Program Announcement for the Department of Defense
Defense Health Program

Peer Reviewed Medical Research Program

Clinical Trial Award

Funding Opportunity Number: HT942525PRMRPCTA

Pre-Application Due: June 9, 2025

Application Due: July 21, 2025

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

Content

Before You Begin 3

1 **Basic Information** 4
Contains a summary of the funding opportunity, funding details, and submission/review dates

2 **Eligibility** 5
Details the factors that determine applicant organization and Principal Investigator eligibility

3 **Program Description** 6
Describes the program mission and intent of the Clinal Trial Award, provides key award information and considerations, and outlines funding restrictions

4 **Application Contents** 17
Introduces the two-step application process and provides instructions for preparing a pre-application and full application

5 **Submission Requirements** 31
Provides locations for application packages, instructions for submitting pre-applications and full applications, and describes application verification

6 **Application Review Information** 34
Outlines the processes associated with application compliance review, pre-application and full application selection/notification, and risk assessment. Also details the complete review criteria for pre-application screening and both tiers of the CDMRP's application review process, Peer Review and Programmatic Review

7 **Federal Award Notices** 40
Outlines what a successful applicant can expect to receive if recommended for funding

8 **Post-Award Requirements** 41
References policy requirements for funded research, outlines reporting requirements, and restrictions related to Principal Investigator changes or institutional award transfers

9 **Other Information** 43
Outlines criteria for administrative actions including application rejection, modification, withdrawal and withhold

Appendix 1 45
Includes a checklist for all full application components to facilitate application submission

Appendix 2 46
Acronym List

Appendix 3 48
DOD and VA Websites

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 Medical Research Program (PRMRP) Clinical Trial Award (CTA) supports the rapid implementation of clinical trials with the potential to have a significant impact on the treatment or management of a disease or condition addressed in one of the congressionally directed FY25 PRMRP topic areas and FY25 PRMRP strategic goals.

Distinctive Features:

- **Clinical trials are required.**
- **Animal studies are NOT allowed under this award mechanism.** All preclinical work must be completed prior to the award start date.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $32 million (M) to fund approximately 4 Clinical Trial Award applications with total cost caps of $8M. The maximum period of performance is 4 years. It is anticipated that awards made from this FY25 funding opportunity will be funded with FY25 funds, which will expire for use on September 30, 2031. Awards supported with FY25 funds will be made no later than September 30, 2026.

Submission and Review Dates and Times

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern Time (ET), June 9, 2025
- **Application Submission Deadline:** 11:59 p.m. ET, July 21, 2025
- **End of Application Verification Period:** 5:00 p.m. ET, July 28, 2025
- **Peer Review:** September/October 2025
- **Programmatic Review:** December 2025

Announcement Type: Initial

Funding Opportunity Number: HT942525PRMRPCTA

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 non-profit 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

Investigators at or above the level of Assistant Professor (or equivalent) may be named by the organization as the Principal Investigator (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.

Each investigator may be named on only one FY25 PRMRP application as a PI, which includes the FY25 PRMRP CTA and the FY25 PRMRP Technology/Therapeutic Development Award (HT942525PRMRPTTDA). If more than one Letter of Intent (LOI) is submitted by the PI to the FY25 PRMRP, the first submission will be accepted, and the second will be administratively withdrawn.

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 PRMRP. Congress initiated the PRMRP in 1999 to support medical research projects of clear scientific merit and direct relevance to military health. Appropriations for the PRMRP from FY99 through FY24 totaled $4.19 billion. The FY25 appropriation is $150M.

The vision of the PRMRP is to improve the health, care, and well-being of all military Service Members, and their Families and Veterans, and its mission is to encourage, identify, select and manage medical research projects of clear scientific merit that lead to impactful advances in health care of Service Members, Veterans, and their Families. The PRMRP challenges the scientific and clinical communities to address the congressionally mandated FY25 PRMRP topic areas with original ideas that foster new directions along the entire spectrum of research and patient care.

3.1. Clinical Trial Award History

The PRMRP first offered the CTA mechanism in FY08. From FY20 through FY24, the PRMRP included a planning phase option for the CTA.

3.2. Intent of the Clinical Trial Award

The PRMRP CTA supports the rapid execution and analysis of clinical trials with the potential to have a significant impact on the treatment or management of a disease or condition addressed in one of the congressionally directed FY25 PRMRP topic areas and FY25 PRMRP strategic goals. Clinical trials may be designed to evaluate promising new products, pharmacologic agents (drugs, biologics, or medical devices), clinical guidance, non-pharmacological interventions, and/or emerging approaches and technologies. Proposed projects may range from small proof-of-concept trials (i.e., pilot, first-in-human, phase 0) to demonstrate the feasibility or inform the design of more advanced trials through large-scale trials, including comparative effectiveness trials that will transform and revolutionize care for the diseases and conditions addressed in the FY25 PRMRP Topic Areas.

Apply the following four questions to determine whether the PRMRP would consider a research study to be a clinical trial:

- Does the study involve human participants?
- Are the participants prospectively assigned to an intervention?
- Is the study designed to evaluate the effect of the intervention on the participants?
- Is the effect being evaluated a health-related biomedical or behavioral outcome?

If the answer to all four questions is “yes,” then the clinical study would be considered a clinical trial.

Animal studies are NOT allowed under this award mechanism. All preclinical work must be completed prior to the award start date.

The PRMRP CTA is intended to support the rapid implementation of clinical trials. For those that require Regulatory Agency oversight, approval or exemption is expected to be in place **before the proposed award start date**. The proposed clinical trial must address one of the FY25 PRMRP topic areas and one of the FY25 PRMRP strategic goals. Patient recruitment for the clinical trial is expected to begin no later than **9 months** after the award date.

- If the proposed clinical trial involves the use of a drug that has not been approved by the relevant Regulatory Agency for the country where the research will be conducted, then submission of an Investigational New Drug (IND) application, or equivalent, that meets all requirements under 21 CFR 312 may be required. It is the responsibility of the applicant to provide evidence from the Institutional Review Board (IRB) of record or the relevant Regulatory Agency if an IND, or equivalent, is not required. If an IND, or equivalent, is required, the regulatory application must be submitted to the relevant regulatory agency by the FY25 PRMRP CTA full application submission deadline. The IND, or equivalent, should be specific for the product and indication to be tested in the proposed clinical trial. For more information on IND applications specifically, review the U.S. Food and Drug Administration (FDA) guidance. If the investigational product is a device, then submission of an Investigational Device Exemption (IDE), or equivalent, application that meets all requirements under 21 CFR 812 may be required. It is the responsibility of the applicant to provide evidence if an IDE, or equivalent, is not required. If an IDE, or equivalent, is required, the IDE application, or equivalent, must be submitted to the relevant Regulatory Agency by the FY25 PRMRP CTA full application submission deadline. The IDE, or equivalent, should be specific for the device and indication to be tested in the proposed clinical trial.
- If an IND/IDE, or equivalent, is required, the application, or equivalent, must be approved/cleared/authorized by the relevant Regulatory Agency before the award start date. The government reserves the right to withdraw funding if an active IND or IDE and/or international regulatory approval is necessary, but an application has not been submitted prior to the application submission deadline and is not in place prior to the award start date.
- Research milestones to be accomplished throughout each phase of the clinical trial must be clearly defined in the project Statement of Work (SOW) and will be finalized during negotiations. The government reserves the right to fund the clinical trial under a base award and subsequent optional research phases. Continued funding of the clinical trial and approval of research options will be contingent upon meeting mutually agreed upon milestones and goals as determined by the USAMRAA Grants Officer.

