End of Application Verification Period:** 5:00 p.m. ET, September 4, 2025
- **Peer Review:** October 2025
- **Programmatic Review:** February 2026

Announcement Type: Modified

Funding Opportunity Number: HT942525PCRPCCA

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural organizations are eligible to apply, ***including foreign and domestic organizations, for-profit and nonprofit organizations, and public or private entities.***

Extramural Organization: An eligible non-Department of Defense (DOD) organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

2.1.2. Principal Investigator

Independent investigators with a faculty-level appointment (or equivalent) may be named as a Principal Investigator (PI).

Individuals affiliated with an eligible organization are eligible to be named as PI regardless of ethnicity, nationality, or citizenship status.

2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

2.3. Other

Awards are made to eligible ***organizations***, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

3. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP at the U.S. Army Medical Research and Development Command (USAMRDC) is the program office managing this FY25 funding opportunity as part of the PCRP. Congress initiated the PCRP in 1997 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY24 totaled $2.37 billion. The FY25 appropriation is $75M.

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 mission of the FY25 PCRP is to fund research that will eliminate death and suffering from prostate cancer and enhance the well-being of Service Members and their Families, Veterans, and all the patients and caregivers 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; therefore, applications are ***required*** to address one or more of the following FY25 PCRP overarching challenges:

- **Define the biology of prostate cancer progression to lethal prostate cancer to reduce death**
    - Applications must be directly related to high-risk, very high-risk, and metastatic prostate cancer. The FY25 PCRP also strongly encourages research involving patient-derived materials or specimens related to ongoing or completed clinical trials.
    - Refer to the National Comprehensive Cancer Network for risk assessment definitions (https://www.nccn.org/patients/guidelines/content/PDF/prostate-advanced-patient.pdf).
- **Develop new treatments or improve upon existing therapies to improve outcomes for patients with lethal prostate cancer**
    - Applications must be directly related to prostate cancer with a high risk of death, including high-risk localized disease, regional disease, and/or metastatic prostate cancer.
    - Treatments may address any stage in the continuum of care, including local therapies such as surgery or radiation designed to treat patients with a high risk of death from the disease. Proposed treatments are highly encouraged to consider preserving patient quality of life and not focus only on survival outcomes.
    - Applications should not focus on active surveillance, low-risk and intermediate-risk prostate cancer, and/or biochemical recurrence. Refer to the National Comprehensive Cancer Network for risk assessment definitions (https://www.nccn.org/patients/guidelines/content/PDF/prostate-advanced-patient.pdf).
- **Improve quality of life to enhance outcomes and overall health and wellness for those impacted by prostate cancer**

  Applications should aim to mitigate the impact of prostate cancer on the quality of life of the cancer survivor, their family, their caregivers, and their community with the goal of improving and enhancing quality of life and overall health and wellness. Studies should consider both short- and long-term quality-of-life outcomes. Areas of particular interest include:

- Biological basis of disease and treatment on quality of life
- The mental health of patients and their families/caregivers
- Identification of groups of patients and their families at high risk of quality-of-life detriments
- Implementation of factors or interventions that improve access to evidence-based care, quality-of-life outcomes, and overall health and wellness

- **Improve access to optimal care for all patients with prostate cancer**

  **Special emphasis on high-risk groups*

  - Applications must be directly relevant to better understanding and/or reduction of factors that impact a person, their family or their caregiver's ability to prevent, detect, manage, and survive prostate cancer.
  - Factors may include physical, mental or emotional health differences, as well as social and financial differences experienced primarily in populations at high-risk for prostate cancer, including Service Members and Veterans.

3.1. Intent of the Clinical Consortium Award

The FY25 PCRP Clinical Consortium Award provides the support to develop and enhance collaborations and resources necessary for a network of organizations to rapidly execute phase 2 or phase 2-linked phase 1 (phase 1/2) prostate cancer clinical trials. These trials will include investigations of high-impact, novel therapeutic agents or approaches for the management or treatment of prostate cancer relevant to the FY25 PCRP Overarching Challenges. Support from this award is directed toward consortium infrastructure needs rather than direct support of the research itself.

The Clinical Consortium Award combines the efforts of leading investigators to bring to market high-impact, novel therapeutic interventions that will ultimately and significantly decrease the impact of the disease. To facilitate global investigations, PIs from both U.S. and international institutions are encouraged to apply. ***Submissions from institutions with enhanced access to patients from high-risk and/or military populations (as described in the FY25 PCRP Overarching Challenges) are especially encouraged.***

The FY25 PCRP Clinical Consortium Award mechanism will be used to select and fund approximately 11 Clinical Research Sites and one Coordinating Center. ***In addition, the consortium will include two or more identified Affiliated Clinical Research Sites to be supported and managed by the Coordinating Center. Affiliated Clinical Research Sites should have enhanced access to patients from high-risk and/or military populations.***

3.1.1. Key Elements for the CCA

PIs will be required to indicate whether the institution is applying as either the Coordinating Center with a Clinical Research Site or a Clinical Research Site only. Institutions applying as the Coordinating Center, if not selected for funding, have the option to still be considered as a Clinical Research Site only. The Coordinating Center and Clinical Research Sites will be jointly responsible for proposing, selecting, and conducting phase 2 and phase 1/2 clinical trials focused on prostate cancer therapeutic interventions. Additional details regarding the structure of the consortium are described in detail below.

The Coordinating Center, in addition to functioning as a Clinical Research Site, will serve as the consortium information and planning nexus providing administrative, operational, and data management support services to participating Clinical Research Sites to implement consortium clinical trials in a timely manner. Responsibilities of the Coordinating Center will include the clinical trial selection process, protocol coordination, regulatory coordination, study management and monitoring, data collection, management and statistics, and intellectual/material property coordination. The Coordinating Center will also be responsible for preparing two clinical trials, with funding already secured, to be initiated by the consortium within the first three months of the performance period. ***All sites (Clinical Research Sites and the Coordinating Center) will be required to participate in at least one of these two initial clinical trials.***

Collectively, the Coordinating Center PI and Clinical Research Site PIs will constitute the Clinical Consortium Committee, which will collaboratively develop and maintain a procedure for the selection of clinical trials to be implemented within the consortium. ***A representative from the PCRP must be invited to meetings of the Clinical Consortium Committee, as well as any other formal meetings of the consortium.*** All sites will be responsible for working collaboratively to identify new clinical trials for implementation. Any site may serve as an entry point for clinical trials that originate from outside the consortium. The Coordinating Center will be responsible for facilitating this entire process.

