Program Announcement for the Defense Health Agency

Peer Reviewed Medical Research Program

Clinical Trial Award

Funding Opportunity Number: HT942526PRMRPCTA

Pre-Application Due: July 23, 2026

Application Due: September 22, 2026

This program announcement must be read in conjunction with the General Application Instructions, version CD26_01.

Content

Before You Begin

- **Active SAM.gov, eBRAP.org and Grants.gov registrations are required for application submission.** User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- **Read this 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 this funding opportunity and that all parties meet eligibility requirements.
- **To support application preparation, additional resources are available** including an application process FAQ, a Guide for Intragovernmental & Intramural Applicants and a CDMRP Video Series detailing the application process.

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 Support 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 the Alt + left arrow keys (Windows) or command + left arrow keys (Macintosh) on your keyboard.

Click ⓘ to be taken to additional guidance and instructions within the General Application Instructions (GAI).

1. Basic Information About the Funding Opportunity

Summary: The fiscal year 2026 (FY26) Peer Reviewed Medical Research Program (PRMRP) Clinical Trial Award supports the rapid implementation of clinical trials with the potential to have significant impact on the treatment and management of a disease or condition addressed in one of the congressionally directed FY26 PRMRP topic areas and FY26 PRMRP strategic goals.

Distinctive Features: Must support a clinical trial. Supports two different application categories, based on the phase of planning for the clinical trial: **Clinical Trial Only** or **Clinical Trial with Planning Phase.** The **Clinical Trial with Planning Phase** option is intended to support the final phase of regulatory activities and planning activities that are necessary to be completed prior to initiation of the clinical trial. The planning phase cannot be used to finalize the intervention or support animal studies. Applications that already have regulatory approvals in place and are submitting to the Clinical Trial Only option may be prioritized over those requesting the Planning Phase option. **Animal studies are not supported.** Studies must complete all preclinical empirical laboratory work prior to the award start date.

- **Supports three funding levels,** each offered with and without a Planning Phase:
    - **Funding Level 1:** Supports phase 0 or phase 1 clinical trials or non-phased trials with fewer than 100 participants.
    - **Funding Level 2:** Supports phase 2 clinical trials or non-phased trials with fewer than 300 participants.
    - **Funding Level 3:** Supports phase 3 clinical trials or non-phased trials with more than 300 participants.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly $94.5M to fund approximately 9 Clinical Trial Award applications with total cost caps of $800,000 for the planning phase of a Clinical Trial with Planning Phase, $6M for Funding Level 1, $10M for Funding Level 2, and $20M for Funding Level 3 per award. The maximum period of performance is 4 years for the clinical trial, and 12 months for the planning phase. It is anticipated that awards made from this FY26 funding opportunity will be funded with FY26 funds, which will expire for use on September 30, 2032. Awards supported with FY26 funds will be made no later than September 30, 2027.

Submission and Review Dates and Times

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), July 23, 2026
- **Invitation to Submit an Application:** August 24, 2026
- **Application Submission Deadline:** 11:59 p.m. ET, September 22, 2026
- **End of Application Verification Period:** 5:00 p.m. ET, September 30, 2026
- **Peer Review:** November/December 2026
- **Programmatic Review:** February/March 2027

Announcement Type: Initial

Funding Opportunity Number: HT942526PRMRPCTA

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural U.S. Department of War (DOW) organizations are eligible to apply, ***including foreign and domestic organizations, for-profit and nonprofit organizations, and public or private entities*.**

2.1.2. Principal Investigator

Independent investigators (e.g., Assistant Professor, Senior Scientist, Principal Scientist, Research Director, or equivalent) may be named by the organization as the Principal Investigator (PI) on the application.

Each investigator may be named on only one FY26 PRMRP application as PI. If more than one pre-application submitted to the FY26 PRMRP names the same PI, the first submission will be accepted, and subsequent submissions will be administratively withdrawn.

Independent investigators affiliated with an eligible organization are eligible to be named as PI on the application, regardless of ethnicity, nationality or citizenship status.

2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

2.3. Other

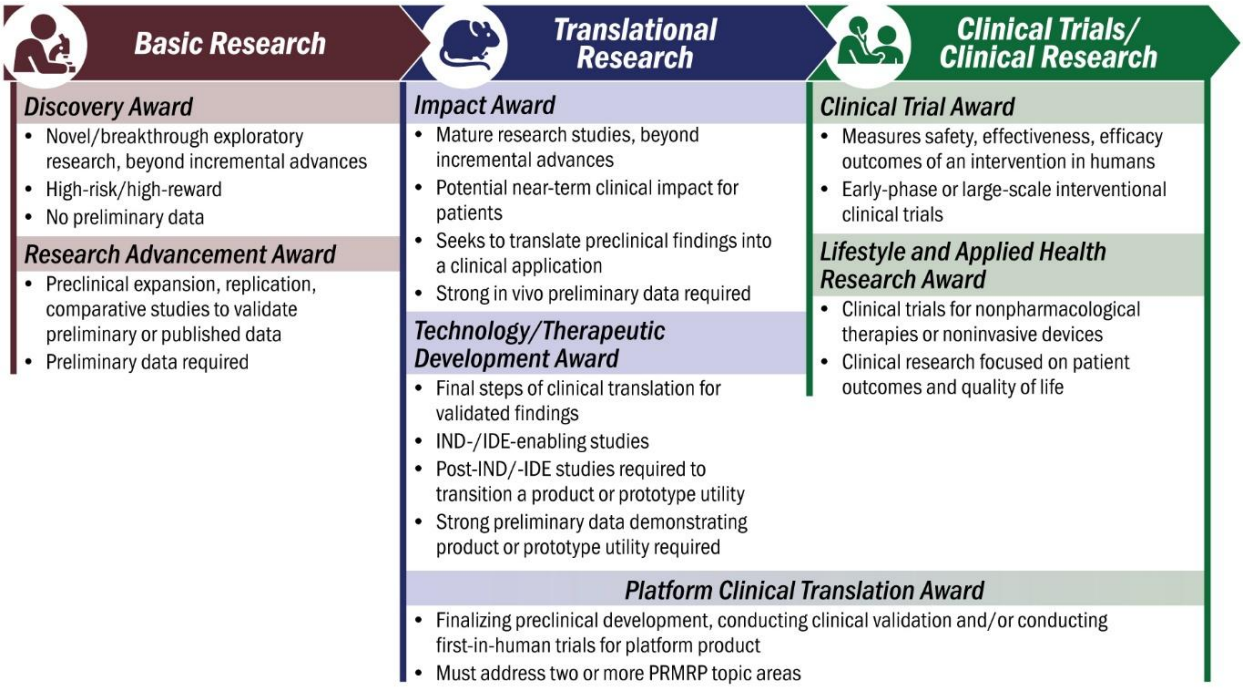
Awards are made to eligible ***organizations***, not to individuals. Refer to the GAI for additional recipient qualification requirements.

3. Program Description

The Defense Health Agency Contracting Activity (DHACA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP is the program office managing this FY26 funding opportunity as part of the Peer Reviewed Medical Research Program (PRMRP). The CDMRP is located within the Defense Health Agency Research and Development (DHA R&D), which is a part of the Department of Defense, DOD, herein referred to using the secondary title Department of War, DOW. 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 FY25 totaled $4.34 billion. The FY26 appropriation is $370 million.

FY26 PRMRP Research Development Pipeline

To address the congressionally directed FY26 PRMRP topic areas in a bench-to-bedside fashion, the FY26 PRMRP award mechanisms are aligned to different phases of the research development pipeline illustrated below.



The **Use-Inspired Basic Research** phase represents novel, exploratory research aimed at generating preliminary data and/or preclinical research that is ready for validation through expansion, replication, or comparative studies. While projects may be aiming to understand fundamental physiological phenomena, “basic research,” they should be driven by a specific clinical need and potential application, “use-inspired.” Applicants seeking support for research aligning to the Use-Inspired Basic Research phase may consider:

- **FY26 PRMRP Discovery Award** (HT942526PRMRPDA) for novel, high-risk, high reward research projects with the potential to yield high-impact findings and new avenues of investigation. Preliminary data is not allowed.

- **FY26 PRMRP Research Advancement Award** (HT942526PRMRPRAA) for building upon existing preliminary data to validate a concept.

