Program Announcement for the Department of Defense
Defense Health Program

Peer Reviewed Cancer Research Program

Impact Award

Funding Opportunity Number: HT942525PRCRPIPA

Pre-Application Due: June 20, 2025

Application Due: September 25, 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) Peer Reviewed Cancer Research Program (PRCRP) Impact Award supports mature research that will have a near-term impact on clinical cancer care in one of the congressionally directed FY25 PRCRP topic areas. Applicants must consider how the research project will lead to the advancement of knowledge in cancer research, patient care and/or treatment options in the Military Health System (MHS).

Distinctive Features:

- Applications must include preliminary data to support feasibility of the study.
- Projects must have strong potential to result in a near-term impact in cancer
- The funding mechanism allows **clinical trials**.
- **This funding mechanism allows for a single Principal Investigator (PI), or two partnering PIs referred to as the Initiating PI and the Partnering PI.** Only the Initiating PI will submit a pre-application, but both PIs will need to submit full applications. The Partnering PI's application is an abbreviated package specific to their distinct portion of the research project. Be advised, both applications for a research project may be withdrawn if the initiating or partnering application is rejected or administratively withdrawn.

Funding Details: ***(New for FY25)*** Funding limits are now listed as ***total cost limits, which is the combination of both direct and indirect costs.***

The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $28 million (M) to fund approximately 20 Impact Award applications with total cost caps of $1.4M, and $17.5M to fund approximately 10 Impact Award – Partnering PI option applications with total cost caps of $1.75M. The maximum period of performance is 3 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 (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), June 20, 2025
- **Invitation to Submit an Application:** July 23, 2025
- **Application Submission Deadline:** 11:59 p.m. ET, September 25, 2025
- **End of Application Verification Period:** 5:00 p.m. ET, September 30, 2025
- **Peer Review:** November 2025
- **Programmatic Review:** February 2026

Announcement Type: Initial

Funding Opportunity Number: HT942525PRCRPIPA

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 at or above the level of Assistant Professor (or equivalent) are eligible to be named as the PI on the application. Industry titles may not be analogous to the faculty hierarchy in academia. For industry, investigators at or above an independent scientist level may be named by the company as the PI on the application.

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 PRCRP. Congress initiated the PRCRP in 2009 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the PRCRP from FY09 through FY24 totaled $1.04 billion. The FY25 appropriation is $130M.

Congressional language stipulates the FY25 PRCRP must be relevant to Service Members, and address at least one of the congressionally directed FY25 PRCRP topic areas listed below.

- Bladder cancer
- Blood cancers
- Brain cancer
- Colorectal cancer
- Endometrial cancer
- Esophageal cancer
- Germ cell cancers
- Kidney cancer
- Liver cancer
- Lung cancer
- Lymphoma
- Mesothelioma
- Metastatic cancers
- Myeloma
- Neuroblastoma
- Neuroendocrine tumors
- Pancreatic cancer
- Pediatric, adolescent, and young adult cancers[1]
- Pediatric brain tumors
- Sarcoma
- Stomach cancer
- Thyroid cancer

Research proposed to the PRCRP must not address research in melanoma, or cancers originating in the breast, prostate, or ovary. In addition, FY25 PRCRP funds must not be used to study rare cancers except FY25 PRCRP topic area cancer types that are rare by definition.

FY25 PRCRP Portfolios and Strategic Goals

To meet the intent of the funding opportunity, ***all applications for FY25 PRCRP funding must specifically address one of the FY25 PRCRP topic areas as directed by the U.S. Congress and have direct relevance to military health***. Additionally, the PRCRP implements a portfolio-driven approach by grouping related topic areas with strategic goals as a framework within which to address critical gaps in cancer research and patient care. ***All applications must address one of the FY25 PRCRP strategic goals as it relates to the portfolio-assigned FY25 PRCRP topic area. Topic areas may be included in more than one portfolio, but the application must be aligned to the strategic goals of the portfolio in which a topic area is included.*** If the proposed research does not specifically address one FY25 PRCRP topic area and one FY25 PRCRP strategic goals from a single portfolio, then the government reserves the right to administratively withdraw the application. The government reserves the right to reassign

[1] The definition of adolescents and young adults is derived from the National Cancer Institute (https://www.cancer.gov/types/aya). Research should be targeted toward pediatric (ages 0-14 years), adolescents (ages 15-24 years), and/or young adults (ages 25-39 years).

the application's topic area if submitted to an incorrect topic area. The table below lists the FY25 PRCRP topic areas and strategic goals in each PRCRP portfolio category.

Portfolio: Blood Cancers	
All applications under this portfolio must address one topic area and one strategic goal listed below.	
Topic Areas: Blood, Lymphoma, Myeloma	
Strategic Goals:	
Prevention and Etiology	• Improve risk assessment of precancerous conditions • Develop early intervention strategies to prevent initiation and/or progression • Investigate autoimmune disorders as risk factors for lymphoma to inform surveillance strategies • Understand the role of cancer stem cells and the tumor microenvironment in the development of blood cancers
Diagnosis and Prognosis	• Improve methods for early detection, prognostic evaluation, and/or therapeutic stratification • Develop more cost-effective molecular diagnostics • Identify biomarkers to predict progression from indolent disease • Identify unique prognostic factors in pediatric, adolescent, and young adult malignancies
Treatment	• Develop new, less toxic therapies • Develop methods to predict therapeutic vulnerabilities • Develop therapies that don't require hospitalization • Develop therapies employing gene editing technologies and cell therapies • Identify contribution of immune niche to initial treatment response and relapse • Develop therapeutic options for patients who fail last line therapies
Survivorship	• Develop strategies to minimize and mitigate treatment toxicities • Improve quality of life for survivors and/or caregivers • Identify long-term effects of gene editing and cell therapies and develop risk-based standards for surveillance of treated patients • Improve understanding of the effects of long-term immunosuppression
Epidemiology	• Design population-based studies to identify and characterize risk factors related to malignancy