- **Responsibilities of the Consortium Participants:** Procedures for the consortium, while proposed by the Coordinating Center, will be fully developed and agreed upon by all participants working collaboratively. All references to clinical trials in the outlined responsibilities are specific to phase 2 or phase 1/2 trials; phase 3 or higher clinical trials are not included.
    - **Coordinating Center:** Responsibilities specific to the Coordinating Center include:
        - Adherence to the responsibilities delineated below for a Clinical Research Site.
        - Coordination and facilitation of at least 12 clinical trials at any given time after the first 12 months of the performance period.
        - Development and execution of plans for the incorporation, support, and involvement of no fewer than two Affiliate Clinical Research Sites (of U.S. or international origin) intended to enhance the impact of the consortium by contributing unique patient populations to consortium trials, including those from high-risk and/or military populations (as described in the FY25 PCRP Overarching Challenges). The Coordinating Center will establish performance metrics for Affiliate Clinical Research Sites, which should emphasize higher accrual rates for the unique patient population(s) the site has enhanced access to. ***The government reserves the right to request the identification of alternative Affiliate Clinical Research Sites prior to award if those described in the application do not demonstrate sufficient access to identified patient populations.***
        - Development and maintenance of the consortium organizational structure.
        - Provision of at least two funded initial clinical trial protocols for implementation by the consortium within the first three months of the performance period.
        - Management of consortium-developed procedures for review, selection, and implementation of clinical trials proposed by or through consortium members.
        - Establishment and management of procedures to ensure compliance with the local Institutional Review Boards (IRBs) of all sites for the conduct of clinical trials and the protection of human subjects.

- Establishment and management of procedures for ensuring compliance with U.S. Food and Drug Administration (FDA) requirements for investigational agents, devices, and procedures.
- Establishment and management of a communications plan and an ongoing communications system between the Coordinating Center and Clinical Research Sites.
- Management of consortium-developed quality assurance and quality control mechanisms for study monitoring, including:
  - Real-time and remote monitoring program
  - Management plan for the handling, distribution, analysis, and banking of specimens and/or imaging products generated from consortium studies necessary for the conduct and analyses of clinical trials during the performance period of the award
  - Registration, tracking, and reporting of participant accrual
  - Timely medical review and assessment of participant data
  - Rapid reporting and communication of adverse events
  - Interim evaluation and consideration of measures of outcome
- Management of consortium-developed comprehensive data collection and data management systems that addresses the needs of all sites in terms of access to data, data security, and data integrity measures.
- Development of statistical plans for all consortium clinical trials.
- Management of consortium-developed intellectual and material property issues among institutions participating in the consortium.
- Management of consortium-developed procedures for the timely publication of major findings and other public dissemination of data.
- Development and execution of a plan for financial sustainability leveraging collaborations, industry sponsors, and/or other funding opportunities to allow consortium activities to continue beyond the award period of performance.
- Presentation of written and/or oral briefings to the PCRP Programmatic Panel and USAMRDC staff at one-day meetings typically held virtually and/or in the National Capitol Area.

- **Clinical Research Sites:** The responsibilities of each site include:
  - Full participation in the consortium, including but not limited to, clinical trial introduction and selection, patient accrual for consortium studies (to include accrual from high-risk and/or military populations), data collection and timely submissions, meeting attendance, and adherence to the consortium's operating procedures.
  - Presentation of at least two clinical trials for the consortium's consideration per year. ***For the Coordinating Center, this requirement is in addition to the initial two clinical trials required at the beginning of the award.***
  - Meeting minimum accrual requirements of 25 patients per year, either independently or in partnership with other non-consortium institutions. At least 20% of these patients must be contributions to trials from other consortium sites, and at least 5% of all accrued patients at each site must be from high-risk and/or military populations.

  - Provision for a Clinical Research Coordinator who will interact with the Clinical Research Coordinators of other Clinical Research Sites and the Supervising Clinical Research Coordinator of the Coordinating Center to expedite and guide clinical protocols through the regulatory approval processes and to coordinate patient accrual and study activities across sites.
  - Implementation of the consortium's core data collection methodology and strategies.
  - Compliance with consortium-developed quality assurance and quality control procedures, as appropriate, including:
    - Participation in a monitoring program to be managed by the Coordinating Center.
    - Implementation of the consortium-developed management plan for acquisition, delivery, and storage of biological samples and study data.
    - Submission of appropriate data and materials to allow for verification and review of protocol-related procedures, for example, pathology, imaging techniques, surgical methods, and therapeutic use.
  - Implementation of procedures established by the Coordinating Center for ensuring compliance with FDA requirements for investigational agents, as appropriate.
  - Implementation of procedures established by the Coordinating Center to meet the local IRB requirements for the conduct of clinical trials and the protection of human subjects.
  - Serving as a resource for the conduct of protocol-specified laboratory projects (such as tumor biology studies).
  - Participation in consortium-developed procedures for the timely publication of major findings.
  - Participation in consortium-developed procedures for resolving intellectual and material property issues among institutions participating in the consortium.
  - Submission of annual written progress reports, a final written comprehensive report, and any other reports required by the government to be outlined in the assistance agreement.

- **Performance Metrics:** The Clinical Consortium Award recipients will be accountable to the following performance metrics to be clearly disclosed through annual technical reporting. All references to clinical trials in the outlined responsibilities are specific to phase 2 or phase 1/2 trials; phase 3 or higher clinical trials are not included.
  - **Metrics for Coordinating Center Performance:**
    - Completion of at least four trials in the initial 12-month period of the award period of performance.
    - Maintain a portfolio of at least 12 open trials at any given time after the first 12 months of the period of performance.
    - Successfully move agents for at least 20% of consortium trials forward for additional testing (e.g., phase 3), which ultimately have the potential to change clinical practice. **Note:** The Clinical Consortium Award is not intended to support the conduct of clinical trials that test the next logical iteration of an existing treatment.
    - Enrollment of at least 5% of patients from high-risk and/or military populations (as described in the FY25 PCRP Overarching Challenges) in consortium trials overall.