The **Translational Research** phase seeks to transition scientific data towards treatment, diagnostic and/or preventive strategies. Research projects are expected to have significant near-term impact on patients' lives. Examples of projects in the translational phase include product/device development and clinical translation of concepts previously validated through expansion, replication or comparative studies. Applicants seeking support for research aligning to the Translational Research phase may consider:

- **FY26 PRMRP Impact Award** (HT942526PRMRPIPA) for mature research products that are ready to translate ideas into solutions. Initial product discovery, development, and optimization are supported.
- **FY26 PRMRP Technology/Therapeutic Development Award** (HT942526PRMRPTTDA) for finalizing preclinical development of tangible products (drugs or biologics), knowledge-based products and/or devices. The research outcome should be a regulatory filing or translation of findings into clinical practice, as applicable.

The **Translational to Clinical Transition** phase represents the final stages of product development with early, phase 0/1, or equivalent, clinical trials. Products may include both knowledge and tangible items that will be used to impact patient care.

- **FY26 PRMRP Platform Clinical Translation Award** (HT942526PRMRPPCTA) for finalizing preclinical development, conducting clinical validation studies, and/or conducting first in human clinical trials for a platform product with the potential to impact clinical care for two or more FY26 PRMRP topic areas.

The **Clinical Research** phase represents small- and large-scale confirmatory trials and/or applied clinical research that will revolutionize the clinical management of the diseases and conditions assigned to the program as topic areas. Applicants seeking support for trials and studies aligned to the Clinical Research phase may consider:

- **FY26 PRMRP Lifestyle and Applied Health Research Award** (HT942526PRMRPLAHRA) for clinical trials focused on efficacy of non-pharmacological interventions or noninvasive devices or clinical research to examine the impact of prevention, diagnostic, treatment or health care delivery approaches on health outcomes. Animal research is not allowed.
- **FY26 PRMRP Clinical Trial Award** (HT942526PRMRPCTA) for projects to determine the safety or efficacy outcomes of pharmacological interventions, devices or implants on prospectively recruited human participants. Animal research, preclinical experiments, and optimization/validation of the intervention are not allowed.

NOTE: The scope of research proposed in applications in response to the FY26 PRMRP program announcements must align with the research phases outlined above. It is the responsibility of the applicant to select the award mechanism that aligns with the scope of the proposed research. The funding mechanism should be selected based on the research scope defined in the program announcement, and not on the amount of the budget. Applications submitted under a mechanism that is not deemed appropriate for the scope of research proposed will not be funded.

3.1. Award History

The PRMRP first offered the Clinical Trial Award mechanism in FY08. In FY20, the PRMRP introduced the planning phase option to the Clinical Trial Award. The PRMRP offers multiple funding levels supporting specifical clinical trial phases for the first time in FY26.

3.2. Intent of the Clinical Trial Award

The PRMRP Clinical Trial Award (CTA) mechanism 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 FY26 PRMRP Topic Areas and FY26 PRMRP Strategic Goals. Clinical trials may be designed to evaluate promising new products, pharmacologic agents (drugs, biologics or medical devices), clinical guidance, and/or emerging approaches and technologies. Proposed projects may range from small proof-of-concept trials (i.e., pilot, first-in-human, phase 0) that demonstrate the feasibility or inform the design of more advanced trials through to large-scale trials, including comparative effectiveness trials that will transform and revolutionize care for the diseases and conditions addressed in the congressionally directed FY26 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.

The PRMRP CTA is intended to have near-term impact on clinical care. Proposed interventions must be intended to change the health status of the participants. Studies that meet the definition of a clinical trial but are designed to understand a basic physiological phenomenon should consider one of the other FY26 PRMRP program announcements that allows for both clinical research and trials. Additionally, animal studies are NOT allowed under this award mechanism. All preclinical empirical laboratory work must be completed prior to the award start date.

Applicants seeking funding for research that does not meet the above definition for a clinical trial or does not otherwise meet the intent of this mechanism should consider one of the other FY26 PRMRP program announcements being offered. For information about these award mechanisms, see the FY26 PRMRP Research Development Pipeline.

Two different application categories, based on the phase of planning for the clinical trial, are available under this program announcement (summary available in Appendix 3):

(1) Clinical Trial With Planning Phase: Intended to support the final phase of regulatory activities necessary to initiate the planned clinical trial. The proposed clinical trial must address one of the congressionally directed FY26 PRMRP Topic Areas and one of the FY26 PRMRP Strategic Goals. **Funding of the clinical trial will be considered an optional research effort that is contingent upon meeting the milestones of the planning phase.** Patient enrollment for the clinical trial is expected to begin within three months after PRMRP exercises the option for the clinical trial.

- The planning phase should be limited to the activities that are necessary to be completed prior to the initiation of the clinical trial. Allowable tasks under the planning phase may include, but are not limited to, the following:
  - Planning for and obtaining appropriate regulatory approvals (for example, U.S. Food and Drug Administration (FDA) or equivalent international regulatory agency, Investigational New Drug [IND] or Investigational Device Exemption [IDE] submissions, Institutional Review Board [IRB] submissions, exception to informed consent and DOW Office of Human Research Oversight [OHRO] submissions)
  - Developing the clinical protocol
  - Developing training procedures
  - Establishing access to appropriate patient populations or resources
- Within the maximum 12-month period of performance of the planning phase, recipients must submit an IND or IDE application to the FDA, if required, and obtain a statement that the IND or IDE is active/safe to proceed. If the clinical trial will be conducted at international sites, equivalent requirements for the host country(ies) must be met during the planning phase. Regulatory Agency approval or exemption to proceed with the clinical trial must be obtained, if applicable, before the optional clinical trial effort may be funded. ***The PRMRP will not exercise the option for the initiation of the proposed clinical trial if any of the following milestones are not met (for additional details, refer to Attachment 1: Project Narrative):***
  - A copy of the FDA acknowledgment letter, to include submission date and receipt date, and a statement that the FDA did not raise concerns and/or did not place the clinical trial on hold, or
  - A copy of the FDA acknowledgment letter and meeting minutes (pre-IND/pre-IDE and/or Type C) that ascertain the FDA's concurrence with the proposed regulatory approach if a technical or a protocol amendment to an active IND/IDE is necessary to complete the clinical trial, or
  - A copy of the relevant national regulatory agency approval if the clinical trial will be conducted at an international site(s), or
  - Evidence in writing from the IRB of record, or the FDA, that the proposed investigational drug/agent/device is exempt, or the proposed investigational device qualifies for an abbreviated IDE.
- Human participants research is not allowed under the planning phase.
- The planning phase is intended to be for projects truly requiring this time to mitigate risk of not being able to obtain the necessary regulatory approvals to proceed with the proposed clinical trial. The government reserves the right to switch applications to the Clinical Trial Only option if the planning phase is not needed for this purpose.
- Research milestones to be accomplished by the end of the planning phase must be clearly defined in the project Statement of Work (SOW) and will be finalized during negotiations. The PI will be required to present an update on progress toward accomplishing research milestones and goals of the project at a Milestone Meeting, to be held virtually, at the discretion of the government. Milestone Meetings will be held nearing the conclusion of the planning phase and will be attended by members of the PRMRP Programmatic Panel, CDMRP staff, and the DHACA Grants Officer.

- The agreement to support the clinical trial option will be contingent upon (1) all necessary regulatory approvals obtained under the base award; (2) availability of funds; and (3) accomplishment of research milestones and goals as determined by the PRMRP Programmatic Panel and DHACA Grants Officer.

(2) Clinical Trial Only: Intended to support clinical trials having Regulatory Agency approval or exemption **at the time of application submission.** The proposed clinical trial must address one of the congressionally directed FY26 PRMRP Topic Areas and one of the FY26 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 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 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 FY26 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 FDA guidance. If the investigational product is a device, then submission of an 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 FY26 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 amendments to the IND/IDE, or equivalent, are needed before the proposed trial can begin, these must be submitted prior to the FY26 PRMRP CTA full application submission deadline.
- Research milestones to be accomplished throughout each phase of the clinical trial must be clearly defined in the project 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 DHACA Grants Officer.
- Refer to Attachment 8, Regulatory Strategy, for additional details on documents of regulatory submissions. The government reserves the right to withdraw applications submission under the Clinical Trial Only option if an active IND or IDE, IND or IDE amendment, or equivalent, is required but has not been submitted prior to the full application submission deadline and is not approved prior to the proposed award start date.

The FY26 PRMRP CTA offers three different funding levels with or without the Planning Phase. Each funding level describes a defined clinical trial scope:

- **Funding Level 1:** Supports phase 0 or phase 1 clinical trials or non-phased trials with fewer than 100 participants.
- **Funding Level 2:** Supports phase 2 clinical trials or non-phased trials with fewer than 300 participants.

- **Funding Level 3:** Support phase 3 clinical trials or non-phased trials with more than 300 participants.

Applicants may request a funding level outside of the specified phase or participant requirements by submitting additional justification for the budget in both the pre-application and the full application (see Attachment 12, Funding Level Justification).