3.2.1. FY25 Topic Areas and Strategic Goals

To meet the intent of the funding opportunity, ***all applications for FY25 PRMRP funding must specifically address one of the FY25 PRMRP topic areas as directed by the U.S. Congress and have direct relevance to military health***. Additionally, the PRMRP implements a portfolio-driven approach by grouping related topic areas with strategic goals as a framework within which to address critical gaps in major research areas. ***All applications must address one of the FY25 PRMRP strategic goals as it relates to the portfolio-assigned FY25 PRMRP topic area.*** If the proposed research does not specifically address one FY25 PRMRP topic area and one FY25 PRMRP strategic goal, then the government reserves the right to administratively withdraw the application. The government reserves the right to reassign the application's topic area if submitted to an incorrect topic area. The section below lists the FY25 PRMRP topic areas and strategic goals for each PRMRP portfolio category.

FY25 PRMRP Portfolio Categories with Associated FY25 PRMRP Topic Areas and FY25 PRMRP Strategic Goals

AUTOIMMUNE DISORDERS AND IMMUNOLOGY

All applications under this portfolio must be aligned to Autoimmune Disorders and Immunology by addressing one topic area and one strategic goal listed below.

TOPIC AREAS

- Celiac Disease
- Eczema
- Food Allergies
- Guillain-Barré Syndrome
- Inflammatory Bowel Disease
- Multiple Sclerosis
- Proteomics
- Scleroderma

STRATEGIC GOALS

Prevention

- Develop and test strategies to prevent the onset, relapse and/or progression of the disease/condition.

Diagnosis

- Develop innovative noninvasive methods (e.g. biomarkers, multi-omics approaches) for the diagnosis and continuous monitoring of inflammation.
- Develop tools to assess neurologic outcomes of the disease/condition.

Treatment

- Develop and test new or improved treatments, including therapeutic and/or lifestyle interventions, to improve outcomes, reduce inflammatory responses, promote tissue healing, provide neuroprotection/repair, improve/delay symptom onset, minimize toxicity, reduce the effects of disease/condition sequelae, and/or mitigate immune-mediated disease/condition states.
- Parallel to treatment development, develop/validate methods (e.g. clinical biomarkers) to evaluate treatment response and/or mechanism of action of a therapeutic intervention.

Epidemiology

- Conduct patient-centered research on onset, exacerbation, outcomes, treatment preferences, and quality of life measures.
- Conduct population-based studies to identify risk factors that contribute to onset and/or progression of the disease/condition and its comorbidities.
- Conduct research to better understand and decrease disparities in incidence and/or outcomes in populations affected disproportionately or differently.
- Conduct research, including natural history and longitudinal studies, to better understand incidence, prevalence, diagnosis rates, treatment regimens, and/or progression of the disease/condition.

CARDIOVASCULAR HEALTH

All applications under this portfolio must be aligned to Cardiovascular Health by addressing one topic area and one strategic goal listed below.

TOPIC AREAS

- Cardiac Health
- Congenital Heart Disease
- Proteomics

STRATEGIC GOALS

Prevention

- Develop strategies to understand and prevent disease onset.
- Develop and test strategies to prevent or reduce the impact of the disease/condition on the heart, brain, arteries, and additional target organs.

Diagnosis

- Develop and test strategies to enable detection before clinical symptoms are apparent.
- Develop and rigorously test novel technologies for accurate diagnosis, predicting clinical outcomes and comorbid conditions, and tracking disease progression, including analytical tools, noninvasive methods and/or screening tools.

Treatment

- Develop and evaluate novel therapeutics or improved treatment regimens.

Epidemiology

- Conduct population-based studies to identify risk factors that contribute to the disease/condition.
- Conduct research to better understand and decrease disparities in incidence and/or outcomes in populations affected disproportionately or differently.

INFECTIOUS DISEASES

All applications under this portfolio must be aligned to Infectious Diseases by addressing <u>one</u> topic area and <u>one</u> strategic goal listed below.

TOPIC AREAS

- Congenital Cytomegalovirus
- Far-UVC Germicidal Light
- Hepatitis B
- Malaria
- Post-Acute Sequelae of SARS CoV-2 Infection
- Proteomics
- Tick-Borne Disease
- Tuberculosis

STRATEGIC GOALS

Prevention

- Develop or optimize vaccine strategies, vaccine platforms, or compounds (including active or passive immunoprophylaxis), to prevent disease onset or inhibit disease progression; research on agile platforms is encouraged.
- Develop strategies to eliminate/reduce maternal-fetal transmission.
- Develop strategies for rapid prediction of protective antigens/epitopes.

Diagnosis

- Identify testable correlates of protection induced by prophylactic treatment or natural infection.
- Develop pathogen-agnostic diagnostic tools/assays, or improve existing next-generation tools, that use noninvasive, patient-derived samples (e.g., urine, sweat, biometrics).

Treatment

- Expand upon current treatments or establish new disease-specific clinical networks for therapeutic drug testing for severe or chronic disease (does not include discovering or testing new chemical entities).
- Develop and test more effective and shorter treatment regimens, including those that address treatment resistance (does not include discovering or testing of new chemical entities).

Epidemiology

- Identify strategies for surveillance or develop modeling tools and/or biomarkers to predict outbreaks or epidemics.

INTERNAL MEDICINE

All applications under this portfolio must be aligned to Internal Medicine by addressing one topic area and one strategic goal listed below.

TOPIC AREAS

- Endometriosis
- Focal Segmental Glomerulosclerosis
- Interstitial Cystitis
- Menopause
- Nephrotic Syndrome
- Pancreatitis
- Polycystic Kidney Disease
- Proteomics
- Reconstructive Transplantation
- Vision

STRATEGIC GOALS

Prevention

- Develop and test strategies to prevent the onset, progression, recurrence, and/or comorbidities of the disease/condition/injury.

Diagnosis

- Develop and test tools or technologies for early detection, accurate diagnosis, or tracking of disease/condition/injury progression, including analytical tools, noninvasive methods, and/or screening tools.
- Conduct prognostic or diagnostic biomarker and genetic studies to better understand and differentiate subtypes, heterogeneity, progression and measuring/monitoring of disease/condition.