- **Metrics for Clinical Research Site Performance:**
  - Accrual of at least 25 patients per year to consortium trials, either independently or in partnership with other non-consortium institutions. At least 20% of these patients must be contributions to trials from other consortium sites.
  - Participation in a minimum of eight trials initiated by other consortium sites over four years.
  - Presentation of at least two trials per year or eight trials over four years to the consortium for consideration.
  - Accrual of at least 5% of patients from high-risk and/or military populations (as described in the FY25 PCRP Overarching Challenges).
  - Timely submission of quality data as outlined by the Coordinating Center.

- **Plan for Financial Sustainability:** It is expected that the collaborations and infrastructure developed under the Clinical Consortium Award will continue past the period of performance on this award. Coordinating Center applications must include a plan for financial sustainability that leverages collaborations, industry sponsors, and/or other funding opportunities to allow consortium activities to continue beyond the award period of performance.
- **Past Performance *(if applicable)*:** Applications from institutions that have previously received a PCRP Clinical Consortium Award must include a description of the past performance of the award, including compliance with the metrics of the previous award as well as other individual contributions made to consortium activities. If past performance was directly affected by a significant event (e.g., natural disaster), describe its impact on performance metrics and how those issues will be resolved or mitigated to increase performance for the new award.

3.1.2. Other Important Considerations for the CCA

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. An ***intervention*** includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

(1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease; (b) diagnostic or detection studies (e.g., biomarker or imaging); (c) health disparity studies; and (d) development of new technologies.

(2) Epidemiologic and behavioral studies that do ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.

(3) Outcomes research and health services research that do not fit under the definition of clinical trial.

Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

Investigators are strongly encouraged to incorporate the following components into their study design, where appropriate, in order to maximize the potential impact of the proposed research project: authentication of proposed cell lines; statistical rigor of preclinical animal experiments; and incorporation of experiments to assess clinical relevance and translatability of findings. Studies utilizing data derived from large patient studies that include long-term health records, biospecimen repositories, and pre-existing research and apply state-of-the-art genomic and/or proteomic analysis, bioinformatics, and/or mathematical models to such data are also encouraged. Investigators are highly encouraged to provide a letter of support indicating access to and the availability of any resources required to support the study.

The proposed research must be relevant to Service Members, Veterans, military beneficiaries, and/or the American public. Applications from investigators within the DOD and applications involving multidisciplinary collaborations among academia, industry, the DOD, the U.S. Department of Veterans Affairs (VA), and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. If the proposed research relies on access to unique 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.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research. The standards are described in SC Landis et al., “A call for transparent reporting to optimize the predictive value of preclinical research,” *Nature* 490 (2012):187-191, https://doi.org/10.1038/nature11556. While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies.

3.2. CDMRP-wide Encouragements

The following encouragements are broadly applicable across many CDMRP programs, including the PCRP. Investigators are encouraged to consider addressing these areas in their applications if doing so is appropriate for their line of research and meets the intent of this funding opportunity.

A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY25 PCRP priorities.

Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of Service Members and their Families is encouraged. Such research could improve diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

3.3. Funding Instrument

The types of awards made under the program announcement will be assistance agreements. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of CDMRP during the project's period of performance is the key factor in determining whether to award a grant or cooperative agreement. If "no substantial involvement" on the part of CDMRP is anticipated, a grant will be made (31 USC 6304). Conversely, if "substantial involvement" on the part of CDMRP is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement means that, after award, CDMRP staff will assist, guide, coordinate, or participate in project activities including but not limited to:

- Collaboration 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.

3.4. Funding Details

Coordinating Center

Period of Performance: The maximum period of performance is **4** years.

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **$10.5M**. 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.

Funds requested are for all Coordinating Center functions, administrative and clinical (i.e., Clinical Research Site functions), as well as for the required support of two or more Affiliate Clinical Research Sites as described in this program announcement.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.

Cost sharing and utilization of other funding sources are encouraged.

Clinical Research Sites

Period of Performance: The period of performance is **4** years.

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **$2.0M**. 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.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.

The appropriateness of the budget for the proposed research will be assessed during peer review.

Direct Cost Restrictions: For this award mechanism, the **Coordinating Center** direct costs:

Must be requested for:

- Support for ***each*** of the identified Affiliate Clinical Research Sites, as described in this program announcement, at no less than **$250,000 per site per year ($500,000 per year, total of $2M)**.
- Costs associated with meetings described in Section 8.3. Additional Requirements.

May be requested for (not all-inclusive):

- Salary support for personnel needed to meet the goals of the consortium, such as the PI, Supervising Clinical Research Coordinator, Administrative Assistant(s), Research Nurse(s), Statistician(s), Database Manager, and Informatics Manager.
- Consortium-related meetings, teleconferences, and travel among participating investigators.
- Database generation, software development, and website design.
- Purchase of computers, specialized software, and specialized software licenses pertinent to Coordinating Center-specific responsibilities for use at participating institutions.
- Costs related to establishing financial sustainability (e.g., fees for legal consultation).
- Other costs directly associated with planning and developing the consortium collaborations and resources.
- Costs for two investigators to travel to two scientific/technical meetings per year in addition to the required meeting described in Section 8.3. Additional Requirements. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY25 PCRP Clinical Consortium Award.

The **Clinical Research Sites** direct costs:

May be requested for (not all-inclusive):

- Salary support for personnel needed to meet the goals of the consortium such as the PI, Clinical Research Coordinator, Research Nurse, and Data/Informatics Coordinator.
- Consortium-related meetings, teleconferences, and travel among participating institutions
- Computers and general software required to participate in the consortium.
- Other costs directly associated with planning and developing the consortium.
- Costs for up to two investigators to travel to up to two scientific/technical meetings per year. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY25 PCRP Clinical Consortium Award.

4. Application Contents and Format

4.1. Application Overview

Application submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP) and a ***full application*** submitted through eBRAP or Grants.gov. Depending on the submission portal, certain aspects of the application will differ.

Intramural DOD organizations submitting a full application should follow instructions for submission through eBRAP.

Extramural organizations submitting a full application must follow instructions for submission through Grants.gov.

4.2. Step 1: Pre-Application Components

Pre-application submissions must include the following components.

Letter of Intent (one-page limit): Provide a brief description of the research to be conducted. Include FY25 PCRP Overarching Challenge under which the application will be submitted.

4.3. Step 2: Full Application Components

Each application submission must include the completed full application package for this program announcement. See Appendix 1 for a checklist of the full application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(a), for detailed information.