3.2.1. FY26 PRMRP Topic Areas and Strategic Goals

To meet the intent of the funding opportunity, ***all applications for FY26 PRMRP funding must specifically address one of the FY26 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 FY26 PRMRP strategic goals as it relates to the portfolio-assigned FY26 PRMRP topic area.*** If the proposed research does not specifically address one FY26 PRMRP topic area and one FY26 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 FY26 PRMRP topic areas and strategic goals in each PRMRP portfolio category.

FY26 PRMRP Portfolio Categories with Associated FY26 PRMRP Topic Areas and FY26 PRMRP Strategic Goals

AUTOIMMUNE DISORDERS AND IMMUNOLOGY

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

TOPIC AREAS

- Celiac Disease
- Eczema
- Food Allergies
- Inflammatory Bowel Disease
- Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcus (PANDAS)
- Sarcoidosis
- Scleroderma

STRATEGIC GOALS BY CONTINUUM OF CARE

Foundational Studies

- Investigate the mechanisms driving the pathobiology of the disease/condition.
- Investigate factors affecting disease/condition onset, progression, or heterogeneity, such as environmental exposures, comorbidities, behaviors, genetics, stress, infections, neuroimmune interactions, or microbiome dynamics.
- Investigate sex differences in the immune system.

Epidemiology

- Conduct patient-centered research to identify factors driving incidence trends, including recent increases.
- Conduct patient-centered studies to better understand differences between childhood- and adult-onset immune-mediated diseases/conditions, focusing on underlying pathobiology and treatment response.
- Conduct population-based studies to identify risk factors and enhance methods for detecting individuals at high risk.
- Conduct research to better understand sex differences in incidence and/or outcomes.

- Conduct population-based studies to examine variations in incidence and outcomes across different population subgroups.

Prevention

- Develop and test innovative strategies to prevent the onset, relapse, and/or progression of the disease/condition.
- Identify and test approaches to establish immune tolerance early in life.

Diagnosis

- Identify and validate biomarkers for continuous monitoring of disease/condition progression or to evaluate intervention response.
- Develop and validate improved diagnostic tools to enable early, accurate detection and to standardize diagnostic strategies.

Treatment

- Develop and test curative and immune reset interventions.
- Develop and test therapies effective across all or multiple allergens or autoantigens.
- Develop and test strategies to improve outcomes, reduce inflammation, promote healing, provide neuroprotection, delay symptom onset, or minimize toxicity, including lifestyle changes, targeted drugs, nutraceuticals, and personalized treatments.
- Generate evidence for repurposing and off-label use of potential treatments.

CARDIOVASCULAR HEALTH

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

TOPIC AREAS

- Brain Injury Impact on Cardiac Health
- Hypoxia

STRATEGIC GOALS BY CONTINUUM OF CARE

Foundational Studies

- Investigate the mechanisms driving the pathobiology of the disease/condition.
- Investigate the mechanisms driving cardiovascular dysfunction following brain injury.
- Enhance understanding of oxygen sensing and the biological response to low oxygen levels.
- Identify risk factors, with a focus on comorbidities and genetic predispositions.

Epidemiology

- Conduct population-based studies to monitor cardiovascular changes over time.
- Conduct population-based research to identify risk factors, including but not limited to brain injury, and improve methods to detect individuals at high risk.
- Conduct population-based studies to examine variations in incidence and outcomes across different population subgroups.

Prevention

- Develop and test strategies to prevent or reduce the impact of the disease/condition on the heart, brain, arteries, and additional target organs.
- Develop and test strategies to reduce/prevent risk factors associated with disease onset, progression, or complications.

Diagnosis

- Develop and test strategies to enhance detection accuracy and sensitivity, including strategies to identify maladaptive vascular remodeling or to enable continuous monitoring or detection of tissue- or cell-specific oxygen levels.
- Develop and validate less invasive diagnostic methods.
- Identify and validate biomarkers that reliably predict outcomes.

Treatment
- Generate evidence to support the repurposing and off-label use of treatments, including research on optimal dosing regimens.
- Develop and test innovative therapeutic strategies, with an emphasis on targeted, localized, and personalized approaches.

INFECTIOUS DISEASES

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

TOPIC AREAS

- Congenital Cytomegalovirus
- Hepatitis B
- Tuberculosis

STRATEGIC GOALS BY CONTINUUM OF CARE

Foundational Studies
- Investigate the mechanisms of infection, transmission, pathogenicity, or drug resistance.
- Develop innovative preclinical models to investigate disease pathobiology, host response, and to support drug discovery and testing.
- Enhance understanding of interactions between infection and comorbid conditions.
- Identify risk factors contributing to adverse outcomes.
- Discover and evaluate new drug targets.

Epidemiology
- Conduct population-based studies to collect data on disease trends, including those establishing, affiliated with, or contributing to clinical networks, biorepositories, or databanks.
- Conduct population-based studies to improve understanding of transmission, disease progression, and risk factors for complications.
- Conduct retrospective studies to assess the impacts of disease on quality of life.

Prevention
- Develop and test strategies to prevent complications and adverse outcomes following infection.
- Develop and test innovative strategies to prevent disease onset or inhibit its progression.
- Develop and test methods to eliminate maternal-fetal transmission.

Diagnosis
- Develop and validate innovative diagnostic tools, focusing on less- or non-invasive methods, point-of-care applications, early detection, or improved sensitivity.
- Identify and validate biomarkers to improve infection diagnosis and/or prognosis, assess infection-related complications, or measure protection against infection.

Treatment
- Develop and test curative interventions or treatments that eliminate all symptoms, including precision medicine approaches and those that address latent infection.
- Develop and assess new therapeutic strategies that are more potent, act directly, require shorter dosing regimens, provide longer-lasting effects, better mitigate complications, address treatment resistance, and/or address latent infection.
- Generate evidence for optimal treatment regimens, including strategies tailored to specific age groups, combination therapies, and antiviral or vaccine dosing schedule recommendations.

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

- Accelerated Aging Processes Associated with Military Service
- Endometriosis
- Hypertrophic Dyschromia
- Infertility Associated with Military Aviators and Aviation Support Personnel
- Interstitial Cystitis
- Pancreatitis
- Polycystic Kidney Disease

STRATEGIC GOALS BY CONTINUUM OF CARE

Foundational Studies

- Improve understanding of how military service or exposures contribute to physiological dysregulation, reproductive health issues, the aging process, and epigenetic changes.
- Investigate the mechanisms and pathophysiology underlying disease onset and/or progression.
- Improve understanding of disease/condition heterogeneity, comorbidities, systemic impacts, and long-term complications.

Epidemiology

- Conduct comparative studies to determine military-specific risks and enhance understanding of diseases/conditions that have increased incidence in the active-duty and Veteran population.
- Conduct population- and/or patient-based studies to improve understanding of disease heterogeneity and phenotypic variability.
- Conduct research to better understand sex differences in incidence and/or outcomes.
- Conduct population-, occupational-, and/or patient-based studies to identify risk factors that influence disease development, progression, treatment, and outcomes.

Prevention

- Develop and test strategies to reduce the health impacts of military service and exposures and prevent long-term consequences.
- Develop and test innovative strategies to prevent disease onset, progression, and/or associated comorbidities.

Diagnosis

- Develop and validate screening tools to detect conditions associated with premature aging processes.
- Develop and validate innovative diagnostic approaches, focusing on less invasive methods, faster timelines, and methods that account for disease heterogeneity.
- Develop and validate biomarkers, imaging techniques, or other tools for diagnosis, objective prognosis, subtype differentiation, monitoring, or assessing treatment response.
- Develop and validate methods for identifying and measuring toxic agents and their pathophysiological effects.

Treatment

- Develop and test efficacy of lifestyle and other non-drug interventions.
- Develop and test novel treatment strategies aimed at cures or improved symptom management to enhance quality of life, including drug repurposing studies, combination therapies, and innovative drug delivery techniques.
- Develop and assess strategies to enable personalized care recommendations or optimize treatments for specific population subgroups, including studies on the efficacy of existing treatment options.

- Develop and test innovative approaches for pain management as a symptom of the disease/condition.
- Develop and test innovative approaches to improve organ transplant outcomes or transplant alternatives, such as artificial organs, xenotransplants, and novel strategies to prevent rejection.