Portfolio: Gastroenterological Cancers	
All applications under this portfolio must address one topic area and one strategic goal listed below.	
Topic Areas: Colorectal, Esophageal, Liver, Stomach, Pancreatic cancer	
Strategic Goals	
Prevention and Etiology	• Identify modifiable and non-modifiable risk factors to inform prevention strategies • Identify factors driving the increasing rates of early-age onset disease • Identify environmental and genetic factors associated with an increased cancer risk • Identify key drivers of conversion from precancerous lesions into cancer • Explore the interplay between the microbiome and infectious agents in cancer initiation and progression • Conduct integrative studies that analyze stool, blood, and the microbiome as they impact disease onset and patient outcomes
Diagnosis and Prognosis	• Improve methods for early detection, prognostic evaluation, and/or therapeutic stratification • Develop cost-effective and minimally invasive tools for early detection • Develop preclinical models to study disease development
Treatment	• Develop new, less toxic therapies • Develop effective treatments for advanced disease • Develop immunotherapies and novel targeting therapies • Identify combination therapies to improve patient outcomes • Identify predictive biomarkers to determine treatment response • Develop integrated treatment plans to address short and long-term impacts of cancer
Survivorship	• Develop strategies to minimize and mitigate treatment toxicities • Improve quality of life for survivors and/or caregivers • Improve post treatment surveillance guidelines • Develop validated tools to measure patient quality of life
Epidemiology	• Design population-based studies to identify and characterize risk factors related to malignancy • Implement systems to analyze disease patterns and track patient outcomes to inform best practices • Examine the influence of familial genetics and geographic location on disease onset and treatment outcome

Portfolio: Neurological Cancers	
All applications under this portfolio must address one topic area and one strategic goal listed below.	
Topic Areas: Brain cancer, Pediatric Brain Tumors	
Strategic Goals:	
Prevention and Etiology	• Identify biological and environmental exposures, including maternal exposures during pregnancy, that increase risk
Diagnosis and Prognosis	• Develop early detection methods that avoid diagnostic uncertainties • Develop effective monitoring for recurrence/refractory disease • Develop less invasive diagnostic procedures
Treatment	• Develop new, less toxic therapies • Prevent or overcome treatment resistance • Develop personalized oncological care and synergistic multi-modal therapies • Identify protective therapies to be used in conjunction with toxic therapies to reduce treatment-related damage • Develop less invasive treatment options • Develop therapies that cross the blood-brain-barrier
Survivorship	• Develop strategies to minimize and mitigate treatment toxicities • Improve quality of life for survivors and/or caregivers • Develop effective screening, monitoring, and provision of psychosocial support/care for the patient and family • Develop care for patients as they transition from pediatric to adult survivors
Epidemiology	• Analyze and assess the incidence/prevalence of brain tumors over time to identify changes in trends
Technology Development	• Advance the development or adoption of technologies in areas including artificial intelligence and machine learning, human microbiota, genomics, nanoparticles, and robotics

Portfolio: Pediatric Adolescent and Young Adult Cancers (PAYAC)	
All applications under this portfolio must address one topic area and one strategic goal listed below.	
Topic Areas: PAYAC, Germ cell cancers, Neuroblastoma, Sarcoma, Thyroid cancer	
Strategic Goals:	
Prevention and Etiology	• Determine the molecular basis of cancer predisposition syndromes • Determine the extent to which development of disease is attributable to genetic versus environmental differences • Increase understanding of epigenetic influences on cancer development and progression • Identify biological and environmental exposures, including maternal exposures during pregnancy, that increase risk • Investigate the role of microbiome composition in cancer risk and outcomes
Diagnosis and Prognosis	• Improve methods for early detection, prognostic evaluation, and/or therapeutic stratification • Develop noninvasive techniques for monitoring progression and recurrence • Identify biomarkers present in early-stage disease • Develop preclinical models that accurately mimic disease • Improve accurate and rapid diagnosis of sub-types of disease
Treatment	• Develop new, less toxic therapies • Develop treatments for relapse/recurrence, metastatic, and advanced disease • Increase the number of clinical trials, including ones that may not be curative but may improve the quality of life for terminal patients • Generate evidence-based treatment and surveillance strategies to preserve fertility • Reduce secondary cancers arising from treatment regimen
Survivorship	• Develop strategies to minimize and mitigate treatment toxicities • Improve quality of life for survivors and/or caregivers • Develop strategies to improve the full implementation of survivorship guidelines • Develop survivorship guidelines based on current/modern therapeutic agents
Epidemiology	• Design population-based studies to identify and characterize risk factors related to malignancy

Portfolio: Solid Tumors	
All applications under this portfolio must address one topic area and one strategic goal listed below.	
Topic Areas: Bladder cancer, Endometrial cancer, Mesothelioma, Sarcoma, Germ cell cancers, Thyroid cancer, Kidney cancer, Lung cancer, Neuroendocrine tumors	
Strategic Goals:	
Prevention and Etiology	• Develop methods that mitigate or identify risk • Develop prevention strategies • Explore the mechanistic relationship between novel and known risk factors and oncogenesis • Identify convergent etiologies underlining the development of malignancies
Diagnosis and Prognosis	• Improve methods for early detection, prognostic evaluation, and/or therapeutic stratification • Investigate the interactions of pre-existing autoimmune disease and cancer
Treatment	• Develop new, less toxic therapies • Develop feasible precision medicine approaches • Identify ways to tailor therapeutic strategies to minimize toxicity
Survivorship	• Develop strategies to minimize and mitigate treatment toxicities • Improve quality of life for survivors and/or caregivers
Epidemiology	• Design population-based studies to identify and characterize risk factors related to malignancy

Portfolio: Metastatic Disease	
All applications under this portfolio must address one topic area and one strategic goal listed below.	
Topic Area: Metastatic Cancers, limited to PRCRP Topic Area Cancers	
Strategic Goals:	
Prevention and Etiology	• Identify biomarkers in primary disease that could predict metastatic potential • Prevent immune evasion by circulating tumor cells • Identify how dormant, disseminated tumor cells (DTCs) persist • Identify drivers that initiate DTCs progression to metastatic colonies • Prevent metastatic colonization by maintaining dormancy of DTCs • Investigate clonal divergence of primary tumor cells between metastatic sites to immunological disease
Diagnosis and Prognosis	• Improve early detection of metastasis and dormant residual disease • Develop biomarkers that predict and monitor treatment efficacy
Treatment	• Develop new, less toxic therapies • Revert metastatic cells to a dormant state • Identify strategies to prevent or overcome treatment resistance • Investigate abscopal effects of primary disease treatment • Determine optimal sequencing of treatments • Eliminate chemotherapy-induced metastasis
Survivorship	• Develop strategies to alleviate treatment toxicities • Improve quality of life for survivors and/or caregivers

Metastatic cancer is cancer that has spread from its original location to another place in the body, representing what are known as stage III and stage IV cancer diagnoses. While recent research has revealed that there is a genetic basis for susceptibility or resistance to metastasis, more research is needed to develop a comprehensive understanding of this complex process.