Treatment

- Develop and test novel treatments (including but not limited to, new pharmacological interventions, devices, lifestyle/behavioral interventions, and surgical treatment strategies), and/or improve upon existing treatments (includes repurposed drugs, personalized medicine approaches to optimize treatment, and preservation methods for allografts) to improve outcomes (including psychosocial functioning and quality of life).
- Develop and test combination therapy and/or intervention treatment approaches to slow the progression of the disease/condition/injury, restore function, and/or address long-term pain management (includes pharmaceuticals, lifestyle/behavioral changes, devices and surgical interventions).
- Advance the development of artificial organs, including xenobiology research.
- Test efficacy of excision surgical procedures for endometriosis.*
- Develop and test improved treatment strategies that can couple diagnosis and treatment for endometriosis within a single surgery.*

*Multi-institutional partnerships performing complementary endometriosis research are encouraged.

Epidemiology

- Conduct population-based studies to identify risk factors (e.g., medication toxicity, genetic predisposition, infections, environmental exposures) that influence development, progression, and outcomes (including psychosocial functioning and quality of life).
- Conduct population-based studies to inform the development of surrogate endpoints to accelerate approval of new treatments.
- Conduct population-based studies to improve functional-based and patient-reported information to measure treatment outcomes.
- Develop and test the effectiveness of health educational and health tracking programs and platforms to increase awareness for prevention and/or to contribute to shared decision making and treatment preferences.

NEUROSCIENCE AND BEHAVIORAL HEALTH

All applications under this portfolio must be aligned to Neuroscience and Behavioral Health by addressing one topic area and one strategic goal listed below.

TOPIC AREAS

- Autism
- Dystonia
- Eating Disorders
- Hydrocephalus
- Maternal Mental Health
- Myalgic Encephalomyelitis/Chronic Fatigue Syndrome
- Parkinson's
- Peripheral Neuropathy
- Proteomics
- Sleep Disorders and Restrictions
- Suicide Prevention
- Traumatic Brain Injury and Psychological Health

STRATEGIC GOALS

Prevention

- Develop and test the efficacy of strategies (e.g., screening, education programs, counseling, etc.) to prevent or reduce risk factors associated with the disease/condition and/or associated comorbidities.
- Develop and test approaches to maintain optimal cognitive functioning and mental resilience.

Diagnosis

- Improve and validate methods for initial diagnosis, prognostic prediction, and/or real-time monitoring of symptoms for neurological and/or psychological health, which may include developing and testing personalized clinical decision-making tools or objective diagnostic criteria.
- Develop and test strategies to identify and prioritize at-risk individuals who would benefit from screening and/or diagnostic testing.

Treatment

- Develop and evaluate novel pharmacological or nonpharmacological treatments or intervention strategies, which may include repurposing of existing drugs.
- Conduct studies to optimize intervention strategies for improved patient outcomes.

Epidemiology

- Conduct population-based studies to identify risk factors that contribute to disease/condition onset and/or progression.
- Conduct research to better understand and decrease disparities in incidence and/or outcomes in populations affect disproportionately or differently.
- Conduct population-based studies to assess prevalence, medical service usage, and/or quality of life for those affected by the disease/condition.

ORTHOPAEDIC MEDICINE

All applications under this portfolio must be aligned to Orthopaedic Medicine by addressing <u>one</u> topic area and <u>one</u> strategic goal listed below.

TOPIC AREAS

- Orthotics and Prosthetics Outcomes
- Proteomics

STRATEGIC GOALS

Prevention

- Optimize patient-specific rehabilitation regimens, including focus on provider competencies and/or patient training, to mitigate secondary health deficits.

Diagnosis

- Develop and test novel proteomic-based strategies for early and precise diagnosis of orthopaedic conditions.
- Develop and test standardized assessments of joint function following treatment with an orthotic or prosthetic device.

Treatment

- Develop and test proteomics-based strategies to halt/slow orthopaedic disease progression.
- Develop and test computational strategies or artificial intelligence approaches to inform appropriate device choice.
- Optimize and test rehabilitation regimens and/or device use to enhance functionality.
- Evaluate which orthotic and prosthetic interventions can provide the most improvement in health status, functionality, and quality of life.

Epidemiology

- Conduct patient-reported outcomes research to inform device choice; research with a focus on large data sets is encouraged.

RARE DISEASES AND CONDITIONS

All applications under this portfolio must be aligned to Rare Diseases and Conditions by addressing <u>one</u> topic area and <u>one</u> strategic goal listed below.

TOPIC AREAS

- Angelman Syndrome
- Ehlers-Danlos Syndrome
- Epidermolysis Bullosa
- Fibrous Dysplasia/McCune-Albright Syndrome
- Fragile X
- Frontotemporal Degeneration
- Hereditary and Acquired Ataxia
- Hermansky-Pudlak Syndrome
- Mitochondrial Disease
- Myotonic Dystrophy
- Neurofibromatosis
- Proteomics
- Rett Syndrome
- Sickle-Cell Disease
- Tuberous Sclerosis Complex
- Von Hippel-Lindau Disease

STRATEGIC GOALS

Diagnosis

- Identify and validate objective biomarkers to predict onset, response to therapy, disease complications and/or disease progression.
- Develop and validate improved diagnostic criteria and screening tools for early detection, accurate detection, or to track disease progression.
- Determine the physiological impact related to diagnosis and/or timing of a diagnosis.

Prevention

- Develop and test strategies, including advancements in gene therapy, to prevent transmission of rare diseases.

Treatment

- Develop and test pharmacological or nonpharmacological treatments, or improve upon existing treatments, especially those that will minimize side effects.
- Develop and test curative strategies to include tissue engineering, genetic approaches, or protein replacement.
- Develop and test interventions to improve neuropsychological outcomes and cognitive symptoms and other comorbidities as defined by those with lived experience.
- Develop and test strategies to support ongoing treatments during life transitions (i.e., pediatric to adult care).

Epidemiology

- Conduct population-based studies to identify risk (i.e., carrier status), lifestyle determinants of health or protective factors that influence onset, progression and/or outcomes.
- Conduct natural history/longitudinal studies to understand incidence, prevalence, and progression of the disease/condition and carrier and modifier gene status.

- Develop and validate research tools to collect, mine, and integrate real-world data (patient-reported data, longitudinal data, etc.) with electronic medical records to guide precision medicine approaches.
- Develop clinically relevant endpoints for clinical trials.

RESPIRATORY HEALTH

All applications under this portfolio must be aligned to Respiratory Health by addressing one topic area and one strategic goal listed below.

TOPIC AREAS

- Burn Pit Exposure
- Proteomics
- Pulmonary Fibrosis
- Respiratory Health

STRATEGIC GOALS

Prevention

- Develop and test strategies to prevent lung injury caused by trauma, transfusion, mechanical ventilation, infection, or hemorrhagic shock.
- Develop and test interventions to prevent lung diseases following exposure to environmental pollutants and/or occupational respiratory toxicants.
- Develop and test methods and devices to minimize the extent of population exposure to environmental pollutants.