NEUROSCIENCE AND MENTAL HEALTH

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

TOPIC AREAS

- Brain Injury Impact on Cardiac Health
- Dystonia
- Eating Disorders
- Gambling Addiction
- Hydrocephalus
- Intranasal Ketamine Anesthetics
- Maternal Mental Health
- Myalgic Encephalomyelitis/Chronic Fatigue Syndrome
- PANS and PANDAS
- Peripheral Neuropathy
- Post-Traumatic Stress Disorder
- Sleep Disorders and Restrictions
- Suicide Prevention

STRATEGIC GOALS BY CONTINUUM OF CARE

Foundational Studies

- Investigate the mechanisms underlying disease/condition pathobiology, progression, and associated comorbidities at multi-organ/system, circuit, or cellular/molecular levels.
- Identify factors that predispose individuals to the disease/condition, predict adverse outcomes, or contribute to resilience.
- Enhance understanding of disease/condition heterogeneity, including variations in phenotypic, symptom, and behavioral presentation.
- Develop and evaluate innovative models that can be used to understand etiology and will facilitate drug discovery and testing.

Epidemiology

- Conduct population-based studies to identify and track trends and treatment responses, generating data on treatment efficacy to inform the development of personalized treatments.
- Conduct population-based studies to enhance understanding of risk factors and progression of disease/condition.
- Conduct comparative studies to identify military-specific aspects of diseases/conditions, including risk factors, comorbidities, quality of life impacts, treatment preferences, prevalence, and ability to return to duty.
- Conduct research to better understand sex differences in incidence and/or outcomes.
- Conduct population-based studies to examine variations in incidence and outcomes across different population subgroups.

Prevention

- Develop and test strategies to prevent the disease/condition, as well as its downstream complications, including methods for relapse prevention or mitigation of risk factors.
- Develop and test innovative strategies to maintain optimal cognitive functioning and mental resilience.

Diagnosis

- Develop and validate objective diagnostic methods that are accurate, sensitive, enable early detection, and account for heterogeneity in disease/condition phenotypes, includes screening tools.
- Identify and validate biomarkers that predict risk for the primary disease/condition and its secondary complications.

- Develop and validate methods for continuous monitoring and evaluating treatment efficacy.

Treatment

- Develop and test treatments to achieve curative or regenerative outcomes, preserve cognition, and enhance quality of life, including gene therapies, noninvasive stimulation techniques, alternatives to brain surgery, pharmaceuticals, and behavioral interventions.
- Evaluate repurposed drugs to accelerate strategies for improving symptom management and enhancing quality of life.
- Develop and assess guidelines for optimal intervention use, including evidence for safety and efficacy across diverse populations, precision medicine approaches, dosing regimens, safety monitoring, side effect management, and delivery methods.
- Develop and test innovative strategies to increase access to treatments, such as telemedicine approaches and adaptations tailored to specific populations.

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

- Accelerated Aging Processes Associated with Military Service
- Musculoskeletal Health
- Orthotics and Prosthetics Outcomes

STRATEGIC GOALS BY CONTINUUM OF CARE

Foundational Studies

- Investigate mechanisms driving musculoskeletal disease/condition pathology and progression, focusing on muscle, connective tissue, genetics, epigenetics, aging, pain, sex differences, physical or mental stress, mechanobiology, cell senescence, and/or systemic interactions.
- Identify risk factors for orthopaedic diseases/conditions, including those that accelerate musculoskeletal degeneration, contribute to adverse outcomes, or lead to more severe symptoms.
- Develop and evaluate disease/injury using preclinical models to improve understanding of mechanisms and support intervention discovery and testing.
- Develop and evaluate small joint disease/injury models improve understanding of mechanisms and support intervention discovery and testing.
- Investigate the impact of life stage impacts musculoskeletal health and related diseases/ conditions, including the effects of childhood growth, hormonal changes throughout the lifespan, and aging-related processes.

Epidemiology

- Leverage large data sets to generate evidence-based treatment guidelines to optimize joint longevity.
- Conduct patient-reported outcomes research incorporating both objective measures and quality-of-life metrics to evaluate treatment efficacy and guide intervention decisions.
- Conduct research to better understand sex differences in incidence and/or outcomes.
- Conduct comparative studies to better understand musculoskeletal degeneration in Veterans and identify military-specific risk factors.

Prevention

- Develop and test strategies that improve point-of-injury care, focusing on reducing the risk of secondary complications and promoting joint preservation.
- Optimize and test personalized treatment or rehabilitation plans to address adverse outcomes and mitigate risk factors.
- Develop and test strategies to prevent inflammatory joint damage caused by aging or overuse.

Diagnosis

- Develop and validate strategies for early and precise diagnosis of musculoskeletal dysfunction, including screening methods tailored for pediatric populations.
- Identify and validate biomarkers that indicate the severity or progression rate of musculoskeletal disease or age-associated degeneration.
- Identify and validate biomarkers or outcome measures to monitor disease/condition progression, understand variability, assess treatment efficacy, and evaluate impacts on quality of life.

Treatment

- Advance innovative treatment strategies targeting etiology, preserving joint integrity, retaining functionality for daily activities, improving muscle strength and range of motion, reducing pain or fatigue, and/or regenerating damaged tissues.
- Develop and assess treatment strategies to enhance quality of life by increasing mobility, halting/slowing disease progression, or accelerating return to duty, including exercise regimens, regenerative or immune-modulating therapies, and device optimization.
- Develop and assess methods to optimize treatment, including patient-specific strategies, combination therapies, or refinement of intervention timing and dosing.
- Develop and test improved orthopedic devices, such as AI-driven auto-adjusting devices, better integrated designs for enhanced stability or accelerated healing, improved braces, prosthetic limbs, joint replacements, and strategies to enhance comfort.

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
- Facioscapulohumeral Muscular Dystrophy
- Fibrous Dysplasia/McCune-Albright Syndrome
- Fragile X
- Frontotemporal Degeneration
- Hereditary and Acquired Ataxias
- Hereditary Hemorrhagic Telangiectasia
- Hermansky-Pudlak Syndrome
- Mitochondrial Disease
- Myotonic Dystrophy
- Prader-Willi Syndrome
- Rett Syndrome
- Sickle-Cell Disease
- Spinal Muscular Atrophy
- von Hippel-Lindau Disease

STRATEGIC GOALS BY CONTINUUM OF CARE

Foundational Studies

- Develop and evaluate innovative models for drug discovery and testing, with an emphasis on patient-derived cell models.
- Investigate the mechanisms driving symptoms to identify new strategies for symptom management, including novel drug targets and paradigm-shifting insights into pathobiology.

Epidemiology

- Conduct population- or patient-based studies to evaluate intervention efficacy, incorporating patient-reported outcomes and objective metrics to refine clinical guidance, develop personalized treatments, and validate clinically relevant endpoints.
- Conduct population-based studies to monitor disease progression and identify factors that drive onset, progression, and outcomes.
- Conduct population-based studies to improve understanding of relationships between the disease/condition and comorbidities or conditions with shared symptoms.
- Integrate electronic medical records with real world data to improve the accuracy of prevalence estimates and guide precision medicine approaches.

Prevention

- Develop and test approaches to prevent complications associated with the disease/ condition.
- Develop and test approaches, including gene therapy, to prevent symptoms or familial aggregation of the disease/condition.
- Develop and test evidence-based strategies to reduce disease/condition severity, including investigations promoting better health during pregnancy.

Diagnosis

- Develop and validate diagnostic strategies that are objective, noninvasive, accurate, and enable early detection, subtype distinction, disease progression tracking, and complication prediction.
- Develop and validate methods to objectively measure symptoms and evaluate their impact on daily functioning.
- Develop and validate diagnostic, monitoring, or prognostic biomarkers.
- Identify and validate clinically relevant endpoints for assessing treatment response, suitable for use in FDA-regulated clinical trials.

Treatment

- Develop and test innovative treatment approaches, emphasizing early intervention, therapies that slow/halt disease/condition progression, therapies that address phenotypic/ subtype differences, and disease-modifying or curative treatments.
- Develop and assess strategies to optimize existing treatments to reduce side effects and tailor interventions to specific patients.
- Generate evidence to support and guide the use of off-label drugs for symptom relief.
- Develop and test pharmacological or non-pharmacological interventions to manage symptoms and improve quality of life for patients and caregivers, including strategies for care transitions.

RESEARCH AND CLINICAL TOOLS

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

TOPIC AREAS

- Proteomics

STRATEGIC GOALS BY CONTINUUM OF CARE

Foundational Studies

- Utilize proteomics to deepen understanding of the molecular mechanisms, progression, comorbidities, and long-term complications of the disease/condition/injury.
- Investigate the functional impact of post-translational modifications and proteoforms, beyond protein abundance, to guide management of the disease/condition/injury.
- Further the integration of proteomic databases and validated proteome subsets into advanced informatics tools.