IMPORTANT: When completing the SF424 R&R, enter the eBRAP log number assigned during pre-application submission into Block 4a – Federal Identifier.

(b) Attachments:

Each attachment of 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 2.

- **Attachment 1: Project Narrative (60-page limit for a Coordinating Center plus Clinical Research Site application; 20-page limit for a Clinical Research Site application): 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 (uniform resource locators) that provide additional information that expands 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.

  - **Coordinating Center (40-page limit):** The application should clearly articulate the ability of PI's group to serve as the consortium Coordinating Center and support the design and conduct of consortium clinical trials.

Describe the qualifications of the group and plans for the development of key features of the consortium Coordinating Center using the following general outline:

- **Commitment to and Experience in Multidisciplinary and Multi-Institutional Prostate Cancer Clinical Research:** Describe previous experience and accomplishments related to the design, administration, and fiscal management of multi-institutional prostate cancer clinical trials, with particular emphasis on phase 2 trials of high-impact, novel therapeutic agents or approaches for the management or treatment of prostate cancer. Describe previous experience with establishing communications systems and data management resources for multi-institutional projects. Reference relevant publications and submit reprints with the application. If the institution is a previous recipient of a PCRP Clinical Consortium Award, whether as Coordinating Center or Clinical Research Site, a description of the past performance of that award must be included.
- **Institutional Resources:** Provide evidence of institutional commitment to provide the necessary resources needed to develop and support standardized data collection, data management and analysis, and data security and integrity for the consortium participants.
- **Consortium Organizational Structure:** Provide a detailed description of the overall consortium organization, plans for ongoing communications, procedures for transference of funds, and standardized operating procedures for selection and implementation of clinical trials. The organizational structure should include the following key features:
  - Coordinating Center for administration and day-to-day management of consortium operations; developing the clinical trial selection process, protocol coordination; regulatory coordination; study management and monitoring; data collection, management, and statistics; intellectual/material property coordination; and performance as a Clinical Research Site.
  - Clinical Research Sites for conceiving, developing, and conducting clinical trials in prostate cancer, as well as serving as entry points for clinical trials from outside the consortium.
  - Clinical Consortium Committee composed of the PIs from the Coordinating Center and Clinical Research Sites, for the clinical trial selection process and for the continual development and operation of the consortium. A representative from the USAMRDC is to be invited to all official meetings for the Clinical Consortium Committee.
  - Plans for ongoing communications among Clinical Research Sites and between Clinical Research Sites and the Coordinating Center that will enable them to function as an integrated unit; plans should address methods for information distribution within the consortium, and how information technologies will be used to (1) facilitate routine multi-institutional communication and (2) provide ongoing communication and data sharing.
- **Affiliate Clinical Research Sites:** Identify the two institutions that are proposed to be incorporated into the consortium as Affiliate Clinical Research Sites and provide the rationale for their selection. Describe the plan for supporting the affiliate sites and incorporating them into consortium activities. Describe the available prostate cancer patient population (including size, age range, and clinical manifestations) at the identified sites, with emphasis on patients from

high-risk and/or military populations. Provide evidence of each site's prior success in recruiting patients for clinical trials, emphasizing any unique populations, and provide examples of prior successful multi-center clinical trial collaborations. Outline the performance metrics the Affiliate Clinical Research Sites will be expected to achieve, with an emphasis on higher accrual rates for the unique patient population(s) the site has enhanced access to.

- **Clinical Trials Implementation:** Describe plans for coordinating the submission, review, selection, and implementation of clinical trials within the consortium.
  - Outline plans for coordinating IRB submissions and approvals at participating sites.
  - Outline plans for developing procedures to ensure compliance with FDA requirements for investigational agents, as appropriate.
- **Study Management and Monitoring:** Describe plans for ongoing communication among all institutions participating in the consortium.
  - Include a **named** Supervising Clinical Research Coordinator; describe how their prior experience will support their ability to interact with and oversee the Clinical Research Coordinators located at other consortium sites in order to guide clinical protocols through the regulatory approval processes, coordinate participant accrual, and coordinate study activities across sites.
  - Outline procedures for quality assurance, quality control, and study monitoring.
  - Describe plans for the development of methods for the handling, distribution, analysis, banking, and security of specimens and/or imaging products generated from consortium-sponsored studies.
- **Data Management:** Outline a strategy for the development and implementation of a comprehensive data management and statistical analysis plan that will provide access to data, data security, and data integrity, including:
  - Descriptions of the overall approach to data collection and management.
  - A statistical plan that includes methods to monitor quality and consistency of data collection and methods to measure outcomes.
  - A plan for ongoing data transfer.
  - Data security and integrity measures.
- **Publication and Data Dissemination:** Describe plans for ensuring rapid publication and other public dissemination of data; address potential privacy issues of study participants.
- **Fiscal Administration:** Describe previous experience with acquiring funding for clinical trials, and with the financial management of multi-institutional clinical research studies. Outline a detailed strategy for achieving financial sustainability that leverages collaborations, industry sponsors, and/or other funding opportunities to allow consortium activities to continue beyond the award period of performance.
- **Two Initial Clinical Trials: (Nested 10-page limit within the previously stated 40-page limit; Start section on a new page)** Provide brief descriptions of two currently funded phase 2 or phase 1/2 prostate cancer clinical trials proposed to

be implemented by the consortium within the first three months of the award period. It is expected that most, if not all, of the patients for these studies will be accrued from within the consortium. Therefore, the two initial clinical trials must be ready to initiate patient accrual just prior to or at the initiation of the award, as demonstrated by the proposed timelines and regulatory and funding status for each trial requested below.