Applications submitted under any PRCRP topic area, including the Metastatic cancers topic area, may not address or include research focused on melanoma or cancers that originate in the breast, prostate, or ovaries, or rare cancers (excluding relevant subtypes of the FY25 PRCRP topic areas) as part of the research study; such applications will be administratively withdrawn.

FY25 PRCRP Military Health Focus Areas

It is central to the Vision and Mission of the PRCRP that applications are related to military health and mission readiness, and investigators must demonstrate how the proposed research will decrease the burden of cancer on Service Members, their dependents, Veterans and other military beneficiaries (i.e., Retirees and their Family members) (https://cdmrp.health.mil/pubs/video/prc/prcrp_vision_video).

In addition to addressing at least one of the required FY25 PRCRP Topic Areas and FY25 Strategic Goals, ***applications for the FY25 Impact Award must define how the research is relevant to Service Members, Veterans, and their Families by addressing at least one of the FY25 PRCRP Military Health focus areas listed below.***

FY25 PRCRP Military Health focus areas:

- ***Environmental exposure risk factors associated with cancer***
    - Environmental and/or occupational risk factors should be relevant to activities specific to the military, such as assigned duties or deployments that may lead to exposures to potential carcinogens (ionizing radiation, chemicals, infectious agents, etc.). For more information on military-related exposures and risk factors for cancer, applicants should refer to Exposure-Related Health Concerns at https://www.publichealth.va.gov/exposures/health-concerns.asp or to the PRCRP website (https://cdmrp.health.mil/prcrp/default).
- ***Mission Readiness and Gaps in Cancer Research***
    - Gaps in cancer prevention, early detection/diagnosis, prognosis, and/or treatment that may impact mission readiness and the health and well-being of military members, Veterans, their beneficiaries and the general public.
    - Gaps in quality of life and/or survivorship that may impact mission readiness and the health and well-being of military members, Veterans, their beneficiaries, and the general public.

Mission readiness under the FY25 PRCRP Military Health focus areas refers to the impact of cancer on the Service Member. Decreasing the impact of cancer on active-duty Service Members and/or their Families protects the overall military mission. Some examples of relevant research to decrease the impact on mission readiness may include, but are not limited to:

- Studies on the improvement in survival while minimizing effects that would allow an active-duty Service Member to return to full duty;
- Treatments to minimize a cancer patient's (either a Service Member's or their Family member's) time in the hospital, thus maximizing the time the Service Member is on duty;
- Effective ways to minimize cancer relapse for Service Members or their Families; and
- Research into improvements in cancer detection that would lead to earlier diagnosis, thus allowing for improved treatment of the Service Member and early return to duty.

For more information on military health and cancer:

- PRCRP Vision Video (https://cdmrp.health.mil/pubs/video/prc/prcrp_vision_video)
- PRCRP (https://cdmrp.health.mil/prcrp/default)
- MHS (https://www.health.mil)
- U.S. Department of Veterans Affairs (VA) (https://www.va.gov/)

Investigators are strongly encouraged to collaborate, integrate, and/or align their research projects with DOD and/or VA research laboratories and programs (Refer to Appendix 3).

3.1. Intent of the Impact Award

The FY25 PRCRP Impact Award supports high-impact and translational research that can accelerate promising findings toward clinical applicability. The intent of the Impact Award mechanism is to ***fund mature research projects*** that specifically focus on critical scientific or clinical cancer issues, which have the potential to make a major near-term impact on at least one of the FY25 PRCRP Topic Areas and in at least one of the FY25 PRCRP strategic goals as outlined in the FY25 PRCRP portfolio categories.

The Impact Award is not intended for basic research. Applicants performing basic research in innovative, high-risk/high-gain studies should apply to the FY25 PRCRP Idea Award (HT942525PRCRPIA).

3.1.1. Key Elements for the IPA

- **Impact:** Research supported by the Impact Award (IPA) will demonstrate the potential to accelerate promising findings and have a major impact in the near term on an area of paramount importance in cancer. The proposed study should demonstrate potential to improve patient outcomes in at least one of the FY25 PRCRP Topic Areas and in at least one of the FY25 PRCRP Strategic Goals as outlined in the FY25 PRCRP portfolio categories. Proposed projects may include translational or clinical research, including clinical trials. ***The potential impact of the proposed research is expected to be near-term, and while it fundamentally may include the next step in research, it must be significant and go beyond an incremental advance.*** The applicant must articulate the potential impact the proposed work will have on cancer research and/or patient outcomes.
- **Preliminary Data:** The Impact Award is intended to support transformative investigations that leapfrog the cancer research field forward by utilizing previous research findings. ***Applications must include preliminary data to support feasibility of the study.*** Any unpublished, preliminary data provided should originate from the laboratory of the PI or a member of the research team.
- **Continuity of Research:** The Impact Award is intended to support established projects that have moved beyond the realm of basic research.
- **Data Evaluation:** The proposed research should be rigorously designed to include a statistical plan and data analysis plan. The Impact Award is intended to have near-term relevance to patients; therefore, the statistical plan and data analysis plan should represent how significant the results and/or outcomes may be on patient outcomes.
- **Relevance to Military Health:** Relevance to the health care needs of military Service Members, Veterans, and their Families is a key feature of this award. Investigators are encouraged to consider the following characteristics as examples of how a project may demonstrate relevance to military health:
    - Explanation of how the project addresses an aspect of the target disease that has direct relevance to the health of military Service Members, Veterans, and their Families.
    - Description of how the knowledge, information, products, or technologies gained from the proposed research could be implemented in a dual-use capacity to benefit the civilian population and also address a military need.
    - Use of military or Veteran populations, samples, or datasets in the proposed research, if appropriate.

- Collaboration with DOD or VA investigators or consultants. A list of websites that may be useful in identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration within the FY25 PRCRP topic areas can be found in Appendix 3.