Diagnosis

- Develop and validate physiological sensors to assess environmental pollutants and/or physiological levels of exposure to airborne hazards or toxins.
- Develop a fieldable toolset to monitor lung dysfunction/failure.
- Improve early detection for respiratory illnesses, including developing and validating wearable sensors for early detection of chronic pulmonary diseases.
- Identify biomarkers to diagnose and/or monitor progression of chronic respiratory diseases.

Treatment

- Develop and test novel treatments, including precision medicine approaches, to slow progression and/or promote lung repair.
- Develop improved fieldable systems to treat traumatic/acute lung injury in far forward settings (e.g., miniature and/or semi-automated ventilators or devices that will enable correct airway placement of oxygenation in austere settings).
- Develop and test minimally invasive or noninvasive methods of facilitating gas exchange when the lungs are compromised.

Epidemiology

- Conduct natural history/longitudinal studies to improve understanding of risk factors, outcomes, and disease progression for personalized medicine.

3.2.2. Key Elements for the Clinical Trial Award

When developing the application to the FY25 PRMRP CTA mechanism, applicants are required to provide evidence to demonstrate the following key considerations in addition to items outlined above.

- Availability of, and access to, the study population.
- Intervention access and availability.
- Statistical considerations, data management, and analysis plans appropriate for the proposed research.

- Preliminary data originating from the laboratory of the PI or a member of the research team that is sufficient to demonstrate feasibility of completing the proposed trial and generating interpretable data.
- **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/condition/technology 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 U.S. Department of Veterans Affairs (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 PRMRP topic areas can be found in Appendix 3.

3.2.3. Other Important Considerations for the Clinical Trial Award

Funding from this award mechanism must support a clinical trial. A clinical trial is defined in the Code of Federal Regulations, Title 32, Part 219 (32 CFR 219) 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. Additionally, studies that retrospectively analyze data generated from previously conducted clinical trial(s) are not considered clinical trials.

For more information, a Human Subject Research Resource document is available on the CDMRP website.

Unless otherwise noted, for the purposes of this funding opportunity, Regulatory Agency refers to the FDA or any equivalent international regulatory agency.

If an IND application, IDE, or equivalent, is required, a regulatory application ***must be submitted to the relevant regulatory agency by the Clinical Trial Award application submission deadline***. The regulatory application should be specific for the product and indication to be tested in the proposed clinical trial.

Animal studies are NOT allowed under this award mechanism. All preclinical work must be completed prior to the award start date.

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 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.

3.3. CDMRP-wide Encouragements

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

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.

3.4. Funding Instrument

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

3.5. Funding Details

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

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **$8M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

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

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

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

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.

- Costs for up to four investigators to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the PRMRP FY25 Clinical Trial Award.
- Research subject compensation and reimbursement for trial-related out-of-pocket costs (e.g., travel, lodging, parking, costs associated with caregiving, and resources/equipment to enable participation).

Must not be requested for:

- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.
- Tuition.

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 PRMRP portfolio addressed by the proposed research.
- Select the FY25 PRMRP topic area addressed by the proposed research.
- Select the FY25 PRMRP continuum of care category addressed by the proposed research.
- Select the FY25 PRMRP strategic goal addressed by the proposed research.

Letter of Intent (one-page limit): Provide a brief description of the research to be conducted. Include the PRMRP portfolio, FY25 PRMRP topic area, and FY25 PRMRP strategic goal under which the application will be submitted.

4.3. Step 2: Full Application Components

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

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

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

(b) Attachments:

Each attachment of the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 2.

- **Attachment 1: Project Narrative (20-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair

competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below. It should be clear from this description that the proposed study meets the definition of a clinical trial.

- **Background:** Describe in detail the scientific rationale for the study. Provide a review and analysis of the available literature and completed/ongoing studies relevant to the proposed clinical trial.
  - Describe the preliminary studies and/or preclinical data that support the proposed clinical trial.
  - Summarize key preclinical pharmacological findings, dosage studies, and other clinical studies (if applicable) that examine the safety and stability (as appropriate) of the intervention.
  - Provide a summary of other relevant ongoing, planned, or completed clinical trials and describe how the proposed study differs.

  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(s) of prior funding. Identify the specific portions of the study that will be supported with funds from this award.
- **Intervention:** Identify the intervention to be tested. Include the following components, as applicable: intervention type (drug, device, behavioral, surgical, etc.), complete name and composition, source, general concept of design, administration route. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights, along with access to the intervention itself, for conduct of the clinical trial. As applicable, appropriate letters of commitment should be provided in Attachment 2: Supporting Documentation demonstrating the study team's access to the intervention(s) for the duration of the clinical trial. Describe how the intervention addresses current clinical needs and how it compares with currently available interventions and/or standards of care.
- **Objectives/Specific Aims/Hypotheses:** Describe the purpose of the proposed study with detailed objectives. State the hypothesis/research question to be tested in the proposed clinical trial and detail the specific aims that will address the hypothesis/research question. Indicate whether the research addresses health areas and conditions that affect women uniquely, disproportionately, or differently from men.
- **Study Design:** Describe the proposed clinical trial in sufficient detail to evaluate its appropriateness and feasibility, relating to both the scientific success of the study and setting reasonable expectations for what study participants will experience.
  - Describe the type of study to be performed (e.g., treatment, prevention, diagnostic studies, screening trials, multi-arm/multi-stage trials, single/multiple cohort trials, case control trials) the study phase or class (if applicable), and the study models (e.g., single group, parallel, crossover). Outline the proposed clinical trial methodology and study variables in sufficient detail to demonstrate a clear course of action and justification. Describe the interaction with the human subject, including the study intervention that they will experience, and include the dose and administration route. Provide sufficient detail in chronological order for

a person uninvolved in the study to understand what the study participant will experience.

- Provide a schedule (e.g., flowchart or diagram) of study intervention(s), evaluation(s), and follow-up procedures, including, if applicable, the biospecimen that will be collected along with the collection schedule and amount. Describe measures to ensure consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions). Define each arm/study group of the proposed trial, if applicable, and describe how group assignment will occur. Include a description of controls, as appropriate. Specify the approximate number of study participants to be enrolled. Indicate whether subjects, clinicians, data analysts, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias.
- Define all endpoints/outcome measures relevant to the objective of the study, explain why they were chosen, and describe how, when, and where they will be measured. Include all evaluations that will be made for study purposes. If questionnaires or other research data collection instruments will be used, include a copy of them within Attachment 2: Supporting Documentation. Describe the reliability and validity of the selected endpoint/outcome measure and evaluation along with the applicable quality standards. Explain how the results of evaluations and/or data collection instruments will be used to meet the objectives of the study (or to monitor safety of human subjects).
- Briefly describe the study population and the inclusion and exclusion criteria that will be used to meet the needs of the proposed clinical trial. Additional details should be provided in Attachment 6: Study Population Recruitment and Safety Plan.