Include the following information for each of the two proposed clinical trials:

- **Clinical Trial Title:** Provide the title of each clinical trial.
- **Phase:** Designate the clinical trial as phase 1/2 or 2.
- **Personnel:** List the names of all personnel (including the PI) who will have significant involvement in the clinical trials; include their practice license(s) (e.g., M.D. or R.N.), highest degree(s), job title(s), and employing institution(s). Describe any relevant expertise the research team has in conducting and completing prostate cancer clinical trials.
- **Location of Study:** List all centers, clinics, or laboratories where the studies are to be conducted; include details as to how consortium Clinical Research Sites will be integrated into these trials.
- **Background:** Describe the rationale for conducting the study, as well as the study's relevance and applicability of findings; include descriptions of preliminary studies, phase 1 results, or other findings.
- **Objectives:** Describe the purpose, goals, and endpoint of the study.
- **Drug or Device:** Describe the drugs or devices to be used in the studies; describe how they meet the mechanism intent of supporting investigation of high-impact, novel therapeutic agents or approaches for the management or treatment of prostate cancer. Include Investigational New Drug (IND)/Investigational Device Exemption (IDE) numbers, sponsors, and sources, if applicable. Describe the procedures that will ensure compliance with FDA regulations for investigational agents.
- **Study Population:** Describe the target population and the proposed sample size and provide patient accrual rate requirements. Describe the strategy for the inclusion of women and minorities in the clinical trial appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex, racial, and ethnic group, and an accompanying rationale for the selection of subjects, if applicable.
- **Protocol Design:** Describe the type of study to be performed (prospective, retrospective, randomized, controlled, etc.) and outline the proposed methodology. Include a description of the proposed timelines for the study, emphasizing points that demonstrate increased efficiency of the study as a result of consortium participation.
- **Funding and IRB Approval Status:** Provide evidence of funding status of the initial clinical trial(s); describe the status of IRB approval for the initial clinical trial(s), including plans for the coordination of IRB submissions and approvals at participating sites.

- **Impact:** Describe anticipated outcomes of the proposed study and the potential impact of the intervention or device, if successful, in addressing the FY25 PCRP Overarching Challenges and on prostate cancer patient care.

– **All Sites (Coordinating Center and Clinical Research Sites) (20-page limit):** The application should clearly articulate the qualifications of the research team and institution to support their ability to successfully integrate into the consortium as a Clinical Research Site and be a contributing member.

Provide evidence that the research team and institution fulfill each of the following criteria for participation in the consortium:

- **Commitment to and Experience in Prostate Cancer Clinical Research**

  If the institution is a previous recipient of an FY21 PCRP Clinical Consortium Award, whether as Coordinating Center or Clinical Research Site, a description of the performance of that award must be included, including performance related to the previous award metrics, and a description of the individual contribution(s) of the institution to consortium activities. If past performance was directly affected by a significant event (e.g., natural disaster), describe its impact on performance metrics and how those issues will be resolved or mitigated to increase performance for the new award.

  - Describe the PI's commitment to prostate cancer clinical research, which may include levels of effort, funding, and interactions with consumer advocacy groups.
  - Describe the experience of the PI and other key members of the research team in conducting collaborative, multi-institutional clinical trials that demonstrate willingness and ability to function in the consortium.
  - Describe the research team's ability and experience to contribute substantially to the design and conduct of consortium clinical trials. Describe specific areas of clinical research interest, such as novel drugs, combinatorial therapy schedules, surgical interventions, imaging techniques, and immunotherapies; explain the relevance and potential impact on the FY25 PCRP Overarching Challenges. Include overall scope of program and demonstration of integration of basic and/or correlative science into the program.
  - Provide details of ongoing or completed prostate cancer-relevant clinical trials, particularly phase 2 clinical trials, with an emphasis on clinical trials that might be brought into the consortium. Reference relevant publications and submit reprints with the application.
  - Describe procedures for ensuring compliance with FDA requirements for investigational agents.
  - Provide evidence of willingness to resolve intellectual and material property issues.

- **Consortium Resources**

  - Include a **named** institutional Clinical Research Coordinator who will interact with the Clinical Research Coordinators at other consortium Clinical Research Sites and the Supervising Clinical Research Coordinator at the Coordinating Center to guide clinical protocols through the regulatory

approval processes, coordinate participant accrual, and coordinate study activities across sites. Describe the relevant experience of the named Clinical Research Coordinator to support their ability to fill this role.

- ❖ Describe the available prostate cancer patient population(s) (including size, age range, and clinical manifestations) and provide evidence of ability to accrue prostate cancer patients into consortium-sponsored studies. Include documentation of access to and ability to recruit patients from high-risk and/or military populations.
- ❖ Provide evidence of success in recruiting patients for clinical trials, and examples of prior successful multi-center clinical trial collaborations.

▪ **Institutional Resources**

- ❖ Provide evidence of expertise in clinical trials within the applicant institution and describe experience in the development and conduct of prostate cancer clinical trials; as appropriate, describe any additional multidisciplinary clinical and/or laboratory expertise that could serve as the basis for the development of clinical trials by the consortium.
- ❖ Describe the resources and expertise available for the collection and processing of specimens from consortium-sponsored studies.
- ❖ Describe the resources and expertise for data management and maintenance of data security/confidentiality.
- ❖ Provide evidence of institutional commitment to facilitating collaborations and to providing facilities and resources in the conduct of consortium operations; and describe any unique resources that may be of benefit to the consortium.

If the proposed research involves access to military and/or VA patient populations and/or DOD or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Also include a plan for obtaining any required data sharing, memorandum of understanding, or other agreements required to access and publish data. Refer to the General Application Instructions, Appendix 4, for additional considerations.

○ **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. 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.
- **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 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 individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOD collaborator(s) and/or access to military populations, databases, or DOD resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or individual designated by the VA Facility Director(s), confirming access to VA patients, resources, and/or VA research space.
- **Intellectual and Material Property Plan:** 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.
- **Clinical Trial Funding and Approval Documentation *(Coordinating Center applications only)*:** Provide documentation of funding and IRB approval status for the two initial clinical trials.

- **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.*** Use only characters available on a standard QWERTY keyboard; spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

  Describe the proposed consortium or, for Clinical Research Site applications, specific participation in the consortium including the following elements:

  - **Background:** Present the ideas and reasoning behind the proposed effort.
  - **Hypothesis/Objective(s):** State the objectives to be achieved. Provide evidence that supports the feasibility.
  - **Specific Aims:** State the specific aims.
  - **Study Design:** Briefly describe the types of clinical trials to be proposed for conduct by the consortium.

- **Clinical Impact:** Briefly describe how the proposed consortium, or participation in the consortium, may lead to a major impact on prostate cancer clinical management.
- **Relevance to Military Health:** Briefly describe how the proposed research is relevant to Service Members, Veterans, and/or their Families.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers and addresses issues of particular interest to the affected community. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard; spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

  The lay abstract is required for Coordinating Center applicants only. Lay abstracts should address the points outlined below ***in a manner that will be readily understood by readers without a background in science or medicine.*** Avoid overuse of scientific jargon, acronyms, and abbreviations.

