

Program Announcement for the Department of Defense Defense Health Program

Prostate Cancer Research Program Idea Development Award

Funding Opportunity Number: HT942525PCRPIDA

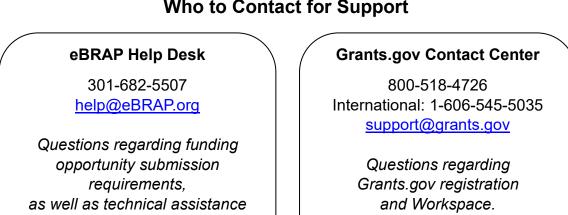
Pre-Application Due: August 11, 2025 Application Due: September 2, 2025

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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

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.

related to pre-application or intramural application submission.

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1. Basic Information About the Funding Opportunity

Summary: The fiscal year 2025 (FY25) Prostate Cancer Research Program (PCRP) Idea Development Award (IDA) supports new ideas that represent innovative approaches to prostate cancer research and have the potential to make an important contribution to the PCRP mission. All applications are required to address one or more of the <u>FY25 PCRP Overarching</u> <u>Challenges</u>.

Distinctive Features:

• **New Investigator Category:** In addition to Established Investigators, the FY25 PCRP Idea Development Award encourages research ideas from investigators in the early stages of their careers (i.e., within 10 years after completion of their terminal degree). Qualified New Investigators must identify a collaborator(s) experienced in prostate cancer research.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$22.1 million (M) to fund approximately 13 Idea Development Award – Established Investigator applications with total cost caps of \$1.7M. The maximum period of performance is 3 years. The CDMRP expects to allot approximately \$8.4M to fund approximately 4 Idea Development Award – New Investigator applications with total cost caps of \$2.1M. 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: HT942525PCRPIDA

Assistance Listing Number: 12.420

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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

Each investigator may be named on only one FY25 PCRP Idea Development Award application as a Principal Investigator (PI).

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

New Investigator

By the application submission deadline date, the PI must:

- Have the freedom to pursue independent research goals without formal mentorship.
- Have not previously received a non-mentored PCRP Award (excluding the Exploration Hypothesis Development Award).
- Be an independent, early-career investigator within 10 years after completion of their terminal degree (excluding time spent in residency or on family medical leave). Time spent as a postdoctoral fellow is not excluded. Lapses in research time or appointments as denoted in the biographical sketch may be articulated in the application.
- New Investigators working within a laboratory team are eligible to apply for this award provided they can demonstrate that they have the freedom to pursue independent research goals without formal mentorship. Graduate students and junior postdoctoral fellows with less than three years of postdoctoral training by the application submission deadline are not eligible for this award.

Investigators named as PI under the New Investigator category must confirm eligibility in <u>Attachment 8, Eligibility Statement</u> and independence, if applicable, in <u>Attachment 9,</u> <u>Statement of Independence</u>.

Established Investigator

• Independent investigators at all levels are eligible.

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

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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.

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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 (<u>https://www.nccn.org/patients/guidelines/content/PDF/prostate-advanced-patient.pdf</u>).
- 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:

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- o Biological basis of disease and treatment on quality of life
- o 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 Idea Development Award

The FY25 PCRP Idea Development Award intends to support new ideas that represent innovative approaches to prostate cancer research and have the potential to make an important contribution to the PCRP mission.

3.1.1. Key Elements for the IDA

- **Innovation:** Research deemed innovative may represent a new paradigm, challenge current paradigms, look at existing problems from new perspectives, leverage unique study populations, or exhibit other highly creative qualities. Research that is an incremental advance upon published data is not considered innovative. Projects involving multidisciplinary and/or data science approaches are especially encouraged.
- Impact: Applications are required to address and provide a solution to one or more of the <u>FY25 PCRP Overarching Challenges</u>. The potential impact of the research, both short-term and long-term, in addressing the FY25 PCRP overarching challenge(s) should be clearly described. High-impact research will, if successful, significantly advance prostate cancer research and/or patient care.
- **Preliminary Data:** Due to this award's emphasis on innovation, the presentation of preliminary data relevant to prostate cancer and the proposed project *is encouraged, but not required.* Any unpublished, preliminary data provided should originate from the laboratory of the PI or member(s) of the research team. Regardless of whether preliminary data are included, applications should be based on a sound scientific rationale that is established through logical reasoning and/or critical review and analysis of the literature.