– **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

- Include a complete power analysis to demonstrate that the proposed clinical trial's anticipated sample size is appropriate to meet the objectives of the study. Describe all clinical and statistical justifications and assumptions that support the sample size calculations. Explain any anticipated subgroup analyses and demonstrate that such analyses will be appropriately powered.
- 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. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.
- For phase 3 clinical trials, describe plans for the valid and sufficiently powered analysis of group differences on the basis on sex, race, and/or ethnicity as appropriate for the scientific goals of the study. Refer to the CDMRP directive on the Inclusion of Women and Minorities as Subjects in Clinical Research for additional information on the requirements for phase 3 studies.

– **Pitfalls and Mitigation Strategy:** Describe potential challenges and discuss alternative methods/approaches that may be employed to overcome them.

- **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 for the duration of the proposed clinical trial. 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.
  - **Questionnaires and Other Research Data Collection Instruments:** Include a copy of the most recent version of questionnaires, data collection forms, rating scales, interview guides, or other instruments. This should include any drafts that are currently in use or underdevelopment.
  - **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 4, 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:** Present the ideas and rationale behind the proposed clinical trial.
  - **Relevance to Topic Area:** First state both the FY25 PRMRP Topic Area and the FY25 PRMRP Strategic Goal addressed by the proposed project, and then state the relevance of the project to the topic area and strategic goal. The topic area and strategic goal must be the same as what was previously selected during pre-application submission.
  - **Hypothesis/Objective(s):** State the objective of the proposed clinical trial and the hypothesis/research question to be addressed.
  - **Specific Aims:** List the specific aims of the study.
  - **Study Design:** Briefly describe the study design, including appropriate controls. State the type of trial to be conducted, the phase of the clinical trial, the intervention being studied, and the primary projected outcome(s) of the clinical trial.
  - **Clinical Impact:** Briefly describe how the proposed clinical trial will have a significant impact on the research field and/or treatment or management of the specified disease(s)/condition(s).
  - **Military Relevance:** Describe the military relevance of the study.

- **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.

  - First state both the FY25 PRMRP Topic Area and the FY25 PRMRP Strategic Goal addressed by the proposed project, and then state the relevance of the project to the topic area and strategic goal.
  - Summarize the objectives and rationale for the proposed clinical trial.
  - Describe the intervention(s).
  - What population will the research help, and how will it help them?
  - What are the expected clinical applications, and potential risks of the anticipated outcomes?
  - Describe the ultimate applicability and impact of the proposed study and the anticipated outcomes to advancing research, patient care, and/or quality of life.

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

  For the Clinical Trial Award refer to the "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work", for guidance on preparing the SOW.

  The SOW should describe only the work for which funding is being requested by this application.

- **Attachment 6: Study Population Recruitment and Safety Plan (no page limit): Upload as "StudyPopPlan.pdf".** Include the components listed below.

  - **Enrollment Distribution:** Provide anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race, and ethnicity using the Public Health Service (PHS) Inclusion Enrollment Report. The enrollment table(s) should be appropriate to the objectives of the study.
  - **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). Provide a table of anticipated enrollment counts at each study site. Demonstrate that the research team has access to the proposed study population at each site and describe the efforts that will be made to achieve accrual goals. Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex. For clinical trials proposing inclusion of military populations, refer to the General Application Instructions, Appendix 4 for more information.
  - **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. Provide detailed justification for exclusions. If limiting inclusion by age, race, ethnicity, or sex, provide strong rationale based on justification from scientific literature, preliminary data, or other relevant considerations. List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Describe how the study population represents the population anticipated to benefit from the intervention.
  - **Women and Minorities in the Study:** Describe the strategy for recruitment and retention specific to women and minorities in the clinical trial appropriate to the objectives of the study.
  - **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care provider identification). Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them. Address the availability of human subjects for the clinical trial for each enrollment site. If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan. Describe the recruitment and advertisement materials. Discuss past efforts in recruiting human subjects from the target population for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention. Identify ongoing clinical trials that may compete for the same patient population and how they may impact enrollment progress.

- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.
  - ***For the proposed study, provide a draft, in English, of the Informed Consent Form.***
  - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.
  - Include information regarding the timing and location of the consent process.
  - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
  - Address how privacy and time for decision-making will be provided and whether the potential human subject will be allowed to discuss the study with anyone before making a decision.
  - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
  - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: In compliance with 10 USC 980, the application must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial.
  - ***Assent:*** If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.
- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry.
- **Risks/Benefits Assessment:**
  - **Foreseeable Risks:** Clearly identify all study risks, including potential safety concerns and adverse events attributable to the intervention as well as examination/data collection procedures. If applicable, any potential risk to the study personnel should be identified.
  - **Risk Management and Emergency Response:** Appropriate to the study's level of risk, describe how safety monitoring and reporting to the IRB and Regulatory Agency (if applicable) will be managed and conducted. Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values. Discuss the overall plan for provision

of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the cost of such care.

- **Potential Benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result from the study.

- **Attachment 7: Data Management and Sharing (no page limit): Upload as "Data_Manage.pdf".** The Data Management attachment should include the components listed below.
  - **Data Management:** Describe the data to be gathered and all methods used for collection, including the following:
    - **Data:** The types of data, software, or other materials to be produced.
    - **Acquisition and Processing:** How the data will be acquired, including the time and location of data acquisition, if scientifically pertinent. If use of existing data resources is proposed, describe the origin of the dataset. Provide an account of the standards to be used for data and metadata format and content. Explain how the data will be processed.
    - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
    - **Confidentiality**
      - Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing Protected Health Information (PHI) should be addressed.
      - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of the DOD are eligible to review study records.
      - Address requirements for reporting sensitive information to state or local authorities.
    - **Data Capture, Verification, and Disposition:** Describe how data will be captured and verified, including the quality assurance and quality control measures taken during collection, analysis, and processing. Describe safety precautions for secure transmittal of data between clinical sites and the data center, if applicable. Describe where data (both electronic and hard copy) will be stored; who will keep the data; how the data will be stored, if applicable; the file formats and the naming conventions that will be used; the process for locking the database at study completion; and the length of time that data will be stored, along with a justification for the time frame of preservation, which may include considerations related to the balance between the relative value of data preservation and other factors such as the associated cost and administrative burden of data storage. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. Describe how data breaches will be handled. Describe the

database lock process. For studies requiring Regulatory Agency oversight, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) is required. Describe procedures for secure backup of the data/database.

- **Data Reporting:** Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with a Regulatory Agency, if applicable.

– **Data and Research Resources Sharing Plan:** Describe the type of data or research resources to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project 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 sharing the data and results/implications of the study with affected communities and/or research participants. In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether the results of screening and/or study participation will be shared with human subjects or their primary care provider, including results from any screening or diagnostic tests performed as part of the study. In cases of national security or controlled unclassified information concerns, include a statement that the data cannot be made available to the public (e.g., "This data cannot be cleared for public release in accordance with the requirements in DoD Directive 5230.09."). Refer to CDMRP's Policy on Data & Resources Sharing for more information about CDMRP's expectations for making data and research resources publicly available.