  - Describe the objectives and rationale for the proposed consortium.
  - Describe the ultimate applicability of the research.
  - What patient population(s) will the research help, and how will it help them?
  - What are the potential clinical applications, benefits, and risks of the anticipated outcomes?
  - What is the projected time it may take to achieve an impact on the standard of care for prostate cancer?
  - What are the likely contributions of this study to advancing the field of prostate cancer research and patient care?
  - How is the proposed research relevant to Service Members, Veterans, and/or their Families?

- **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the "Suggested SOW Format".

  For the Clinical Consortium Award, refer to "Example: Assembling a Generic Statement of Work" for guidance on preparing the SOW.

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** Explain in detail the anticipated impact of the applicant's participation in the consortium, as follows:

  Describe the Short-Term Impact: Explain how the research team's areas of clinical research interest will support the presentation of clinical trials to evaluate high-impact, novel therapeutic agents or approaches for the management or treatment of prostate cancer. Detail the anticipated outcomes from the institution's participation in consortium-led clinical trials, including the potential impact the institution is expected to have in recruiting patients from high-risk and/or military populations to consortium-led studies. Explain how these results/outcome(s)/product(s) will have the potential to impact the FY25 PCRP Overarching Challenges.

  Describe the Long-Term Impact: Explain the long-term gains from the research team's contributions to the consortium, including how the outcomes or products will ultimately contribute to the elimination of death and suffering from prostate cancer and enhancing well-being of Service Members and their Families, Veterans, and all the patients and

caregivers who are experiencing the impact of the disease.

Relevance to Military Health: Briefly describe how the proposed research is relevant to Service Members, Veterans, and/or their Families.

- **Attachment 7: Data and Research Resource Sharing Plan (one-page limit): Upload as "Sharing.pdf".** Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe how data and resources generated during the period of performance will be shared with the research community and other affected communities. Include the name of the repository(ies) where scientific data and resources arising from the proposed clinical trial will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP's Policy on Data & Resources Sharing for more information about CDMRP's expectations for making data and research resources publicly available.

  Note: In preparing requested budgets, applicants may include anticipated costs associated with data and research resource sharing (i.e., making a large dataset available to the public or developing an important resource for the scientific community).

- **Attachment 8: Inclusion of Women and Minorities (six-page limit): Upload as "Inclusion.pdf". (*Attachment 8 is only required for Coordinating Center applications).*** For each of the initial clinical trials described in the application, provide anticipated enrollment tables for the inclusion of women and minorities using the "Public Health Service (PHS) Inclusion Enrollment Report", a three-page fillable PDF form, that can be downloaded from eBRAP. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

- **Attachment 9: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the "Required Representations" document that is available on eBRAP. For more information, see the General Application Instructions, Appendix 8, Section B, Representations.

- **Attachment 10: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the "Suggested Intragovernmental/Intramural Budget" form that is available for download on eBRAP. Refer to the General Application Instructions, Section V.B.(c), for instructions and considerations.

(c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).

(d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and senior/key person's current/pending support information must be attached to

the individual's profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.

- **Biographical Sketch:** Upload as "Biosketch_LastName.pdf".

  The CDMRP staff and reviewers use biosketches to evaluate whether research teams are equipped with the expertise necessary to carry out the proposed research.

  Biosketches must conform to the federal-wide Biographical Sketch Common Form. To prepare their biosketch attachments, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for the National Institutes of Health (NIH) or the U.S. National Science Foundation (NSF).

- **Current/Pending Support:** Upload as "Support_LastName.pdf".

  Current and pending (other) support information are used to assess the capacity or any conflicts of commitment that may impact the ability of the individual to carry out the research effort as proposed. The information also helps to assess any potential scientific and budgetary overlap/duplication with the project being proposed.

  Current and pending support documentation must conform to the federal wide format. To prepare their Current and Pending Support form, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for NIH or NSF.

(e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).

- **Budget Justification (no page limit):** For instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c), Section L; for eBRAP submissions, refer to General Application Instructions, Section V.B.(c), Budget Justification Instructions.

(f) Project/Performance Site Location(s) Form: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov Submissions only)*: Refer to the General Application Instructions, Section IV.C.(e), for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload it through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward. Combine them into a single document, then upload the file to Grants.gov as an attachment named "IGBudget.pdf".

4.4. Other Application Elements

- The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942525PCRPCCA from Grants.gov or eBRAP, depending on which submission portal will be used.

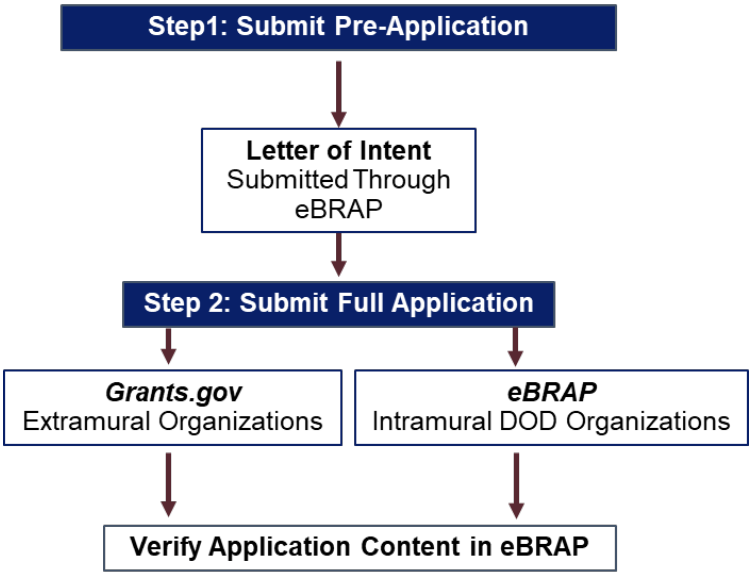
5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), SAM.gov, and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the unique entity identifier (UEI) generated by the SAM in applications to this funding opportunity and maintain an active registration in the SAM at all times during which it has an active Federal award or an application under consideration. More information regarding SAM registration can be found in the General Application Instructions, Section IV.A.

5.3. Submission Instructions

The CDMRP uses two portal systems to accept pre- and full application submissions.