New Investigator Category: The FY25 PCRP Idea Development Award mechanism encourages research ideas from investigators in the early stages of their careers. The New Investigator category is designed to allow applicant organizations to name PIs who are **early in their faculty appointments or in the process of developing independent research careers.** Applications submitted to the New Investigator category will be assessed using different <u>peer</u> review criteria for personnel and **are required to include a collaborator (or collaborators)** who has (have) experience in prostate cancer research, as demonstrated by a record of funding and publications. The application must describe the potential of the collaboration(s) to be

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successful and how the collaboration(s) will augment the PI's expertise to better address the research question. In addition, applicants are strongly encouraged to provide a letter of collaboration from the collaborator(s) describing the collaborator(s) involvement in the proposed work. All PIs named under the New Investigator category must meet specific <u>eligibility criteria</u>.

Multidisciplinary projects are encouraged, and multi-institutional projects are allowed. Each proposed study must include a clearly stated plan for interactions among all team members and organizations involved. The plan must include communication, coordination of research progress and results, and data transfer. Additionally, multi-institutional applications must provide an intellectual property plan to resolve potential intellectual and material property issues and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful completion of this award.

3.1.2. Other Important Considerations for the IDA

Clinical trials are not allowed. 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 $\frac{646.104(d)(4)}{64.104(d)(4)}$ 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

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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,

<u>https://doi.org/10.1038/nature11556</u>. 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 <u>recommendations</u> 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 funding instrument for awards made under the program announcement will be grants (31 USC 6304).

3.4. Funding Details

Established Investigator

Period of Performance: The maximum period of performance is 3 years.

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Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **\$1.7M**. 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 **3** years.

New Investigator

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 **\$2.1M**. 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.

An award's maximum period of performance and maximum total costs depend on the eligibility of the PI, as defined in <u>Section 2.1.2, Principal Investigator</u>.

Direct Cost Restrictions: For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY25 PCRP Idea Development Award.

Must not be requested for:

- Clinical trial costs.
- Costs for travel to scientific/technical meeting beyond the limits stated above.

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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 (<u>eBRAP</u>) 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 the <u>FY25 PCRP Overarching Challenge</u> 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 <u>Appendix 1</u> 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.

<u>IMPORTANT: When completing the SF424 R&R, enter the eBRAP log number</u> 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 (15-page limit): Upload as "ProjectNarrative.pdf". The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (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.

 Background: Present the ideas and reasoning behind the proposed research and the <u>FY25 PCRP Overarching Challenge(s)</u> that will be addressed. The application must demonstrate logical reasoning and provide a sound scientific rationale for the proposed project as established through a critical review and analysis of published literature; include relevant literature citations. Describe previous experience most

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pertinent to this application. While not required, include any preliminary data to support the scientific rationale.

- Hypothesis or Objective: State the hypothesis to be tested or the objective to be reached.
- Specific Aims: Concisely explain the project's specific aims. If this application is part
 of a larger study, present only tasks that this award would fund.
- Research Strategy and Feasibility:
 - Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for scientific evaluation that will include an assessment of overall project feasibility.
 - Address potential problem areas and present alternative methods and approaches.
 - Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis, including the statistical expertise available to support the analysis, if applicable. If animal studies are proposed, describe how they will be conducted in accordance with the <u>ARRIVE</u> <u>guidelines 2.0A</u> (Animal Research Reporting *In Vivo* Experiments) to achieve reproducible and rigorous results.
 - If human subjects or human biological samples will be used, provide evidence supporting the availability of and access to any populations/samples required for the study, including any clinical expertise. Include a detailed plan for the recruitment of subjects or the acquisition of samples, and for acquiring any additional research resources necessary for conducting the proposed research project. *This award does not support clinical trials.* For <u>clinical research</u>, see <u>Attachment 10</u> for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study.
 - Clearly identify the source of any proposed cell lines and whether they were recently authenticated and/or tested for mycoplasma contamination, if applicable.
 - Describe how the clinical relevance of the anticipated findings will be determined and whether the results will be validated in the appropriate patient cohorts, if applicable.
- Required Collaborator (for New Investigator category only): Name the required collaborator(s); describe their prostate cancer-related expertise and how the contribution of the collaborator(s) will support the PI and project.