○ **Attachment 8: Regulatory Strategy (no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".** Answer the following questions and provide supporting documentation as applicable.

– State the product/intervention name.

For products/interventions that do not require regulation by a Regulatory Agency:

– Provide evidence that the clinical trial does not require regulation by a Regulatory Agency. Submissions providing "not applicable," "none," or similar responses do not satisfy this request. No further information for this attachment is required.

For products that require regulation by a Regulatory Agency:

– Describe the overall regulatory strategy and product development plan that will be performed during the project's period of performance to support the planned product indication/label. Include, as appropriate, a description of the regulatory application submission strategy.

- State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the United States. If the product is marketed in the United States, state the product label indication. State whether the proposed research involves a change to the approved label indication.
- If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use and whether an IND or IDE application was submitted. ***If***

an IND or IDE is required, the application must be submitted to the FDA prior to the FY25 PRMRP Clinical Trial Award application submission deadline. The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed clinical trial. Provide the date of submission, the application number, and a copy of the FDA letter acknowledging the submission.

- Provide a summary of any meetings the research team had with regulatory agencies or consultants regarding the proposed research. Include key outcomes, action items, and recommendations. If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.
- If the clinical trial will be conducted at international sites, provide equivalent information and supporting documentation relevant to the product indication/label and regulatory approval and/or filings in the host country(ies).

– If an active IND or IDE for the investigational product is in effect, but an amendment is needed to include the proposed trial, describe the type and nature of the amendment(s) and the timeline for submission. Indicate whether the amendment increases the risk of the intervention.

– Provide the current status for manufacturing development (e.g., manufacturer's name, GMP-compliant lots available, status of stability testing), nonclinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support phase 1 testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).

– Describe the overall regulatory strategy and product development plan that will be performed during the project's period of performance to support the planned product indication/label. Include, as appropriate, a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of Regulatory Agency meetings that will be held/planned, and the submission filing strategy. Include considerations for compliance with current GMP, GLP, and GCP guidelines.

○ **Attachment 9: Study Personnel and Organization (no page limit): Start each document on a new page. Combine into one document and upload as "Personnel.pdf".** The Study Personnel and Organization attachment should include the components listed below.

– **Organizational Chart:** Provide an organizational chart that identifies key members of the study team and provides an outline of the governing structure for multi-institutional studies. Identify collaborating organizations, centers, and/or departments and name each person's position on the project. Include any separate laboratory or testing centers. Identify the data and clinical coordinating center(s) and note any involvement from Contract Research Organizations, as appropriate, including the location of the organization. If applicable, identify the Regulatory Agency sponsor and any external consultants or other experts who will assist with Regulatory Agency sponsor applications. While there is no specified format for this information, a table(s) or diagram is recommended.

– **Study Personnel Description:** Describe the composition of the study team in enough detail to determine whether the team includes relevant subject matter expertise to accomplish the proposed work. Include the roles of individuals named in the organizational chart along with any external consultants or advisors who will

provide critical guidance and input to the study team (e.g., statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate). Study coordinator(s) should be included. Describe how the levels of effort for each individual are appropriate to successfully support the proposed clinical trial.

- **Study Management Plan:** Describe the day-to-day management of the proposed clinical trial. Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial involves more than one institution, clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. If applicable, describe how communication and data transfer between/among the collaborating institutions will occur, as well as how data, specimens, and/or imaging products obtained during the study will be handled and shared. Provide a plan for resolving intellectual and material property issues among participating organizations.

- **Attachment 10: Post-Award Transition Plan (three-page limit): Upload as "Transition.pdf".** Discuss the anticipated methods and strategies necessary to move the anticipated research outcome (e.g., intervention, product, methodology, finding) to the next phase of development (e.g., clinical trials, commercialization, and/or delivery to the civilian or military market), assuming a positive outcome from the proposed clinical trial. Investigators are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. Applicants are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development when preparing the transition plan. ***The post-award transition plan should address the following:***

  - Details of the funding strategy to transition to the next level of development and/or commercialization (e.g., specific industry partners, specific funding opportunities to be applied for). 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 strategic goal; 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 (e.g., next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by a Regulatory Agency).
  - 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.
  - A risk analysis for cost, schedule, manufacturability, and sustainability.

- **Attachment 11: Impact and Relevance to Military Health Statement (three-page limit): Upload as "Impact.pdf".** The impact statement summarizes the potential short- and long-term impact of the proposed clinical trial. The statement should address the points outlined below written ***in a manner that will be readily understood by readers without a background in science or medicine***.
  - Summarize the potential benefit(s) of the intervention and/or research outcome of the proposed clinical trial as it relates to the FY25 PRMRP Topic Area and Strategic Goal that were previously selected during pre-application submission.
  - Identify the sample population(s) that will participate in the proposed intervention, inclusive of sex, ethnicity, and/or minorities if applicable; describe how they represent the target population that would benefit from the intervention and describe the potential impact and anticipated outcomes of the proposed clinical trial on the lives and health of the target population with regard to the FY25 PRMRP Topic Area addressed.
  - If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
  - ***Describe the Short-Term Impact:*** Detail the anticipated outcomes that will be directly attributed to the results of the proposed clinical trial and describe anticipated short-term benefits for individuals.
  - ***Describe the Long-Term Impact:*** Explain the long-range vision for implementation of the intervention in the clinic or field and describe the anticipated long-term benefits on patient care and/or quality of life for the targeted population.
  - Describe any relevant controversies or treatment issues that will be addressed by the proposed clinical trial.
  - Describe any potential issues that might limit the impact of the proposed clinical trial.
  - Describe how the intervention represents an improvement over currently available interventions and/or standards of care.
  - Describe how the proposed study is responsive to the health care needs of military Service Members, Veterans, and their Families. Provide information about the incidence and/or prevalence of the disease or condition in the general population as well as in military Service Members, Veterans, and their Families.
  - If active-duty military, military Families, and/or Veteran population(s) or dataset(s) will be used in the proposed research project, describe the population(s)/dataset(s) and the appropriateness of the population(s)/dataset(s) for the proposed study. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., military Service Members, Veterans, and their Families).
  - If applicable, show how the proposed research project aligns with DOD and/or VA areas of research interests. Provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to benefit the civilian population and address a military need, as appropriate.
- **Attachment 12: Prior Outcomes Statement (if applicable; one-page limit): Upload as "Outcomes.pdf".** If applicable, list all of the PI's prior or in-progress CDMRP/PRMRP research projects/awards including resulting publications, abstracts,

patents, or other tangible outcomes. Only research and outcomes directly relevant to this application should be listed. **Attachment 12 will be available for programmatic review only.**

- **Attachment 13: 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 14: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the "Suggested Intragovernmental/Intramural Budget" form that is available for download on eBRAP. Refer to the General Application Instructions, Section V.B.(c), for instructions and considerations.

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

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

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

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

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

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

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

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

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

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

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

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

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

4.4. Other Application Elements

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

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942525PRMRPCTA from Grants.gov or eBRAP, depending on which submission portal will be used.