Epidemiology
- Conduct population-based longitudinal proteomics studies to guide disease/ condition/injury management strategies and support the development of personalized care approaches.
- Leverage existing proteomic databases to conduct large-scale research.

Prevention
- Develop and validate proteomics-based technologies to prevent the onset, progression, recurrence, and/or comorbidities of the disease/condition/injury.

Diagnosis
- Develop and validate proteomics-based technologies or biomarkers for early detection, accurate diagnosis, subtype differentiation, monitoring disease/condition progression, or evaluating treatment response.

Treatment
- Develop and test proteomics-based technologies to support personalized treatment strategies.
- Use proteomics-based approaches to identify novel treatments or targets.

RESPIRATORY AND ENVIRONMENTAL HEALTH

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

TOPIC AREAS

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

STRATEGIC GOALS BY CONTINUUM OF CARE

Foundational Studies
- Identify factors driving respiratory distress or chronic respiratory disease progression with the goal of identifying novel treatment targets.
- Investigate the mechanisms by which airborne hazards cause respiratory injury/disease, including research linking the toxicant to the specific pathobiology.

Epidemiology
- Conduct population-based studies to generate data on risk factors, disease progression, and treatment outcomes to guide personalized medicine approaches.
- Conduct retrospective studies to correlate toxicant exposure with long-term illnesses.

Prevention
- Develop and test strategies to prevent lung disease following exposure to airborne pollutants, toxicants, or infectious agents.
- Develop and test strategies to prevent the extent of lung damage caused by trauma, transfusion, mechanical ventilation, infection, acute respiratory distress syndrome, or hemorrhagic shock.

Diagnosis
- Identify and validate biomarkers to diagnose, monitor progression, and predict adverse outcomes and complications of chronic respiratory diseases.
- Identify and validate biomarkers to support the development of personalized treatment strategies.
- Develop and validate tools to enable early and accurate detection of respiratory diseases/ conditions, focusing on noninvasive approaches and point-of-care strategies.
- Develop and test fieldable toolsets to monitor lung dysfunction.
- Develop and validate methods to quantify individual exposure levels to airborne hazards.

Treatment

- Develop and test innovative treatments to slow progression of the disease/condition and promote lung repair, emphasizing progress towards precision medicine and regenerative approaches.
- Develop and test treatments for respiratory infections.
- Develop and test minimally invasive or noninvasive methods of delivering oxygen and facilitating gas exchange when the lungs are compromised.
- Develop and test fieldable systems to treat lung injury in far-forward settings.

3.2.2. Key Elements for the Clinical Trial Award

- **Impact:** The PRMRP CTA intends to support impactful clinical trials that will provide new interventions or clinical guidance to transform patient care. The research must show clear alignment and impact towards a congressionally directed FY26 PRMRP Topic Area and aim to fulfill an FY26 PRMRP Strategic Goal.
- **Preliminary Data:** 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.
- **Study Design:** When developing applications for the PRMRP CTA mechanism, the PRMRP strongly encourages applicants to provide sufficient evidence to demonstrate the following key considerations:
    - The availability of, and access to, the study population.
    - Intervention access and availability.
    - The study team composition is appropriate for the proposed research.
    - The statistical considerations, data management and analysis plans are appropriate for the proposed research.
- **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 DOW 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 DOW and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 10 of the GAI.

3.2.3. Other Important Considerations for the Clinical Trial Award

Funding from this award mechanism must support a clinical trial. Preclinical research and animal studies are not supported in this funding opportunity. All empirical laboratory research or optimization of the intervention must be completed prior to the award start date. For help determining whether the proposed study meets the definition of a clinical research study or a clinical trial, refer to these case study examples.

Applicants seeking funding for research that does not meet the definition of a clinical trial should consider other FY26 PRMRP funding opportunities. For information about these award mechanisms, see the FY26 PRMRP Research Development Pipeline.

An informational resource for preparing an application, the Human Subject Research Resource, is available on the CDMRP website.

Clinical Trial Start Date: Patient recruitment for the proposed clinical trial should begin no later than 9 months after the award date of the Clinical Trial Only option or 3 months after exercising the option for the clinical trial phase under the Clinical Trial with Planning Phase option.

For applications submitted under the clinical trial only option (not applicable to planning phase applications): If required, an active IND, IDE, or equivalent, deemed safe to proceed that covers the proposed trial, **must be in place by the FY26 PRMRP Clinical Trial Award application submission deadline** (this includes clinical trials requesting exception from informed consent under 21 CFR 50.24). The regulatory application should be specific to the product and indication to be tested in the proposed clinical trial.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research, such as those described in the STROBE, CONSORT, SPIRIT and ARRIVE 2.0 guidelines.

Applications from investigators within the DOW and applications involving multidisciplinary collaborations among academia, industry, the DOW, 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, their Families and the American Public. 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. Funding Instrument

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

3.4. Funding Details

Clinical Trial With Planning Phase:

Period of Performance: The maximum period of performance is **12** months for the planning phase. The maximum period of performance for the subsequent clinical trial phase is **4** years.

Cost Cap: The application's total costs budgeted for the entire planning phase should not exceed **$800,000**, while the budget for the proposed clinical trial should match the selected funding level. 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.

Approval of the clinical trial effort will be contingent upon the completion of the planning phase to include all necessary regulatory approvals under the base award. Additionally, clinical trial efforts will be contingent on PRMRP Programmatic Panel approval and may be dependent on the availability of future year funds. ***The budget for the planning phase should correspond to Budget Period 1 on the Research & Related Budget Attachment Form. The clinical trial phase should correspond to Budget Periods 2-5 on the Research & Related Budget Attachment Form. The Budget Justification should clearly separate the Planning Phase from the Clinical Trial Phase and provide discrete totals for each phase.***

Clinical Trial Funding Level 1:

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 **$6M**. The requested budget must be justified and appropriate to the scope of the clinical trial proposed. 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.

Clinical Trial Funding Level 2:

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 **$10M**. The requested budget must be justified and appropriate to the scope of the clinical trial proposed. 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.

Clinical Trial Funding Level 3:

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 **$20M**. The requested budget must be justified and appropriate to the scope of the clinical trial proposed. 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.

For All CTA Applications:

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 FY26 Clinical Trial Award.
- Research participant 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.
- Animal studies or other preclinical empirical laboratory research.
- 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 DOW 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. Pre-Application Components

Pre-application submissions must include the following components.

Include the FY26 PRMRP portfolio, congressionally directed FY26 PRMRP Topic Area, FY26 PRMRP continuum of care category, and FY26 PRMRP Strategic Goal under which the application will be submitted.

Select the appropriate mechanism option as described in Section 5.3.1. Pre-Application Submission.

Upload documents as individual PDF files unless otherwise noted. Files must comply with the formatting guidelines listed in the GAI.

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

  The Preproposal Narrative should include the following:

  - **Research Idea:** State the congressionally directed FY26 PRMRP Topic Area and FY26 PRMRP Strategic Goal that will be addressed by the project. The topic area and strategic goal should be the same as those selected from the dropdown menus and phrased exactly as they appear in section 3.2.1. Please avoid paraphrasing. Additionally, describe how the proposed research project will address the stated congressionally directed FY26 PRMRP Topic Area and FY26 PRMRP Strategic Goal. Describe the ideas and scientific rationale on which the proposed clinical trial is based; include relevant literature citations. State the clinical intervention, participant population(s), phase of the clinical trial proposed, regulatory status, and sponsor.

    Trial Readiness: Briefly describe the project readiness to include the level of scientific evidence that supports the initiation of the proposed clinical trial, and the availability of, and accessibility to, the intervention and the proposed participant population. If the planning phase option is selected, briefly describe the proposed planning phase activities and how they will mitigate risk of the trial phase not being able to proceed as planned.

- **Research Strategy:** Concisely state the project's hypothesis and/or objectives and specific aims. Briefly describe the experimental approach, including study design, endpoints/outcome measures, and statistical methods for analysis.
- **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the clinical trial. Note any DOW- or VA-relevant collaborations.
- **Impact and Relevance to Military Health:** Describe how the proposed work will have an impact on accelerating the movement of a promising intervention into clinical application. Explain how the project is relevant to the health care needs of military Service Members, Veterans and their Families.

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:
  - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
  - **List of Abbreviations, Acronyms and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
  - **Budget:** Provide an estimated budget for direct costs for the clinical trial, and if applicable, the planning phase, and include a brief justification of those costs. A detailed budget is not required at this time but will be required if invited to submit a full application.
  - **Funding Level Justification (two-page limit):** Provide justification for the selected funding level. The justification should include a brief description of the main goal of the study and the number of participants that will be recruited. For phased trials, the phase should be explicitly stated.