Application Submission Workflow



5.3.1. Pre-Application Submission

All pre-application components must be submitted by the PI through eBRAP.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, 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 eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

When starting the pre-application, applicants will be asked to select a "Mechanism Option". Be sure to select the correct option appropriate to your pre-application:

Application Includes:	Select Option:
Coordinating Center	Clinical Consortium Award – Coordinating Center
Clinical Research Site	Clinical Consortium Award – Clinical Research Site

Refer to the General Application Instructions, Section III.A, for considerations and detailed instructions regarding pre-application submission.

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding Grants.gov submissions.

eBRAP Submissions: Only intramural DOD organizations may submit full applications through eBRAP. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding eBRAP submissions.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure the proper ordering as specified in the program announcement. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted through the appropriate portal prior to the full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in this program announcement.

There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant.***

All submission dates and times are indicated in Section 1, Basic Information above.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

6. Application Review Information

6.1. Application Compliance Review

Submitting applications that 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).

While it is allowable to propose similar research projects to different programs within CDMRP or to other organizations, duplication of funding or accepting funding from more than one source for the same research is prohibited. See the CDMRP's full position on research duplication.

Including classified research data within the application and/or proposing research that may produce classified outcomes or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

Members of the FY25 PCRP Programmatic Panel should not be involved in any pre-application or full application including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic panel members ***may*** provide letters to confirm PI eligibility and access to laboratory space, equipment, and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). ***A list of the FY25 PCRP Programmatic Panel members can be found on the CDMRP website.***

Additional restrictions and associated administrative responses are outlined in Section 9.2, Administrative Actions.

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

Pre-applications submitted to this funding opportunity are used for program planning purposes only (e.g., reviewer recruitment) and will not be screened.

6.2.2. Peer Review Criteria

To determine technical merit, all applications will be individually evaluated according to the following **scored criteria**:

- **Coordinating Center *(to be reviewed in addition to the Clinical Research Sites criteria below)*:** All Coordinating Center applications will be evaluated according to the following criteria. Of these, Personnel, Consortium Components, and Study and Data Management are ***equally the most important***, with the remaining criteria listed in decreasing order of importance.
    - **Personnel**
        - How well the PI or other key personnel have demonstrated appropriate expertise in prostate cancer and in the design and administration of multi-institutional prostate cancer clinical trials.

- Whether the PI and key personnel have previous success in acquiring funding for clinical trials.
- Whether the Supervising Clinical Research Coordinator, who will interact with all Clinical Research Coordinators, possesses the appropriate expertise to guide clinical protocols through the regulatory approval process, coordinate participant accrual, and coordinate study activities across sites.

- **Consortium Components**
  - Whether the application includes all required components to develop the Consortium Organizational Structure (e.g., Clinical Consortium Committee, Coordinating Center, and Clinical Research Sites, including Affiliate Clinical Research Sites).
  - How well the components as proposed will function as an integrated unit.
  - To what degree the identified Affiliate Clinical Research Sites will be able to function in the consortium as demonstrated by prior multi-center clinical trial collaborations.
  - Whether the identified Affiliate Clinical Research Sites have access to unique patient populations (high-risk and/or military populations with prostate cancer) that will enhance the consortium's trials, and whether they have demonstrated prior success with recruiting the available patient populations for clinical trials that will enable them to achieve the performance metrics outlined by the Coordinating Center.
- **Study and Data Management**
  - How the strategies for the development and implementation of data management and statistical plans will provide access to data, data security, and data integrity.
  - Whether there is an outline of an appropriate study management plan, including plans for ongoing communication, quality assurance, quality control, and study monitoring.
  - Whether there are appropriate plans for the development of methods for the handling, distribution, analysis, banking, and security of specimens and/or imaging products generated from consortium-sponsored studies.
  - Whether there are appropriate plans for rapid publication and other public dissemination of data generated by the consortium.
  - Whether all relevant privacy issues have been addressed appropriately.
- **Fiscal Management**
  - Whether the PI and/or other key personnel have appropriate experience and expertise in financial management of multi-institutional clinical research studies.
  - How well the Coordinating Center personnel demonstrate ability and commitment to achieving financial sustainability of the consortium beyond the award period of performance.
- **Coordinating Center Two Initial Clinical Trials**
  - **Personnel (applicable if a clinical trial originates from outside the Coordinating Center and key personnel have not been previously listed)**
    - Whether the PI and other key personnel in the clinical trial have been named and whether they have the appropriate expertise in conducting and completing prostate cancer clinical trials.

- **Study Design**
  - Whether the trials are focused on potentially high-impact, novel therapeutic agents or approaches for the management or treatment of prostate cancer.
  - Whether the study population has been adequately described.
  - Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research in each trial.
  - Whether the investigational drugs or devices have been adequately described.
  - Whether the proposed timelines indicate increased efficiency as a result of consortium participation.
- **Regulatory Process**
  - Whether the trials will be ready for initiation at a time appropriate for implementation by the consortium.
  - Whether there are appropriate plans for the coordination of IRB submissions and approvals at participating sites.
  - Whether there is an appropriate description of the procedures to ensure compliance with FDA regulations for investigational agents
  - Whether the appropriate IND/IDE numbers have been provided.
- **Impact**
  - Whether the trials address at least one of the FY25 PCRP Overarching Challenges
  - To what extent the intervention or device to be tested, if the study is successful, will have a significant impact on prostate cancer patient care.

- **All Sites (Clinical Research Sites and Coordinating Center):** All applications will be evaluated according to the following criteria, which are of equal importance.
  - **Personnel**
    - Whether the PI meets the eligibility requirements and demonstrates commitment to prostate cancer clinical research.
    - How well the research team demonstrates a willingness and ability to function in the consortium.
    - To what extent the research team has the ability and experience to contribute substantially to the design and conduct of consortium clinical trials.
    - Whether the named institutional Clinical Research Coordinator has the appropriate experience in guiding clinical protocols through the regulatory approval processes and the ability to foster communication with other consortium Clinical Research Coordinators.
    - Whether there are appropriate levels of effort for successful conduct of the proposed work.
    - If applicable, whether the description of past performance of a previously received FY21 PCRP Clinical Consortium Award demonstrates successful achievement of previous award metrics and other substantive individual contributions to consortium activities; if past performance was directly affected by a significant event, how well

the site describes plans to resolve or mitigate those issues to increase performance for the new award.