- **Clinical Trial, if applicable:** The proposed clinical trial should begin no later than 12 months after the award date. Investigational New Drug/Investigational Device Exemption application submission plans must be submitted to the program office within 60 days of the award. The application should demonstrate the documented availability of and access to the drug/compound, device, and/or other materials needed, as appropriate, for the proposed duration of the study.
- **Partnering PI Option:** The Impact Award includes an option for more than one PI. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. Both PIs should contribute significantly to the development and execution of the proposed research project. If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering PI, refer to Section 5.3, Submission Instructions.

3.1.2. Other Important Considerations for the IPA

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., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, Nature 490:187-191. 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.

Applications from investigators within the DOD and applications involving multidisciplinary collaborations among academia, industry, the DOD, the 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.

Clinical trials are 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 §46.104(d)(4) of the Common Rule.

3.2. CDMRP-wide Encouragements

The following encouragements are broadly applicable across many CDMRP programs, including the PRCRP. 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 PRCRP 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.

The CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

3.3. Funding Instrument

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

3.4. Funding Details

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

New for FY25: Funding limits are now listed as total cost limits, which is the combination of both direct and indirect costs. *This is a change from prior years which listed funding limits for direct costs only.*

Cost Cap:

Application Submissions With a Single PI:

The application's **total costs** budgeted for the entire period of performance should not exceed **$1.4M**. 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.

Application Submissions With the Partnering PI Option:

The combined **total costs** budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should not exceed **$1.75M**. 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.

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

The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

For Both Options Within This Award Mechanism:

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.

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

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

May be requested for (not all-inclusive):

- Costs for one investigator to travel to two 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 PRCRP Impact Award.
- Travel in support of multi-institutional collaborations.

Must not be requested for:

- Costs for travel to scientific/technical meetings beyond the limits stated above.

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.

When starting the pre-application, applicants will be asked to select the following:

- Select the FY25 PRCRP portfolio addressed by the proposed research.
- Select the primary FY25 PRCRP topic area addressed by the proposed research.
- Select the FY25 portfolio classification and strategic goal to be studied.
- When applicable, a secondary FY25 PRCRP topic area should be selected. The secondary topic area may be any topic regardless of selected portfolio. Examples include, (not all-inclusive):
    - Applications addressing more than one cancer type should select the two most applicable.
    - Applications addressing a topic area that is the subtype of another topic area (e.g. Lymphoma and Blood Cancers) should select both.
    - Applications addressing a cancer type in PAYAC populations, should select both the cancer type and the PAYAC topic area.
    - Applications addressing metastatic disease in a cancer type should select both the metastatic disease and cancer type category.
- Select the FY25 PRCRP Military Health Focus Area to be studied.

Note: Upload documents as individual PDF files unless otherwise noted.

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

  The Preproposal Narrative should include the following:

    - **Background:** State the FY25 PRCRP Topic Area(s) and FY25 PRCRP Strategic Goal to be studied.

- **Research Idea:** Describe the rationale and hypothesis and how these support the study's objectives and specific aims.
- **Preliminary Data:** Demonstrate how the research is based on strong preliminary data.
- **Research Strategy:** Describe the methodology and experimental design and explain how they support the project's goals. If a clinical trial will be included, briefly describe the study including the intervention, study population, primary endpoints, and phase of the trial. Describe the strategy to initiate the clinical study within the first year of the award. (Refer to the definition of a clinical trial in Section 3.1.2.).
- **Impact:** Describe the ***potential near-term impact*** of the proposed research on at least one of the FY25 PRCRP Topic Areas.
- **Relevance to Military Health:** Explain how the proposed research will lead to promising outcomes for one or more of the selected FY25 PRCRP Military Health Focus Area(s).

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:
  - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
  - **Key Personnel Biographical Sketches:** ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

4.3. Step 2: Full Application Components

Applicants must receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

Partnering PI Option (IPA-PPIO): The CDMRP requires separate full application package submissions for the Initiating PI and Partnering PI, even if the PIs are located within the same organization. The partnering PI's application is an abbreviated package specific to their distinct portion of the research project. Be advised, all associated applications for a research project may be withdrawn if the initiating or partnering application is rejected or administratively withdrawn.

4.3.1. Full Application Components for the PI or Initiating PI

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 (10-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information 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. ***Inclusion of preliminary data is required***.

  - **Background:** Describe how the proposed project addresses an FY25 PRCRP topic area and corresponding FY25 PRCRP strategic goal. Briefly state how the project addresses an FY25 PRCRP Military Health focus area(s). Additional Detail about the Military Health focus area must be described in Attachment 6.
  - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
  - **Specific Aims:** State the specific aims of the study.
  - **Research Strategy:**
    - Describe the proposed study in sufficient detail to evaluate its appropriateness and feasibility to test the hypothesis and reach the final objective.
    - Include preliminary data and reconcile it with objectives of the research proposed. Demonstrate how the research is based on strong preliminary data and/or previous clinical and/or translational research outcomes. Preliminary data such as published or unpublished results from the laboratory and/or clinic of the PI(s) or collaborators named on this application must be included.
    - Provide a well-developed, well-integrated, and detailed research plan that supports the translational feasibility and promise of the approach. ***Additional details regarding the translational feasibility for clinical studies must be outlined in Attachment 8.***
    - Describe all animal studies and how the studies are designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used, if applicable. Additional detail on animal studies must be described in **Attachment 9**.
    - Demonstrate the availability of tissue, data, or human subjects for the collection of samples, if applicable. If human subjects or human anatomical samples will be used, include a plan for the recruitment of subjects or the acquisition of samples and document the experience of the PI(s) and/or key collaborators in recruiting human subjects for similar projects.
    - If a clinical trial will be included, briefly describe the study including the intervention, study population, primary endpoints, and phase of the trial. Describe the strategy to initiate the clinical study within the first year of the award. (Refer to the definition of a clinical trial in Section 3.1.2.) ***Additional details regarding the Clinical Trial Strategy must be outlined in Attachment 8.***

- Describe potential problems and potential pitfalls and address alternative approaches.
- Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA), if applicable.
- Statistical Plan and Data Analysis for all applications must be submitted in Attachment 10.

- **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 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.

  – **Sex as a Biological Variable Strategy (two-page limit is recommended)**: Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected

and disaggregated by sex. If needed, provide a strong rationale for proposing a single-sex study, based on justification from scientific literature, preliminary data, or other relevant considerations. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.