If the proposed research involves access to active-duty 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. 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.

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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 <u>eligibility criteria</u>. 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.
 - New Investigators (if applicable): Investigators applying for the New Investigator category are strongly encouraged to provide a signed letter from each collaborating individual or organization that describes how they will support the project, to include unique expertise and/or availability of and access to research resources.
- Intellectual and Material Property Plan: Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: 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

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on Data & Resources Sharing for more information about CDMRP's expectations for making data and research resources publicly available.

Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf". The technical abstract is used by all reviewers. *Abstracts of all funded research projects will be posted publicly.* 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.

- **Background:** Present the scientific rationale behind the proposed research project.
- Hypothesis/Objective(s): State the hypothesis to be tested and/or objective(s) to be reached.
- Specific Aims: State the specific aims of the study.
- **Study Design:** Describe the study design, including appropriate controls.
- Impact: Summarize the potential near-term and long-term impact of the proposed research. Include how the anticipated outcomes will provide a foundation for future research projects that will enable progress towards a solution to one or more of the <u>FY25 PCRP Overarching Challenges</u> and ultimately make a major impact toward eliminating death and suffering from prostate cancer.
- 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.

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.

- What are the likely contributions of this study to the <u>FY25 PCRP Overarching</u> <u>Challenges</u>?
- What types of patients will it help and how will it help them?
- What are the potential clinical applications, benefits, and risks?
- What is the projected time it may take to achieve a patient-related outcome?
- If the research is too basic for clinical applicability, describe the interim outcomes.
- 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 <u>"Suggested SOW Format"</u>.

For the Idea Development Award, refer to the <u>"Example: Assembling a Generic</u> <u>Statement of Work"</u> for guidance on preparing the SOW.

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- Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf". Explain in detail why the proposed research project is important, as follows:
 - Describe the Short-Term Impact: Detail the anticipated outcome(s)/product(s) that will be directly attributed to the results of the proposed research, including any clinically relevant results. Summarize how the anticipated outcome(s)/product(s) will provide a foundation for future research projects that will enable progress towards a solution to one or more of the <u>FY25 PCRP Overarching Challenges</u>.
 - Describe the Long-Term Impact: Explain the anticipated long-term gains from the proposed research, including the anticipated advantages that the new understanding may contribute to the goal of elimination of death and suffering from prostate cancer.
 - Relevance to Military Health: Briefly describe how the proposed research is relevant to Service Members, Veterans, and/or their Families.
- Attachment 7: Innovation Statement (one-page limit): Upload as "Innovation.pdf". Describe how the proposed work is innovative by proposing new paradigms, challenging existing paradigms, or otherwise being highly creative. Describe how the proposed research represents more than an incremental advancement on published data.

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

- **Study Concept:** Investigation of a novel idea and/or research question.
- Research Methods or Technologies: Use of novel research methods; new technologies, including technology development; or unique study populations to address a research question.
- Existing Methods or Technologies: Application or adaptation of existing methods or technologies for novel research or clinical purposes.
- Attachment 8: Eligibility Statement (one-page limit): Upload as "Eligibility.pdf" (Attachment 8 is only applicable and required for applications submitted under the New Investigator category). The Eligibility Statement will only be used for administrative purposes to confirm eligibility and will not be forwarded for peer or programmatic review. Provide a statement, signed by the PI and Department Chair, Dean, or equivalent official verifying that the PI will have met the eligibility requirements by the application submission deadline. The statement should clearly state that the PI:
 - Has the freedom to pursue independent research goals without formal mentorship;
 - Has not previously received a non-mentored PCRP Award (excluding the Exploration Hypothesis-Development); and
 - Is an independent, early-career investigator within 10 years after completion of their terminal degree by the time of the application submission deadline (excluding time spent in residency or on family medical leave). Time spent as a postdoctoral fellow is not excluded. Provide an explanation for any lapses in research time or appointments.
- Attachment 9: Statement of Independence (one-page limit): Upload as "Independence.pdf" (required only for investigators not yet in an independent faculty position). For investigators not yet in an independent faculty position, provide a statement, signed by the PI and the PI's mentor, that supports the PI's ability to perform