- **Institutional Resources and Commitment**
  - Whether the institution has demonstrated appropriate commitment to working with the consortium through the provision of facilities and resources.
  - How the PI is supported by the availability of and accessibility to facilities and resources, especially in regard to specimen collection and processing.
  - Whether the institution possesses appropriate resources and expertise for data management and maintaining security and confidentiality.
  - How well the applicant has demonstrated willingness and ability to resolve intellectual and material property issues with other institutions in the consortium.
  - Whether the institution has unique resources that may be of benefit to the consortium.
- **Participant Recruitment**
  - Whether the PI has demonstrated sufficient access to the appropriate prostate cancer patient population(s) for consortium-sponsored studies.
  - Whether the PI has provided sufficient evidence of access to and ability to recruit patients from high-risk and/or military populations.
  - Whether the institution has proven success in recruiting patients for clinical trials.
- **Collaborations**
  - Whether the PI and other key members of the research team have demonstrated appropriate experience in collaborative prostate cancer clinical research.
  - How well the PI will integrate into the consortium and be a contributing member.
  - How well the PI's institution has facilitated the PI's collaborations.
- **Impact**
  - To what extent the research team's areas of clinical research interest, if successfully developed, will support the presentation of clinical trials to evaluate high-impact, novel therapeutic agents or approaches for the management or treatment of prostate cancer.
  - To what degree the anticipated outcomes from the institution's participation in the consortium, including the expected recruitment of patients from high-risk and/or military populations to consortium-led studies, will impact consortium-led clinical studies and the FY25 PCRP Overarching Challenges.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria:**

- **Budget**
  - Whether the budget is appropriate for the proposed research.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

6.2.3. 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 priorities of the FY25 PCRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Program portfolio composition
  - Programmatic relevance to FY25 PCRP Overarching Challenges
  - Relative impact

6.3. Application Review and Selection Process

6.3.1. Pre-Application

There is no review and selection process for pre-applications submitted to this funding opportunity. ***CDMRP will NOT provide an invitation to submit a full application after pre-application submission.*** Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.

6.3.2. Full Application

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. ***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 6.2.3, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found on the CDMRP website.

Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer 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.

6.4. Risk, 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 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. 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.

In accordance with National Security Presidential Memorandum and all associated laws, all fundamental research funded by the DoD must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the DOD Component Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

7. Federal Award Notices

For each full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the application receipt and review process for the PCRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. 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 (i.e., assistance agreement).***

Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to ***intragovernmental and intramural DOD organizations*** will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An 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. For additional information about pre-award costs for Grants.gov submissions, refer to the General Application Instructions, Section I.D, Pre-Award Costs section; and for eBRAP submissions, refer to the General Application Instructions, Section 1.D, Pre-Award Costs section.

8. Post-Award Requirements

8.1. 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 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the USAMRAA Research Terms and Conditions: Addendum to the DoD R&D Terms and Conditions for further information.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

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

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee (IACUC), IRB, or Ethics Committee (EC) review. Refer to the General Application Instructions, Appendix 6, for additional information.

8.2. Reporting

Annual technical progress reports as well as a final technical progress report will be required. Annual and final technical reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

The Award Terms and Conditions will specify whether additional and/or more frequent reporting is required.

Coordinating Center only: PHS Inclusion Enrollment Reporting ***(Required for research proposing clinical research and/or clinical trials)*****:** Enrollment reporting on the basis of sex, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on eBRAP. It is the responsibility of the Coordinating Center to provide Inclusion Enrollment Reports for all trials conducted under the FY25 PCRP Clinical Consortium Award.

Awards resulting from this program announcement may entail 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 $10M are required to provide information to SAM 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. These recipients are required to disclose,

semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

8.3. Additional Requirements

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis. An organizational transfer of a Coordinating Center or Clinical Research Sites under the Clinical Consortium Award mechanism will not be allowed.

The PI is expected to participate in at least one Interim Progress Review (IPR) for each year of the period of performance beginning in year three. For planning purposes, the PI can expect that the IPR will last no longer than one day and require no more than two overnight stays in National Capital Region. The invitation and format for the IPR will be provided by the Grants Officer's Representative at least 90 days prior to the scheduled IPR date.

Refer to the General Application Instructions, Appendix 7, Section H, for general information on PI changes.

9. Other Information

9.1. 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 CD25_01c. The program announcement numeric version code will match the General Application Instructions version code CD25_01.

9.2. Administrative Actions

After receipt of full applications, the following administrative actions may occur.

9.2.1. Rejection

The following will result in administrative rejection of the full application:

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

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents.
- Documents not requested will be removed.

9.2.3. Withdrawal

The following may result in administrative withdrawal of the full application:

- A member of the FY25 PCRP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the pre-application or application processes.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY25, the identities of the peer review contractor and the programmatic review contractor may be found on the CDMRP website.
- 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.
- Applications submitted by a federal government organization (including an intramural DOD organization) if: (a) the organization cannot accept and execute the entirety of the requested budget in FY25 funds; and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.

- 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.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not address at least one of the FY25 PCRP Overarching Challenges.
- The PI does not meet the eligibility criteria.

9.2.4. 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.

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance ***(Grants.gov submissions only)***	☐
Summary (Tab 1) and Application Contacts (Tab 2) ***(eBRAP submissions only)***	☐
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐
Data and Research Resource Sharing Plan – Attachment 7, upload as "Sharing.pdf"	☐
Inclusion of Women and Minorities *(if applicable)* – Attachment 8, upload as "Inclusion.pdf"	☐
Representations *(Grants.gov submissions only)* – Attachment 9, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 10, upload as "IGBudget.pdf"	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach Biographical Sketch for PI and Senior/Key Persons ("Biosketch_LastName.pdf")	☐
Attach Current/Pending Support for PI and Senior/Key Persons ("Support_LastName.pdf")	☐
Research & Related Budget **Include Budget Justification**	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐

Appendix 2. Acronym List

CCA	Clinical Consortium Award
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	U.S. Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IPR	Interim Progress Review
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
NCCN	National Comprehensive Cancer Network
NIH	National Institutes of Health
NSF	U.S. National Science Foundation
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OHRO	(previously Human Research Protection Office)
OUSD R&E	Office of the Under Secretary of Defense Research & Engineering
PCRP	Prostate Cancer Research Program
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RPPR	Research Performance Progress Report
SAM	System for Award Management
SciENcv	Science Experts Network Curriculum Vitae
SF424	Standard Form 424 (Application for Federal Assistance, Research & Related)
SOW	Statement of Work
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	U.S. Department of Veterans Affairs