- **Inclusion Enrollment Plan *(only required if clinical research is proposed)*:** Provide an anticipated enrollment table(s) 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 Institutional Review Board [IRB] review) are exempt from this requirement.
- **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 on Data & Resources Sharing for more information about CDMRP's expectations for making data and research resources publicly available.
- **Use of DOD Resources or VA Resources *(if applicable)*:** 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 3, for additional considerations.

- **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:** State the FY25 PRCRP Topic Area(s) and Strategic Goal to be addressed by the proposed research. Present the ideas and reasoning behind the proposed work, and briefly describe the previous clinical and/or translational research outcomes upon which the study is founded. If applicable, describe the clinical trial to be performed.
  - **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.
- **Clinical Trial:** If applicable describe the clinical trial to be performed.
- **Impact:** Briefly describe how the proposed project will have a near-term impact on a critical scientific or clinical problem in at least one of the FY25 PRCRP Topic Areas.
- **Relevance to Military Health:** Identify the FY25 PRCRP Military Health Focus Area(s) to be studied. Briefly describe how the proposed research is relevant to active-duty Service Members, Veterans, and other military beneficiaries.

○ **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.

- State the FY25 PRCRP Topic Area(s) and FY25 Strategic Goal to be addressed by the research project.
- Describe the scientific objective and rationale for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine***.
- If applicable, describe the clinical trial to be performed.
- Describe the near-term impact for patients and ultimate applicability of the research. What is the projected time it may take to achieve a patient-related outcome?
- Describe what types of patients will it help, and how will it help them. What are the potential clinical applications, benefits and risks?
- State the FY25 PRCRP Military Health Focus Area(s) to be addressed by the research project. Describe how the proposed research is relevant to active-duty Service Members, Veterans, and other military beneficiaries.

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

For the Impact Award, refer to either the "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work" or "Example: Assembling a Generic Statement of Work", whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW.

Partnering PI Option: ***Each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and the Partnering PI should be clearly noted for each task.***

○ **Attachment 6: Relevance to Military Health Statement (one-page limit): Upload as "MilHealth.pdf".** ***The Relevance to Military Health Statement will be evaluated by the FY25 PRCRP Programmatic Panel during programmatic review only.***

- State the FY25 PRCRP Military Health focus area(s) to be addressed in the study.

- Based on published literature of the impact of cancer on military populations, articulate the relevance of the research proposed and show how it will decrease the burden of cancer on Service Members, their Families, and Veterans.
- If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- Identify the environmental and/or occupational exposure risk factors associated with the FY25 PRCRP Topic Area(s) to be studied and their short- and long-term impact on the basic health, welfare and/or psychosocial wellness of active-duty Service Members, Veterans, and other military beneficiaries.

  or

- Identify how the proposed research will support mission readiness through filling a gap in cancer prevention, early detection/diagnosis, prognosis, treatment, quality of life and/or survivorship that may have a profound impact on the health and well-being of Service Members, their Families, Veterans, or other beneficiaries.
- Articulate how the proposed research will advance the knowledge and understanding of cancer, patient care, and/or treatment options in the MHS for the benefit of active-duty Service Members, Veterans and other military beneficiaries.
- Describe the anticipated short-term and/or long-term outcomes of the proposed research and their potential impact on the basic health, welfare and/or psychosocial wellness of active-duty Service Members, Veterans, and other military beneficiaries.

- **Attachment 7: Impact Statement (one-page limit): Upload as "Impact.pdf". *The Impact Statement should be written in plain language for lay persons.***
  - State how the research will accelerate promising findings toward clinical applicability and leverage results to maximize impact. State explicitly how the proposed work addresses a critical problem in at least one of the FY25 PRCRP Topic Areas.
  - State the FY25 PRCRP Strategic Goals to be studied and describe how the research will make a near-term impact.
  - Explain how the application's specific research goals would fit into the pathway of achieving clinical applicability.
  - If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- **Attachment 8: Clinical Strategy Statement, *if applicable* (no page limit): Upload as "Clinical.pdf". If funds for a clinical trial are requested, this attachment is required.**
  - Describe the rationale for the proposed clinical trial. Provide a description of the intervention and the endpoints to be measured. Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.
  - If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically, identify the portions of the study that would be supported with funds from this award.

- Provide detailed plans for initiating the clinical study within the first year, including FDA Investigational New Drug/Investigational Device Exemption application submission plans within 60 days of the award, if applicable. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- Indicate the access to the study population, recruitment plans and inclusion/exclusion criteria. Describe the strategy for the inclusion of women and minorities 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.
- Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race and ethnicity using the PHS Inclusion Enrollment Report, which is a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. Use the form to describe plans for the valid analysis of group differences on the basis of sex, race and/or ethnicity as appropriate for the scientific goals of the study.
- If applicable, describe the process for obtaining informed consent from human subjects and provide a draft, in English, of the Informed Consent Form.

- **Attachment 9: Animal Research Plan (three-page limit), *if applicable* (no page limit): Upload as "AnimalResPlan.pdf".**

  If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. Consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at https://arriveguidelines.org/arrive-guidelines. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the Institutional Animal Care and Use Committee (IACUC). The Animal Research Plan should address the following points to achieve reproducible and rigorous results for each proposed animal study:

  - Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.
  - Summarize the procedures to be conducted. Describe how the study will be controlled.
  - Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
  - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
  - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).