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as an independent researcher. The Statement of Independence must include the following components:

- PI's name, organization, and application title
- Beginning and ending dates (month/year) of postdoctoral training
- Date (month/year) the PI began or will begin independent research in the proposed setting
- Other information that attests to the PI's independence (e.g., grants/fellowships obtained; awards/appointments earned by the PI)
- Attachment 10: Inclusion of Women and Minorities (three-page limit): Upload as "Inclusion.pdf". (Attachment 10 is only applicable and required for applications that propose <u>clinical research</u>.) Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the "<u>Public Health Service (PHS) Inclusion</u> <u>Enrollment Report</u>", 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 Institutional Review Board [IRB] review) are exempt from this requirement.
- Attachment 11: Transition Plan (one-page limit): Upload as "Transition.pdf". Provide information on potential methods and strategies to move the project's findings to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award (e.g., specific potential industry partners, specific funding opportunities to apply for). Provide a realistic timeline for near-term clinical investigation. In addition, provide a plan to distribute the findings or intervention to the prostate cancer community.
- Attachment 12: Representations (Grants.gov submissions only): Upload as "RequiredReps.pdf". All extramural applicants must complete and submit the <u>"Required Representations"</u> document that is available on eBRAP. For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
- Attachment 13: Suggested Intragovernmental/Intramural Budget Form (*if applicable*): Upload as "IGBudget.pdf". If an <u>intramural DOD organization</u> will be a collaborator in the performance of the project, complete a separate budget for that organization using the <u>"Suggested Intragovernmental/Intramural Budget</u>" 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".

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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 <u>SciENcv</u> 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 <u>conflicts of commitment</u> 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 <u>SciENcv</u> 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 "<u>Suggested</u> <u>Intragovernmental/Intramural Budget Form</u>" 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.

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5. Submission Requirements

5.1. Location of Application Package

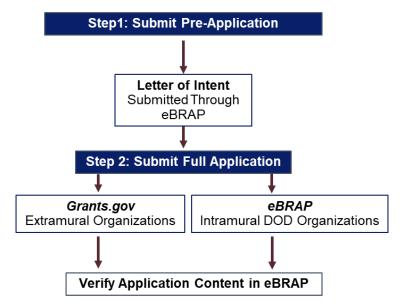
Download the application package components for HT942525PCRPIDA from <u>Grants.gov</u> or <u>eBRAP</u>, depending on which submission portal will be used.

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), <u>SAM.gov</u>, 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 <u>the full application submission process</u>. 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

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any changes need to be made, the applicant should contact the eBRAP Help Desk at <u>help@eBRAP.org</u> 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:
Established Investigator Category	Established Investigator
New Investigator Category	New Investigator

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

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application rejection. The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant.

All submission dates and times are indicated in <u>Section 1, Basic Information</u> above.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

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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 <u>CDMRP's full position on research duplication</u>.

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 <u>letters</u> to confirm <u>PI eligibility</u> 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 <u>FY25 PCRP Programmatic Panel members</u> can be found on the CDMRP website.*

Additional restrictions and associated administrative responses are outlined in <u>Section 9.2,</u> <u>Administrative Actions</u>.

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**, of which **Innovation** and **Impact** are **equally the most important**, with the remaining criteria listed in decreasing order of importance:

- Innovation
 - To what degree the research proposes new paradigms, challenges existing paradigms, or is otherwise highly creative.
 - To what degree the proposed research represents more than an incremental advance upon published data.
- Impact
 - Assuming the objectives/goals of the proposed research project are realized, to what degree:

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- The anticipated short-term outcome(s)/product(s) of the project will be used as the foundation for future research projects that will enable progress towards providing a solution to one or more of the <u>FY25 PCRP Overarching Challenges</u>.
- The proposed research would, in the long term, contribute towards eliminating death and suffering from prostate cancer.