    Applicants may request a funding level outside of the specific phase or participant requirements by using this attachment to explain why the lower funding amount is insufficient for the proposed work, such as unusual requirements or study design considerations. Describe the specific challenges the additional funds will help address, and why the additional funds are critical to achieving the proposed clinical endpoints.
  - **Key Personnel Biographical Sketches:** ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

4.3. Full Application Components

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

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)*:

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 in the GAI.

- **Attachment 1: Project Narrative (page limit varies as noted below): Upload as "ProjectNarrative.pdf".**

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

  Planning Phase, if applicable (eight-page limit):

  - Outline the plan for obtaining IND/IDE status (or other FDA approvals) during the 12-month or less period of performance if an IND or IDE is required. If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification. Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities, as defined in 21 CFR 312.3 (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312/subpart-A/section-312.3), and a commitment to oversee execution of the study.
  - Describe the overall regulatory strategy and product development plan that will support the planned product indication. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance; the types of FDA meetings that will be held/planned; and the submission filing strategy. Include considerations for compliance with current Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), and Good Clinical Practice (GCP) guidelines.
  - If applicable, describe how the planning phase will enable finalization or completion of Study Procedures; Laboratory Evaluations; Questionnaires and Other Research Data Collection Instruments; and/or Clinical Monitoring Plan.
  - If applicable, describe how the planning phase will enable finalization or completion of the Study Population; Inclusion/Exclusion Criteria; Recruitment Process; Informed Consent Process; and/or Screening Procedures.
  - If applicable, describe how the planning phase will enable finalization or completion of Data Management and/or Research Resources Sharing Plan.
  - If applicable, describe how the planning phase will enable finalization or completion of Organizational Chart; Study Personnel Description; and/or Study Management Plan.
  - Describe plans for other administrative approvals (e.g., IRB, DOW, OHRO).

  Clinical Trial (required for all applications; 20-page limit): If applying for the Clinical Trial with Planning Phase, begin this section on a new page. If the clinical trial includes the planning phase, the total page limit is 28 pages (eight pages for the planning phase plus 20 pages for the 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.
- **Objectives, Specific Aims and 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.
- **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 of what study participants will experience. Consult appropriate guidelines to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.
  - 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 participants, including the study intervention that they will experience, and include the dose and administration route. Provide sufficient detail in chronological order for a person not involved in the study to understand what the study participants will experience.
  - 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.

- 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, 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 participants, 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 objectives 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 in Attachment 2, Supporting Documentation. Describe the reliability and validity of the selected endpoints/outcome measures and evaluations, 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 participants).
- 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 for a thorough evaluation of 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".**

  There are no page limits for these components unless otherwise noted. Include only 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 in the Project Narrative using a standard reference format (include URLs, if available).
  - **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; include 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 the original or present government award under which the facilities or equipment items are now accountable. There is not a standardized 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 as follows:
    - Letters of Collaboration (if applicable): Provide letters from collaborating individuals/organizations.
    - Letter of Eligibility Confirmation (required): Provide a letter from the Department Chair or equivalent confirming the PI meets eligibility criteria and has necessary resources.
    - Letter from Patient Advocate (if applicable): Provide a letter from the patient advocate confirming their participation as a member of the research team.
    - Letters of Access (if applicable): Provide a letter from the lowest-ranking person with approval authority confirming participation of intramural DOW collaborator(s), access to access to military populations, databases or DOW resources. Additionally, provide a letter indicating access to VA military populations, databases or resources, provide a letter signed by the VA Facility Director(s), or an individual designated by the VA Facility Director(s), confirming access to VA patients, resources and/or VA research space.
  - **Research Sharing Plan:** Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe the mechanism (e.g., direct sharing, repository, mixed mode) by which data and resources generated during the period of performance will be shared with the research community and other affected communities, including clinical trial participants. Include the name of the repository(ies) where scientific data and resources arising from the proposed clinical trial will be archived, if applicable. Identify and provide the rationale for any data or resources that will not be shared (e.g. for intellectual property, feasibility, cost, or

other considerations). The plan should also protect participant privacy, confidential and proprietary data, and performer/third-party intellectual property. Provide a milestone plan for disseminating data/results including when data and resources will be made available to other users. In cases where the study participant could potentially derive medical or other benefit from the information, explain whether the results of screening and/or study participation will be shared with the participant or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.

Do not submit a copy of the National Institutes of Health Data Management and Sharing Plan or duplicate the Data Management Plan, which will be requested only after a recommendation for funding is made.

Refer to the CDMRP Directive on Sharing Data and Research Resources for more information about the CDMRP's expectations for making data and research resources publicly available.

- **Use of DOW Resources or VA Resources *(if applicable)*:** If the proposed research involves access to military and/or VA patient populations and/or DOW 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 GAI, Appendix 4, for additional considerations.
- **Questionnaires and Other Research Data Collection Instruments *(if applicable)*:** 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.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".**

Write the technical abstract 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:** State the congressionally directed FY26 PRMRP Topic Area and FY26 PRMRP Strategic Goal that will be addressed by the project. The topic area and strategic goal should be phrased exactly as they appear in section 3.2.1 and paraphrasing should be avoided. Additionally, describe how the proposed research project will address the stated congressionally directed FY26 PRMRP Topic Area and FY26 PRMRP Strategic Goal.
- **Hypothesis/Objective(s):** State the objective of the proposed clinical trial and the hypothesis/research question to be addressed.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design, including appropriate controls. Include 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 how the study is relevant to military health.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".**

  The lay abstract should address the points outlined below ***in a manner that is readily understood by readers without a background in science or medicine.*** Avoid overuse of scientific jargon, acronyms and abbreviations. ***Do not duplicate the technical abstract.***

  - State the congressionally directed FY26 PRMRP Topic Area and FY26 PRMRP Strategic Goal that will be addressed by the project. The topic area and strategic goal should be phrased exactly as they appear in section 3.2.1 and paraphrasing should be avoided. Additionally, describe how the proposed research project will address the stated congressionally directed FY26 PRMRP Topic Area and FY26 PRMRP 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.
  - Describe the potential benefit of the proposed study and the anticipated outcomes to Service Members, Veterans and their Families.

- **Attachment 5: Statement of Work (three-page limit for the Clinical Trial; five-page limit for the Clinical Trial with Planning Phase): Upload as "SOW.pdf".** Refer to eBRAP for the Suggested SOW Format.

  For applications to the Clinical Trial with Planning Phase, two SOWs should be uploaded as a single attachment: The first, two-page SOW should describe the major tasks for the planning phase, and the second, three-page SOW beginning on a new page should describe the major tasks for the proposed clinical trial. There is a five-page total limit for Clinical Trial with Planning Phase applications. The SOW should describe only the work for which funding is being requested by this application.

  For guidance on preparing the SOW, refer to the Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work. Include milestones for data or research resource(s) sharing.

- **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.

- **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. 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.
- **Study Population Availability:** Demonstrate that the research team has access to the proposed study population at each site. Describe the approximate number, pertinent demographic information and other relevant characteristics of the study population at each enrollment site. Indicate whether the actual size of available study population may be affected by ongoing clinical trials that compete for the same population. If the proposed research involves access to military and/or VA patient populations and/or DOW 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 GAI, Appendix 4, for additional considerations.
- **Recruitment and Retention Process:** Explain methods for identification of potential study participants (e.g., medical record review, obtaining sampling lists, health care provider identification). Describe the recruitment process in detail; address who will identify potential study participants, who will recruit them, and what methods will be used to recruit them. Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human participants enrolled in the study. If study participants will be compensated, include a detailed description of and justification for the compensation plan. Describe the methods that will be employed to retain participants within the study. Discuss past efforts in recruiting and retaining study participants 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. Estimate the potential for participant loss to follow up and how such loss will be handled/mitigated. Indicate whether the study team has considered barriers to clinical trial participation and, if applicable, how the team aims to mitigate or overcome these barriers.
- **Women and Minorities Recruitment/Retention Strategy:** Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex, racial, and ethnic group, and an accompanying rationale for the selection of participants. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement. Anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race, and ethnicity should be provided as part of the application's Supporting Documentation (Attachment 2). Refer to the CDMRP Directive on Inclusion of Women and Minorities as Subjects in Clinical Research for additional information.
- **Informed Consent Process:** Specifically describe the plan for obtaining informed consent from study participants; include information regarding the timing and location

of the consent process. If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, describe the plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent. Appendix 6 of the GAI contains additional considerations unique to DOW-sponsored research.

- **Risks/Benefits Assessment:**
  - **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Address special precautions to be taken by the human participants before, during and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention). If applicable, identify any potential risk to the study personnel.
  - **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 participants and study personnel or to manage unpreventable risks. 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 costs of such care.
  - **Potential benefits:** Describe known and potential benefits of the study to the human participants 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 participants are reasonable in relation to the anticipated benefits to the human participants and others that may be expected to result.