- **Attachment 10: Statistical Plan and Data Analysis (five-page limit): Upload as "Stats.pdf".** ***All applicants are required to submit a Statistical Plan and Data Analysis.***
  - Describe the statistical methodology and plan including how it supports the stated hypothesis or objective.
  - If an existing dataset is to be used, describe the dataset and how it supports the aims of the project.
  - State the inclusion and exclusion criteria for the subjects with sound rationale for the criteria, if applicable.
  - Describe the power analysis and whether it determined population numbers; if not, justify why the power analysis is not essential to the statistical evaluation.
  - State whether the study will include univariate, bivariate, or multivariate analyses.
  - State the variables to be used in the main analysis; include covariates and how the data will be adjusted to account for covariates, if applicable.
  - Stratification of data (if applicable) should be described and justified.
  - Describe how the study will conform to HIPAA, the 1996 Health Insurance Portability and Accountability Act, if applicable.
  - Explain data capture, verification, disposition, if applicable.
  - Describe how data will be evaluated for reproducibility and adjusted for confounding variables.
  - Articulate how large datasets will be evaluated, if applicable. For laboratory projects, describe the organization and maintenance of large datasets, if applicable.
- **Attachment 11: Letters Confirming Access to Target Military or VA Patient Population(s) or Resource(s) (e.g., Human Anatomical Substances, Databases*), if applicable* (one-page limit per letter): Upload as "Access.pdf".** If the proposed research plan involves access to active-duty military and/or VA patient population(s) or resource(s), include a letter of support, signed by the lowest-ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s). Refer to the General Application Instructions, Appendix 3, for additional considerations.
- **Attachment 12: Post-Award Transition Plan (three-page limit): Upload as "Transition.pdf".**

  Describe/discuss the methods and strategies proposed to move the research products to the next phase of development after successful completion of the award. Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development. The post-award transition plan should include the components listed below:

- Details of the funding strategy to transition to the next level of development. Include a description of collaborations and other resources that will be used to provide continuity of development.
- For knowledge products, a description of collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. (A "knowledge product" is a non-materiel product that addresses an identified need, topic area, or capability gap; is based on current evidence and research; aims to transition into medical practice, training or tools or to support materiel solutions [systems to develop, acquire, provide, and sustain medical solutions and capabilities]; and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.)
- A brief schedule and milestones for transitioning the intervention to the next level of development.
- Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government's ability to access such products or technologies in the future.

- **Attachment 13: Partnership Statement, *if applicable* (two-page limit): Upload as "Partner.pdf".**

  For Partnering PI Option only, describe how the partners' combined experience will better address the research question and explain why the work should be done together rather than through separate efforts.
- **Attachment 14: 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 15: 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 Science Experts Network Curriculum Vitae (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.

Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s) even if they are located within the same organization. Individual awards will be made to each PI. Refer to Section 3.4, Funding Details, for detailed information.

(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".

4.3.2. Full Application Components for the Partnering PI (if applicable)

Refer to the equivalent attachment above for details specific to each of the following application components. See Appendix 1 for a checklist of the full application components required for the Partnering PI.

(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.

NOTE: Enter the eBRAP log number assigned during pre-application submission into Block 4a – Federal Identifier Box

(b) Attachments:

- **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.
- **Attachment 14: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".**
- **Attachment 15: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

(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.

(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):** Upload as "BudgetJustification.pdf".

Initiating and Partnering PI must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Individual awards will be made to each PI. Refer to Section 3.4, Funding Details, for detailed information.

(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 through Grants.gov.

- **Intramural DOD Subaward:** Complete the "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled IGBudget.pdf to Grants.gov.

4.4. Other Application Elements

- If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DoD Instructions 3200.12 will be requested.
- 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 HT942525PRCRPIPA from Grants.gov or eBRAP, depending on which submission portal will be used.

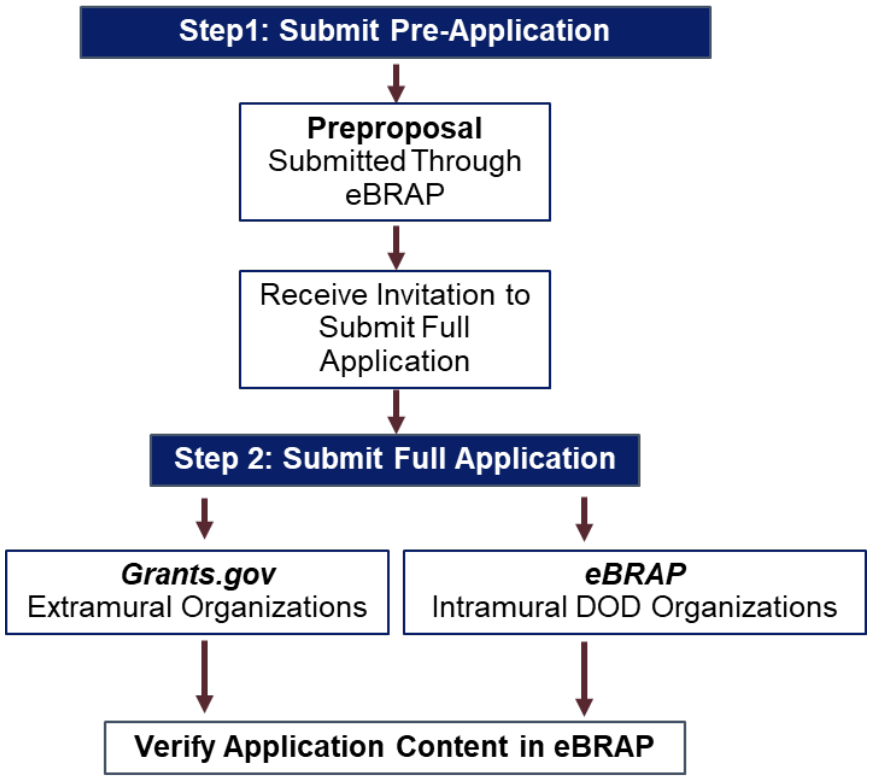
5.2. Unique Entity Identifier and System for Award Management

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 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.

IPA-PPIO: After the Initiating PI confirms submission of the pre-application, the Partnering PI[(s)] will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PI[(s)] must follow the link in the notification email to associate the partnering pre-application with their eBRAP account and confirm their organization and Business Official information.*** If not previously registered, the Partnering PI[(s)] must register in eBRAP.

Partnering PIs should not initiate a new pre-application based on the same research project submitted by the Initiating PI. Partnering PIs are urged to associate the partnering pre-application with their eBRAP account as soon as possible. If this is not completed by the full application deadline:

- The Partnering PI will not be able to view and modify their full application during the verification period in eBRAP.
- Any intramural Partnering PI will not be able to submit their full application package components to eBRAP.