• Research Strategy and Feasibility

- How well the scientific rationale supports the research and its feasibility, as demonstrated by a critical review and analysis of published literature, the presentation of preliminary data (if applicable), and logical reasoning.
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
- How well the application acknowledges potential problems and addresses alternative approaches.
- Whether the application includes an appropriate statistical plan with power analysis (if applicable).
- Whether the application provides sufficient evidence to support the availability of and access to the populations/samples required for the study, and whether the plan for acquiring the necessary research resources is sufficient for the proposed research project (if applicable).
- As applicable, how well the application describes components to increase the impact of the project, including cell line authentication; proper design of animal studies to achieve reproducible and rigorous results; experiments to address clinical relevance; and/or validation in the appropriate patient cohorts.
- If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research. 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.

Personnel

- To what degree the research team's background is appropriate with respect to its ability to perform the proposed work, including whether there is evidence of sufficient clinical and/or statistical expertise (if applicable).
- Whether the levels of effort are appropriate for successful conduct of the proposed work.

• New Investigator Category Only:

- How well the PI's record of accomplishments demonstrates their potential for contributing to the prostate cancer research field and completing the proposed work.
- How well the background, prostate cancer-related expertise, and proposed contribution of the required collaborator(s) will support the PI and the proposed project.
- If applicable, whether the Statement of Independence supports the PI's ability to perform as an independent researcher.

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**:

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Budget

• Whether the budget is appropriate for the proposed research.

• Environment

• How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).

• Data and Resources Sharing Plan

 To what degree the plan for sharing of project data and research resources is appropriate and reasonable to facilitate use by the wider prostate cancer research community.

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 with consideration of New and Established Investigators
 - Programmatic relevance to the <u>FY25 PCRP Overarching Challenges</u>
 - Relative innovation
 - 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,

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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 <u>Section 6.2.3, Programmatic Review</u>. Additional information about the two-tier process used by the CDMRP can be found on the <u>CDMRP website</u>.

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 <u>limited time period</u> 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.

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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; Award Costs section.

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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 <u>DoD R&D Terms and Conditions</u> and the <u>USAMRAA Research</u> <u>Terms and Conditions: Addendum to the DoD R&D Terms and Conditions</u> 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.

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.

Award Expiration Transition Plan: An <u>Award Expiration Transition Plan</u>, using the template available on eBRAP, must be submitted with the final progress report.

PHS Inclusion Enrollment Reporting *(Required for research proposing clinical research)*: Enrollment reporting on the basis of sex, race, and/or ethnicity will be required with each annual and final progress report. The <u>PHS Inclusion Enrollment Report</u> is available on eBRAP.

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).

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

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

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

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 preapplication 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 <u>CDMRP website</u>.
- 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

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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.
- A clinical trial is proposed.
- 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.

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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"	
Innovation Statement – Attachment 7, upload as "Innovation.pdf"	
Eligibility Statement – Attachment 8, upload as "Eligibility.pdf" if applicable	
Statement of Independence (if applicable) – Attachment 9, upload as "Independence.pdf" (required only for investigators not yet in an independent faculty position)	
Inclusion of Women and Minorities – Attachment 10, upload as "Inclusion.pdf" if applicable	
Transition Plan – Attachment 11, upload as "Transition.pdf"	
Representations (Grants.gov submissions only) – Attachment 12, upload as "RequiredReps.pdf"	
Suggested Intragovernmental/Intramural Budget Form (if applicable) – Attachment 13, upload as "IGBudget.pdf"	
Research & Related Personal Data	
Research & Related Senior/Key Person Profile (Expanded)	
Attach <u>Biographical Sketch</u> for PI and Senior/Key Persons ("Biosketch_LastName.pdf")	
Attach <u>Current/Pending Support</u> 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)	

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

Appendix 2. Acronym List

ARRIVE	Animal Research Reporting In Vivo Experiments
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
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IDA	Idea Development Award
IRB	Institutional Review Board
Μ	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)
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