- **Attachment 7: Relevance to Military Health Statement (one-page limit): Upload as "MilRel.pdf". Attachment 7 will be available for programmatic review only.**
  - 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 the planned use of the product is to support the Warfighter, explain how the product meets the needs and requirements for use in the deployed setting.
  - 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 DOW and/or VA areas of research interest. 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 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 about 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 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 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).
    - 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.

For a Clinical Trial Only submission:

- ***If an IND or IDE is required, the application must be submitted to the FDA prior to the FY26 PRMRP Clinical Trial Award application submission deadline (this includes clinical trials requesting exception from informed consent under 21 CFR 50.24).*** 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. If there are any existing cross-references in place, provide the application number(s) and associated sponsor(s). Provide an explanation of the status of the application (e.g., past the critical 30-day period, pending response to questions raised by the FDA, on clinical hold, on partial clinical hold). If the IND or IDE application has been placed on clinical hold or partial hold, explain the conditions that must be met for release of the hold. Provide a summary of any previous meetings with the FDA on development of this product. A copy of the Agency meeting minutes should be included if available. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application.
- If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.

- **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 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 or investors to facilitate moving the product into the next phase of development when preparing the transition plan. ***The post-award transition plan should:***
  - Name the project's anticipated research outcomes including knowledge products and/or clinical products for development. A "knowledge product" is a non-materiel product that aims to transition into medical practice, training, tools or to support materiel solutions; and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.
  - Include a timeline with defined milestones describing the logical next steps to advance the research outcome to the next stage of clinical development/ implementation/dissemination. Include steps regarding Regulatory Agency approval as appropriate.
  - Describe collaborations and other resources (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources) that are in place or will be established to execute the steps described above. Include a discussion of the funding strategy necessary to transition the research outcome to the next level of investigation, development, and/or commercialization. The discussion should include potential opportunities for securing funding through commercial sponsorship, venture capital, federal or nonfederal funding opportunities, or other relevant resources.
  - As appropriate, discuss ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award. Include a plan for resolving intellectual and material property issues among participating organizations. If the intellectual property rights are not owned by the applicant, PI or a member of the study team, describe the planned next steps necessary to make the product available to the target population.
- **Attachment 11: Impact Statement (two-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 is 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 a congressionally directed FY26 PRMRP Topic Area and Portfolio-Specific Strategic Goal.
  - **Describe the short-term impact:** Detail the anticipated research outcome(s) that will be directly attributed to the results of the proposed clinical trial, and describe the anticipated benefits of these outcomes for individuals and the research field. Describe any relevant controversies, treatment issues or health disparities that will

be addressed by the proposed clinical trial. If the proposed trial will have an impact on a subset of the population affected by the disease or condition, then sufficient details should be provided to justify why the research is focused on that population.

- **Describe the long-term impact:** Explain the long-range vision for how implementation/dissemination of the intervention and/or research outcome(s) will improve patient care and/or quality of life for the target population. Describe how the intervention represents an improvement over currently available interventions and/or standards of care.
  - Describe any potential challenges that might limit the impact of the proposed clinical trial, including barriers to implementation or acceptance by users.

- **Attachment 12: Funding Level Justification (two-page limit): Upload as "FundJust.pdf".**

  Provide justification for the selected funding level. The justification should include a brief description of the main goal of the study and the number of participants that will be recruited. For phased trials, the phase should be explicitly stated.

  Applicants may request a funding level outside of the specific phase or participant requirements by using this attachment to explain why the lower funding amount is insufficient for the proposed work, such as unusual requirements or study design considerations. Describe the specific challenges the additional funds will help address, and why the additional funds are critical to achieving the proposed clinical endpoints.

- **Attachment 13: Prior Outcomes Statement (if applicable; one-page limit): Upload as "Outcomes.pdf". Attachment 13 will be available for programmatic review only.**

  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 14: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations document available on eBRAP.

- **Attachment 15: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOW 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 available on eBRAP.

(c) Additional Application Materials:

The following are additional forms for application submission. Follow the instructions specific to the submission portal, as found within the GAI.

Grants.gov	eBRAP.org
i. Research & Related Senior/Key Person Profile (Expanded) ○ **Biographical Sketch** ○ **Current/Pending Support** *Intragovernmental applicants must include their internally supported research and development programs.*	
ii. Research & Related Budget	
iii. Project/Performance Site Location(s) Form	
iv. Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov submissions only)*	

4.4. Other Application Elements

If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DoD Instructions 3200.12 will be requested.

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

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942526PRMRPCTA from Grants.gov or eBRAP, depending on which submission portal will be used.

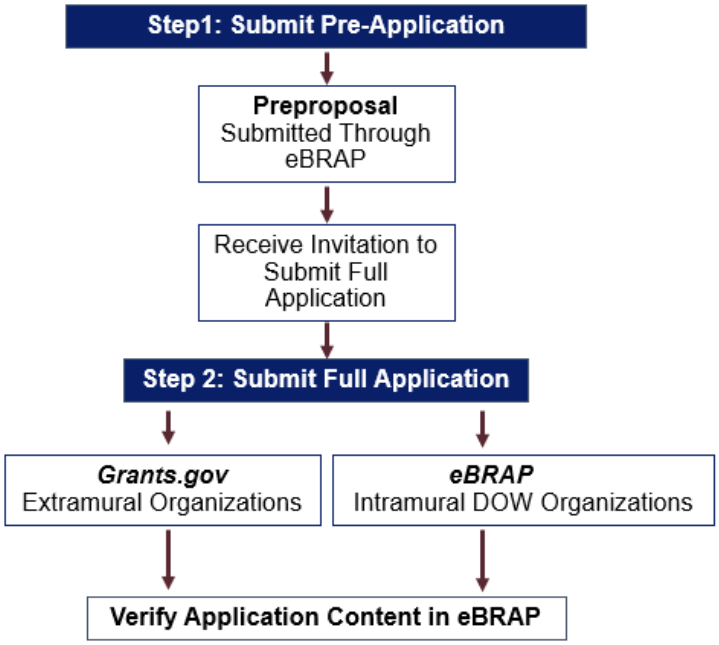
5.2. Unique Entity Identifier and System for Award Management

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.

5.3. Submission Instructions

The CDMRP uses two portal systems to accept pre- and full application submissions. The workflow below shows which portal system to use for pre- and full application submissions, respectively.

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. Contact the eBRAP Help Desk if any changes need to be made.

When starting the pre-application, PIs should select the Mechanism Option appropriate to their pre-application:

Application Includes:	Select Mechanism Option:
Phase 0 or phase 1 clinical trial or non-phased clinical trial with fewer than 100 participants only	**Clinical Trial Award – Funding Level 1**
Phase 0 or phase 1 clinical trial or non-phased clinical trial with fewer than 100 participants with a Planning Phase	**Clinical Trial Award – with Planning Phase – Funding Level 1**
Phase 2 clinical trial or non-phased clinical trial with fewer than 300 participants only	**Clinical Trial Award – Funding Level 2**
Phase 2 clinical trial or non-phased clinical trial with fewer than 300 participants with a Planning Phase	**Clinical Trial Award – with Planning Phase – Funding Level 2**
Phase 3 clinical trial or non-phased clinical trial with greater than 300 participants only	**Clinical Trial Award – Funding Level 3**
Phase 3 clinical trial or non-phased clinical trial with greater than 300 participants with a Planning Phase	**Clinical Trial Award – with Planning Phase – Funding Level 3**

Applicants will be asked to select the following. Select the option appropriate to the application:

- Select the FY26 PRMRP portfolio addressed by the proposed research.
- Select the congressionally directed FY26 PRMRP Topic Area addressed by the proposed research.
- Select the FY26 PRMRP continuum of care category addressed by the proposed research.
- Select the FY26 PRMRP Strategic Goal addressed by the proposed research.

Changes to any of the above selections between the pre-application submission and full-application submission require an email to the eBRAP Help Desk.

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace.

eBRAP Submissions: Only intramural DOW organizations may submit full applications through eBRAP.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of the submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log in to eBRAP to review, modify and verify the full application submission. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the application verification period ends. 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 DHACA cannot make allowances/exceptions for submission problems encountered by the applicant.***

Submission dates and times are specified in Section 1, Basic Information.

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 the 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 Directive 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.