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:
No Clinical Trial, No Partnering PI	No Option
Clinical Trial, No Partnering PI	Clinical Trial Option
No Clinical Trial, Partnering PI	Partnering PI Option
Clinical Trial, Partnering PI	Clinical Trial Option – Partnering PI Option

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 PRCRP 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 PRCRP 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

To determine the technical merits of the pre-application and the relevance to the mission of the Defense Health Program and the PRCRP, pre-applications will be screened based on the following criteria:

- Whether the proposed project addresses at least one of the FY25 PRCRP Topic Areas and at least one corresponding FY25 PRCRP Strategic Goal, and to what degree the research will lead to a breakthrough or make an impact.
- How well the rationale, hypothesis, proposed methodology, and experimental design support the study's objectives and specific aims.
- Whether the proposed research will have a near-term impact on a critical scientific or clinical problem.
- If a clinical trial is proposed, whether the proposed intervention, population, and end points are appropriate.
- To what degree the proposed research may lead to promising outcomes for one or more of the selected FY25 PRCRP Military Health Focus Areas.

6.2.2. Peer Review Criteria

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

- **Research Strategy and Feasibility**
  - How well the hypothesis, specific aims, the scientific rationale, experimental design, methods, data collection procedures and analyses are developed and support completion of the proposed aims.
  - If human subjects, human biological samples, or datasets will be used, how well the studies are designed to achieve reproducible and rigorous results and whether the application provides evidence of availability of, and access to, the necessary study populations and/or resources.
  - If applicable, whether the application includes a feasible plan for the recruitment of human subjects or the acquisition of samples and provides evidence of availability of, and access to, the necessary study populations and/or resources.
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study or whether the justification for a single sex study is sufficiently strong.
  - How well the application acknowledges potential problems and addresses potential pitfalls and alternative methods and approaches.
  - If applicable, how well the application describes how data will be reported and how it will fulfill a regulatory documentation for the FDA.
  - If applicable, whether the application describes the strategy for the inclusion of women and minorities that is appropriate for 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 women and minorities are excluded, to what extent the application provided a justification.
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study or whether the justification for a single sex study is sufficiently strong.
- **Impact**
  - Whether the application explicitly states how the proposed work addresses at least one of the FY25 PRCRP Topic Areas and a corresponding FY25 Strategic Goal and describes how the study will make an impact on the selected goal.
  - If successful, to what degree the research may have a near-term impact on scientific research or patient outcomes.
  - Whether the application demonstrated a pathway to accelerate promising findings toward clinical applicability to have maximize impact.
  - Whether the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- **Clinical Trial Strategy (applicable for applications proposing funding for a clinical trial)**
  - How well the rationale for the proposed clinical trial is supported.

- How well the clinical trial portion of the application is designed with appropriate study variables, controls, endpoints, and data analysis plan.
- Whether the application demonstrates access to a well-defined and appropriate study population, has achievable recruitment goals, and documents the experience of the PI and/or key collaborators in recruiting human subjects for similar projects.
- Whether the strategy for the inclusion of women and minorities and the distribution of proposed enrollment are appropriate for the proposed research, 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.
- Whether an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race, and ethnicity is included.
- Whether the application describes plans for the valid analysis of group differences on the basis of sex, race, and/or ethnicity that are appropriate for the scientific goals of the study.
- Whether the process for obtaining Informed Consent and the Informed Consent Document are adequately disclosing information, including study risks.
- Whether sufficient evidence is provided to support initiation of the clinical study within the first year.
- Whether plans for data reporting are sufficient for the proposed clinical trial, and whether the data will support a regulatory filing with the FDA, if applicable.

- **Statistical Plan and Data Analysis**
  - To what extent the statistical methodology and plan supports the stated hypothesis or objective.
  - If applicable, how well the described dataset supports the aims of the project.
  - If applicable, whether the inclusion and exclusion criteria for the subjects are sound. How well the application describes the power analysis and whether it determined population numbers. If applicable, how well the application justified why a power analysis is not essential to the statistical evaluation.
  - Whether the application states if the analyses will be univariate, bivariate, or multivariate.
  - How well the variables are described and how well any covariates are identified (if applicable). How well the application accounts for covariates and whether the adjustment is justified (if applicable).
  - If applicable, how well the stratification of data is described and if it is justified.
  - How well the application explains the data capture, verification and disposition, if applicable.
  - If applicable for laboratory projects, to what extent evaluations to be made, storage of samples, and organization and maintenance of large datasets are described and justified.
  - To what extent the data have been evaluated for reproducibility and adjusted for confounding variables.
  - Whether there is a plan to evaluate large datasets, if applicable.

- **Post-Award Transition Plan**
  - Whether the application describes the anticipated research outcomes (e.g., knowledge products, clinical products for development).
  - How well the application demonstrates methods (e.g., funding opportunities, collaborations, and intellectual property rights) to move the anticipated research outcomes to the next phase of development or clinical application after successful completion of the project.
  - To what degree the application offers a well laid-out strategy to transition to the next level of investigation, development, and/or commercialization.
- **Personnel**
  - How appropriate the levels of effort are for successful conduct of the proposed work.
  - How well the PI's record of accomplishment demonstrates their ability to perform the proposed work.
  - How appropriate the PI and research team's background and expertise are with regard to their ability to accomplish the proposed work.

For applications submitted under the **Partnering PI Option**:

- **Partnership**
  - How well the research project is supported by the nature of the collaboration.
  - How well the application demonstrates that the combined clinical background and experience of the partnering investigator will enhance the application's impact on patient outcomes.
  - To what extent the PIs' unique expertise, combined as a partnership, will better address the research question rather than through separate efforts.
  - How well the skills and perspectives of the Initiating and Partnering PIs complement each other, bring different strengths to the project and are critical for the research strategy and completion of the SOW.
  - How well the application reflects the requirement that the partners have equal intellectual input into the design of the project.

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.
- **Environment**
  - To what extent the scientific environment is appropriate for the proposed research project, to include the quality and level of institutional support and the availability of and accessibility to facilities and resources.
- **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 PRCRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity.
  - Relative impact.
  - Program portfolio composition.
  - Programmatic relevance to the FY25 PRCRP Military Health Focus Areas.
  - Programmatic relevance to the FY25 PRCRP Strategic Goals as outlined in the FY25 PRCRP portfolio categories.

6.3. Application Review and Selection Process

6.3.1. Pre-Application

Following the pre-application screening, Initiating PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section 1, Basic Information about the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

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 PRCRP 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.

Funded trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Additionally, the CDMRP requires all funded Applicable Clinical Trials to register on ClinicalTrials.gov. Additional data reporting requirements will also apply to Applicable Clinical Trials supported under this funding opportunity. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

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 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 Award Expiration Transition Plan, using the template available on eBRAP, must be submitted with the final progress report.