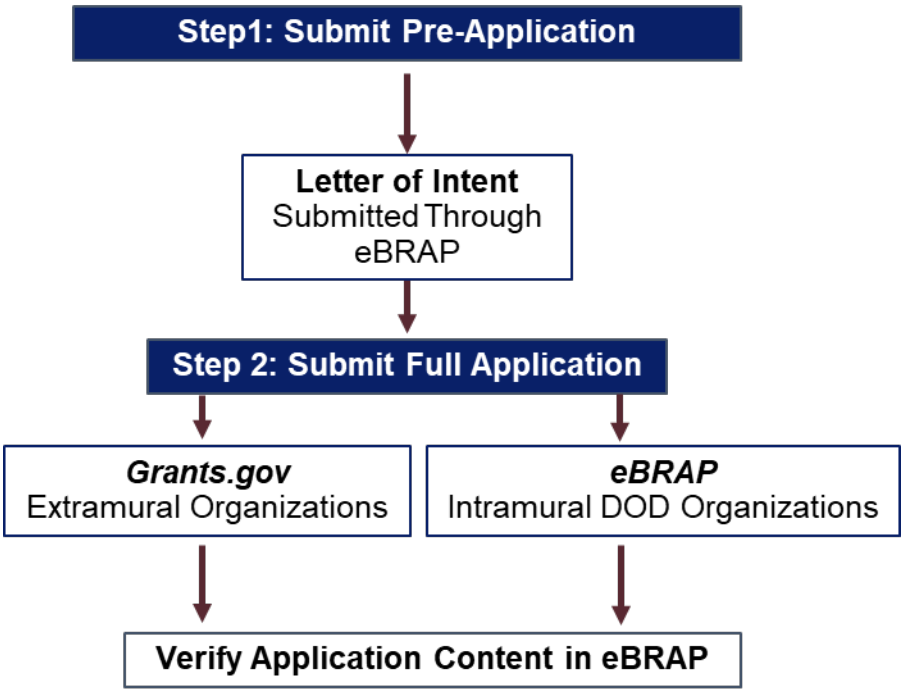
5.2. Unique Entity Identifier and System for Award Management

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

5.3. Submission Instructions

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

Application Submission Workflow



5.3.1. Pre-Application Submission

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

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, Business Official(s), performing

organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

During the pre-application process:

- Select the FY25 PRMRP portfolio addressed by the proposed research.
- Select the FY25 PRMRP topic area addressed by the proposed research.
- Select the FY25 PRMRP continuum of care category addressed by the proposed research.
- Select the FY25 PRMRP strategic goal addressed by the proposed research.

Refer to the General Application Instructions, Section III.B, 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. 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 PRMRP 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 PRMRP Programmatic Panel members can be found on the CDMRP website.***

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

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

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

6.2.2. Peer Review Criteria

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

- **Clinical Impact**
  - To what extent the proposed research project addresses the applicant-select FY25 PRMRP Topic Area and FY25 Strategic Goal, and how impactful the anticipated outcomes of the proposed clinical trial would be to the target population with regard to that topic area and strategic goal.
  - How well the sample population represents the targeted patient population that might benefit from the proposed intervention.
  - How the anticipated outcomes of the proposed clinical trial will provide/improve short-term benefits for individuals.

- How significantly the long-term benefits for implementation of the intervention may impact patient care and/or quality of life.
- If applicable, to what extent the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- If successful, how will the proposed intervention compete with other treatment options available to the intended population.

- **Research Strategy and Feasibility**
  - How well the scientific rationale for the proposed clinical trial is supported by the preliminary studies, preclinical data, review and analysis of the literature, and/or relevant ongoing, planned, or complete clinical trials.
  - How well the study questions, specific aims, hypotheses and/or objective(s), experimental design, methods, data collection procedures, and analyses are designed to clearly answer the clinical objective and purpose.
  - How well the inclusion/exclusion criteria and group assignment process meet the needs of the proposed clinical trial.
  - How well plans to collect specimens and conduct laboratory evaluations are addressed, if applicable.
  - To what degree the data collection instruments, if applicable, are appropriate to the proposed study.
  - To what degree the clinical endpoints are appropriate for the objectives of the study.
- **Recruitment, Accrual, and Feasibility**
  - To what degree the number of human subjects to be enrolled within the study is reasonable based upon the proposed timeline, study procedures, study population, inclusion/exclusion criteria, and planned efforts to achieve accrual goals.
  - How well the application addresses the availability of human subjects for the clinical trial, access to the proposed human subject population, and the prospect of their participation.
  - The degree to which the recruitment, informed consent, screening, and retention processes for human subjects will meet the needs of the proposed clinical trial.
  - How well the application identifies possible delays (e.g., slow/low enrollment, poor retention) and presents adequate mitigation plans to resolve them.
  - To what extent the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study.
  - If applicable, whether the justification for limiting inclusion of any demographic group, including sex, is sufficiently strong.
  - To what extent the strategy for recruitment and retention of women and minorities in the clinical trial is appropriate to the objectives of the study.
  - Whether the distribution of the proposed enrollment on the basis of sex, race, and/or ethnicity is appropriate for the proposed research.

- **Intervention**
  - Whether there is evidence of support, indicating availability of the intervention from its source, for the duration of the proposed clinical trial (if applicable).
  - To what degree the intervention addresses current clinical need(s).
  - How the intervention compares with currently available interventions and/or standards of care.
  - To what degree the application includes preclinical and/or clinical evidence to support the safety and stability (as appropriate) of the intervention.
  - How well research procedures are clearly delineated from routine clinical procedures.
  - Whether measures are described to ensure the consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).
- **Regulatory Strategy and Transition Plan**
  - How the regulatory strategy and development plan to support the product indication or product label change, if applicable, are appropriate and well-described.
  - The extent to which the application includes documentation that the study is exempt from the FDA or other international regulatory agency, or that the IND or IDE application (and/or international equivalent) has been submitted to the Regulatory Agency, as appropriate.
  - How well the documentation provided supports the feasibility of acquiring an active IND or IDE (and/or international equivalent) covering the proposed trial, if applicable.
  - For investigator-sponsored regulatory exemptions (e.g., IND, IDE, or other international equivalent), whether there is evidence of appropriate institutional support.
  - Whether plans to comply with GMP, GLP, and GCP guidelines are appropriate.
  - Whether the identified next level of development and/or commercialization is realistic.
  - Whether the funding strategy described to bring the intervention to the next level of development (e.g., specific industry partners, specific funding opportunities to be applied for) is reasonable and achievable.
  - For knowledge products, whether the proposed collaborations and other resources are achievable to provide continuity of development.
  - Whether the schedule and milestones for bringing the intervention to the next level of development (next-phase clinical trials, transition to industry, delivery to the market, incorporation into clinical practice, and/or approval by the Regulatory Agency) are achievable.
  - Whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
  - How well the application identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent government access to products supported by this program announcement.