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.

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

Unless otherwise restricted, changes in the PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

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

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.

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_01d. The program announcement numeric version code will match the General Application Instructions version code CD25_01.

9.2. Administrative Actions

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

9.2.1. Rejection

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

- Preproposal Narrative is missing.

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

- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter of invitation was not issued.

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 PRCRP 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 invited application proposes a different research project than that described in the pre-application.
- The PI does not meet the eligibility criteria.
- The pre-application or application does not address at least one of the FY25 PRCRP Topic Areas.
- The pre-application or application does not address at least one of the FY25 PRCRP Military Health Focus Areas.
- The pre-application or application does not address at least one of the FY25 PRCRP Strategic Goals as outlined in the FY25 PRCRP portfolio categories.
- The application addresses an FY25 strategic goal from a portfolio that does not include the FY25 topic area being addressed.
- The pre-application or application does not adhere to congressional language and includes a cancer that originates in the breast, prostate, or ovary, or rare cancers (excluding relevant subtypes of the FY25 PRCRP topic areas), or melanoma as part of the research study.
- An application proposing a clinical trial where Attachment 8, Clinical Strategy Statement, is missing.
- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.

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	
	PI/Initiating PI	Partnering PI
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"	☐	☐
Relevance to Military Health Statement – Attachment 6, Upload as "MilHealth.pdf"	☐	
Impact Statement – Attachment 7, upload as "Impact.pdf"	☐	
Clinical Strategy Statement ***(if applicable)*** **– Attachment 8, upload as "Clinical.pdf"**	☐	
Animal Research Plan – Attachment 9, upload as "AnimalResPlan.pdf"	☐	
Statistical Plan and Data Analysis – Attachment 10, upload as "Stats.pdf"	☐	
Letters Confirming Access to Target Military or VA Patient Population(s) or Resource(s) ***(if applicable)*** **– Attachment 11, upload as "Access.pdf"**	☐	
Post-Award Transition Plan – Attachment 12, upload as "Transition.pdf"	☐	
Partnership Statement – Attachment 13, upload as "Partner.pdf"	☐	
Representations ***(Grants.gov submissions only)*** **– Attachment 14, upload as "RequiredReps.pdf"**	☐	☐
Suggested Intragovernmental Budget Form ***(if applicable)*** **– Attachment 15, upload as "IGBudget.pdf"**	☐	☐
Research & Related Personal Data	☐	

Full Application Components	Uploaded	
	PI/Initiating PI	Partnering PI
Research & Related Senior/Key Person Profile (Expanded)	☐	
Attach Biographical Sketch for PI and Senior/Key Persons (Biosketch_LastName.pdf)	☐	
Attach Current and pending (other) support for PI and Senior/Key Persons (Support_LastName.pdf)	☐	
Budget **Include budget justification**	☐	
Project/Performance Site Location(s) Form	☐	
Research & Related Subaward Budget Attachment(s) Form (*if applicable)*	☐	

Appendix 2. Acronym List

ARRIVE	Animal Research: Reporting In Vivo Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DTC	Disseminated Tumor Cells
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
HIPAA	Health Insurance Portability and Accountability Act
IACUC	Institutional Animal Care and Use Committee
IPA	Impact Award
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
NSF	U.S. National Science Foundation
OHARO	Office of Human and Animal Research (previously Office of Research Protections)
OUSD R&E	Office of the Under Secretary of Defense for Research and Engineering
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
PPIO	Partnering PI Option
PRCRP	Peer Reviewed Cancer Research Program
RPPR	Research Performance Progress Report
SAM	System for Award Management
SciENcv	Science Experts Network Curriculum Vitae
SOW	Statement of Work
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

Appendix 3. DOD and VA Websites

Air Force Office of Scientific Research
https://www.afrl.af.mil/AFOSR/

Air Force Research Laboratory
https://www.afrl.af.mil/

Armed Forces Radiobiology Research Institute
https://afrri.usuhs.edu/home

Combat Casualty Care Research Program
https://cccrp.health.mil/

Congressionally Directed Medical Research Programs
https://cdmrp.health.mil/

Defense Advanced Research Projects Agency
https://www.darpa.mil/

Defense Health Agency
https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/

Defense Suicide Prevention Office
https://www.dspo.mil/

Defense Technical Information Center
https://www.dtic.mil/

Defense Threat Reduction Agency
https://www.dtra.mil/

Military Health System Research Symposium
https://mhsrs.health.mil/sitepages/home.aspx

Military Infectious Diseases Research Program
https://midrp.health.mil/

Military Operational Medicine Research Program
https://momrp.health.mil/

Navy Bureau of Medicine and Surgery
https://www.med.navy.mil/

Naval Health Research Center
https://www.med.navy.mil/Naval-Medical-Research-Command/R-D-Commands/Naval-Health-Research-Center/

Navy and Marine Corps Public Health Center
https://www.med.navy.mil/Navy-and-Marine-Corps-Force-Health-Protection-Command/

Naval Medical Research Command
https://www.med.navy.mil/Naval-Medical-Research-Command/

Office of Naval Research
https://www.med.navy.mil/

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics
https://www.acq.osd.mil/

Telemedicine and Advanced Technology Research Center
https://www.tatrc.org/

Uniformed Services University of the Health Sciences
https://www.usuhs.edu

U.S. Army Aeromedical Research Laboratory
https://usaarl.health.mil/

U.S. Army Combat Capabilities Development Command
https://www.army.mil/devcom

U.S. Army Institute of Surgical Research
https://usaisr.health.mil/

U.S. Army Medical Research and Development Command
https://mrdc.health.mil/

U.S. Army Medical Research Institute of Infectious Diseases
https://usamriid.health.mil/

U.S. Army Research Institute of Environmental Medicine
https://usariem.health.mil/

U.S. Army Research Laboratory
https://www.arl.army.mil/

U.S. Army Sharp, Ready and Resilient Directorate
https://www.armyresilience.army.mil/sharp/index.html

U.S. Department of Defense Blast Injury Research Program
https://blastinjuryresearch.health.mil/

U.S. Department of Veterans Affairs, Office of Research and Development
https://www.research.va.gov/

U.S. Naval Research Laboratory
https://www.nrl.navy.mil/

Walter Reed Army Institute of Research
https://wrair.health.mil/