- **Statistical Plan and Data Analysis**
  - To what degree the statistical model and data analysis plan are suitable for the planned study objectives.
  - How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
  - Whether the statistical plan compensates for the use of a subpopulation of a recruited sample population to ensure appropriate power can be achieved within the subpopulation study.
  - 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.
  - If a phase 3 trial is proposed, whether the plans for the valid analysis of group differences on the basis of sex, race, and/or ethnicity are appropriate for the proposed research.
- **Ethical and Safety Considerations**
  - Whether the population selected to participate in the trial stands to benefit from the knowledge gained.
  - If applicable, how well the inclusion of international sites is justified.
  - Whether safety measures minimize and/or eliminate risks to human subjects.
  - Whether the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects.
  - Whether the safety monitoring and reporting plan is appropriate for the level of risk.
  - To what degree privacy and confidentiality issues are appropriately considered.
  - To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
- **Personnel and Communication**
  - To what degree the composition of the study team, including any external consultants or advisors (e.g., statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate, military-relevant subject matter expert), is appropriate to accomplish the proposed work.
  - Whether the levels of effort of the study team members are appropriate for successful conduct of the proposed trial.
  - How well the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, standardization of procedures) meet the needs of the proposed clinical trial.
  - For clinical trials that involve more than one institution, to what degree the multi-institutional structure governing the research protocol(s) across all participating institutions and regulatory submission plan are described and appropriate.
- **Budget**
  - Whether the budget is appropriate for the proposed research.

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**:

- **Women's Health**
  - If applicable, to what degree the proposed research addresses health areas and conditions that affect women uniquely, disproportionately, or differently from men and to what extent the project findings are anticipated to lead to improvements in women's health outcomes and/or advancements in knowledge for women's health.
- **Environment**
  - To what degree the scientific environment, clinical setting, and the accessibility of institutional resources support the clinical trial at each participating center or institution (including collaborative arrangements).
  - Whether there is evidence for appropriate institutional commitment from each participating institution.
- **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 PRMRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Relative clinical impact
  - Relevance to the FY25 PRMRP Topic Area
  - Relevance to the FY25 PRMRP Strategic Goals
  - Relevance to military health
  - Program portfolio composition
  - Relative outcomes form the PI's previous CDMRP-/PRMRP-funded research (if applicable)

6.3. Application Review and Selection Process

6.3.1. Pre-Application

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

6.3.2. Full Application

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section 6.2.3, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found on the CDMRP website.

Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds.

6.4. Risk, Integrity, and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

In accordance with National Security Presidential Memorandum and all associated laws, all fundamental research funded by the DoD must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the OUSD R&E 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 PRMRP 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 I.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 Institutional Animal Care and Use Committee (IACUC), IRB, or Ethics Committee (EC) review. Refer to the General Application Instructions, Appendix 6, for additional information.

8.2. Reporting

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

Enrollment reporting on the basis of sex, race, and ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available in eBRAP.

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.

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. PI Changes and Award Transfers

Unless otherwise restricted, changes in the PI 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.

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_01Td. The program announcement numeric version code will match the General Application Instructions version code CD25_01.

9.2. Administrative Actions

After receipt of pre-application or full applications, the following administrative actions may occur.

9.2.1. Rejection

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

- Project Narrative is missing.
- Budget is missing.
- Pre-application (LOI) was not submitted.
- Study Population Recruitment and Safety Plan (Attachment 6) is missing.
- Data Management and Sharing (Attachment 7) is missing.
- Regulatory Strategy (Attachment 8) is missing.
- Study Personnel and Organization (Attachment 9) is missing.

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 PRMRP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the pre-application or application processes.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY25, the identities of the peer review contractor and the programmatic review contractor may be found on the CDMRP website.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.

- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) if: (a) the organization cannot accept and execute the entirety of the requested budget in FY25 funds; and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application fails to address one of the congressionally directed FY25 PRMRP Topic Areas.
- The application fails to address one of the FY25 PRMRP Strategic Goals.
- The application addresses an FY25 PRMRP Topic Area or an FY25 PRMRP Strategic Goal that is different from what was selected in the pre-application.
- The proposed project includes preclinical research.
- The proposed research is not a clinical trial.
- For clinical trials in which an IND or an IDE is not required/exempt, evidence in the form of formal communication from the FDA or the IRB of record to that effect is not provided.
- For clinical trials in which an IND or an IDE is required, evidence of application submission to the FDA was not included in the application.
- The PI does not meet the eligibility criteria.
- The investigator is named as PI on more than one application submitted to the FY25 PRMRP. If more than one LOI is submitted by the same PI to the FY25 PRMRP, the first submission will be accepted, and the second will be administratively withdrawn.

9.2.4. Withhold

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

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance ***(Grants.gov submissions only)***	☐
Summary (Tab 1) and Application Contacts (Tab 2) ***(eBRAP submissions only)***	☐
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐
Study Population Recruitment and Safety Plan – Attachment 6, upload as "StudyPopPlan.pdf"	☐
Data Management and Sharing – Attachment 7, upload as "Data_Manage.pdf"	☐
Regulatory Strategy – Attachment 8, upload as "Regulatory.pdf"	☐
Study Personnel and Organization – Attachment 9, upload as "Personnel.pdf"	☐
Post-Award Transition Plan – Attachment 10, upload as "Transition.pdf"	☐
Impact and Relevance to Military Health Statement – Attachment 11, upload as "Impact.pdf"	☐
Prior Outcomes Statement *(if applicable)* – Attachment 12, upload as "Outcomes.pdf"	☐
Representations *(Grants.gov submissions only)* – Attachment 13, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 14, upload as "IGBudget.pdf"	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach Biographical Sketch for PI and Senior/Key Persons ("Biosketch_LastName.pdf")	☐
Attach Current/Pending Support for PI and Senior/Key Persons ("Support_LastName.pdf")	☐
Research & Related Budget **Include Budget Justification**	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐

Appendix 2. Acronym List

CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CTA	Clinical Trial Award
DOD	U.S. Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
LAR	Legally Authorized Representative
LOI	Letter of Intent
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 Oversight (previously Office of Research Protections)
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
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
PRMRP	Peer Reviewed Medical Research Program
QWERTY	First six letters of the second row of a standard English-language keyboard
RPPR	Research Performance Progress Report

SAM	System for Award Management
SciENcv	Science Experts Network Curriculum Vitae
SF424	Standard Form 424 (Application for Federal Assistance, Research & Related)
SOW	Statement of Work
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs

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://www.dha.mil//

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/BUMED/Nurse-Corps/?faqs=med.navy.afpims.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 Force Health Protection Command
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.onr.navy.mil/

Office of the Under Secretary of Defense for Acquisition and Sustainment
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://www.t2.army.mil/T2-Laboratories/Designated-Laboratories/US-Army-Research-Institute-of-Environmental-Medicine/

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

U.S. Army Directorate of Prevention, Resilience and Readiness
https://www.armyresilience.army.mil/

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/