Members of the FY26 PRMRP Programmatic Panel must 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 FY26 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

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

- **Research Idea:** The degree to which the proposed clinical trial addresses an important question in one of the congressionally directed FY26 PRMRP Topic Areas and one of the FY26 PRMRP Portfolio-Specific Strategic Goals. How well the scientific rationale is supported, and how well the background and availability of and accessibility to resources and participant population indicate the research is ready to move into the phase of the clinical trial proposed.
- **Research Strategy:** How well the specific aims, patient population, and proposed methodology will address the hypothesis and/or reach the desired objectives.
- **Personnel:** How the background and experience of the PI and other key personnel are appropriate to successfully complete the clinical trial.
- **Funding Level Justification and Budget:** How the estimated budget and justification are reasonable for the proposed work. If the planning phase option is selected, to what degree the planning phase is being appropriately utilized to mitigate risk of the trial not being able to proceed as planned. Whether the funding level selected is appropriate for the proposed trial.

If a funding level is requested outside of the specific phase or participant requirements, whether the rationale is sufficient to justify the request for a higher funding level.

- **Impact and Relevance to Military Health:** The degree to which the proposed clinical trial, if successful, will have an impact on accelerating the movement of a promising intervention into clinical application. How well the research will address a health care issue relevant to military Service Members, Veterans and their Families

6.2.2. Peer Review Criteria

To determine technical merit, all applications will be evaluated individually according to the following **scored criteria**, of which Clinical Impact is of the upmost importance, Budget is of the least importance, and all other criteria are of equal importance:

For the Planning Phase (if applicable):

- **Planning Phase**
  - How well the plan is described for obtaining IND/IDE status (or other FDA approvals) during the 12-month or less period of performance if an IND or IDE is required.
  - Whether there is a regulatory sponsor specified and a signed sponsor commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.
  - If applicable, how well the planning phase will enable finalization or completion of:
    - Study Procedures; Laboratory Evaluations; Questionnaires and Other Research Data Collection Instruments; and/or Clinical Monitoring Plan
    - Study Population; Inclusion/Exclusion Criteria; Recruitment Process; Informed Consent Process; and/or Screening Procedures
    - Questionnaires and Other Data Collection Instruments
    - Data Management and/or Research Resources Sharing Plan; and/or finalization or completion of the Regulatory Strategy
    - Organizational Chart; Study Personnel Description; and/or Study Management Plan
  - To what degree the overall regulatory strategy and product development plan will support the planned product indication.
  - How well the plans for other administrative approvals (e.g., IRB, DOW, OHRO) are outlined.

For all clinical trials:

- **Clinical Impact**
  - To what extent the proposed research project aligns to the applicant-selected congressionally directed FY26 PRMRP Topic Area.
  - To what extent the intervention addresses a critical clinical need and improves upon available interventions and/or standards of care for the target population with regard to the applicant-selected congressionally directed FY26 PRMRP Topic Area.
  - To what extent the proposed research project addresses the applicant-selected FY26 PRMRP Portfolio-Specific 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.

- **Research Strategy and Feasibility**
  - How well the scientific rationale for the proposed clinical trial is supported by the review and analysis of the available literature and preliminary data.
  - To what degree the application includes preclinical and/or clinical evidence to support the safety and stability (as appropriate) of the intervention.
  - How well the specific aims/hypotheses/research question, study design, experimental methods, data collection procedures and evaluations are designed to address the clinical objective and purpose of the study.
  - 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 statistical model and data analysis plan are suitable for the planned study objectives.
  - To what degree the sample size projections are adequate to ensure proper power for the study, and as applicable, any subgroup analysis.
  - To what extent the proposed timeline for completion of the research is reasonable.
  - How well studies are designed to achieve reproducible and rigorous results, including the endpoints/outcomes to be measured.
  - How well potential challenges and alternative strategies are discussed.
  - Whether there is evidence indicating availability of the intervention from its source, for the duration of the proposed clinical trial (if applicable).
  - To what extent the plan for sharing of project data and research resources is appropriate, reasonable, and includes dissemination to affected communities, study participants and/or the scientific community. If applicable, whether specific repository(ies) are named where data and research resources arising from the project will be stored.
  - If applicable, whether measures are described to ensure the consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).
- **Recruitment, Accrual and Retention**
  - To what degree the plan for recruiting, enrolling and retaining study participants is reasonable to 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 degree the number of study participants to be enrolled is reasonable based upon the proposed timeline, study procedures, available study population, inclusion/ exclusion criteria, and planned efforts to achieve accrual goals.
- Whether the distribution of the proposed enrollment on the basis of age, sex, race, and/or ethnicity is appropriate for the proposed research.
- 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.
- If applicable, to what degree barriers to clinical trial participation have been considered and/or addressed.

- **Regulatory Strategy and Transition Plan**
  - To what extent the regulatory strategy and product development plan are well described and appropriate to support the product indication or product label change, if applicable.
  - Whether the application includes documentation that the study is exempt from regulatory agency oversight, 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 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.
  - To what degree ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award are considered and planned for.
  - To what degree the next logical steps to be taken upon successful completion of the proposed clinical trial are realistic and appropriate to bring the research outcome(s) to the next stage of clinical development/implementation/dissemination.

- To what degree the collaborations and other resources (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/ execution committees, training providers/resources) intended to help advance the research outcome(s) are established and/or achievable.

- **Ethical Considerations**
  - Whether the population selected to participate in the trial stands to benefit from the knowledge gained.
  - How the level of risk to human participants is minimized, and how the safety monitoring and reporting plan is appropriate for the level of risk.
  - To what degree the process of seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
  - To what extent the proposed clinical trial might affect the daily lives of the individual human participants participating in the study.
  - To what degree privacy and confidentiality issues are appropriately considered.
  - To what extent the proposed clinical trial might affect the daily lives of the individual human participants participating in the study.
  - To what degree the planned route and schedule of study intervention(s), evaluations(s) and follow-up procedures are reasonable for study participants to experience.
- **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), 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, multi-institutional structure governing the research protocol[s]) are appropriate and meet the needs of the proposed clinical trial.
  - If applicable, whether the inclusion of any personnel working at international sites is adequately justified
- **Budget**
  - To what extent the proposed budget is adequately justified and reflects the proposed research.
  - Whether the proposed research aligns to the applicant-selected funding level.
  - If a funding level is requested outside of the specific phase or participate requirements, whether the rationale is sufficient to justify the request for a higher funding level.
  - ***For the Planning Phase:*** Whether the costs exceed the allowable costs as published in the program announcement, if applicable.

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:**

- **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 peer reviewers
- Relevance to the priorities of the FY26 PRMRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Relative clinical impact
  - Relevance to the congressionally directed FY26 PRMRP Topic Area
  - Relevance to the FY26 PRMRP Strategic Goals
  - Relevance to military health
  - Program portfolio composition
  - Relative outcomes from the PI's previous CDMRP-/PRMRP-funded research (if applicable)

6.3. Application Review and Selection Process

6.3.1. Pre-Application

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

6.3.2. Full Application

All applications are evaluated by scientists, clinicians and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria

to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are subject to review and approval by a designated official. ***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 the SAM.

An applicant organization may review the 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-33 and all associated laws, all fundamental research funded by the DOW must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the DOD Component Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

7. Federal Award Notices

For each compliant 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. After all awards are made, the CDMRP includes individual award information in a searchable database.

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 DHACA 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).***

Intragovernmental 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 DOW 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 DOW 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.

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.

The GAI contain information regarding administrative requirements and national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the DHACA Terms and Conditions for further information.

If there are delinquencies in technical reporting requirements for any existing DHA or U.S. Army Medical Research and Development Command awards at the applicant organization, DHACA will not issue any new awards 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 clinical trials to register and submit study results on ClinicalTrials.gov.

Applications recommended for funding that involve animals, human data, human specimens, human subjects or human cadavers must be reviewed for compliance with federal animal and/or human subjects protection requirements and must be approved by the DHA R&D Office of Research and Regulatory Compliance (ORRC), 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.

8.2. Reporting

Quarterly and annual technical progress reports, as well as a final technical progress report, will be required. Technical progress 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 the SAM about certain civil, criminal and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with their 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.

8.3. Additional Requirements

For Clinical Trials with Planning Phase, the PI may be required to present their progress toward accomplishing research milestones and project goals at a Milestone Meeting. The Milestone Meeting will be held virtually at the conclusion of the planning phase.

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.

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.

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

9. Other Information

9.1. Program Announcement Version

Questions related to this program announcement should refer to the program name, the program announcement name and the program announcement version code CD26_01Td.

9.2. Administrative Actions

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

9.2.1. Rejection

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

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

- The Project Narrative is missing.
- The Budget is missing.
- Submission of an application for which a letter of invitation was not issued.
- The Project Narrative exceeds page limit.
- The Study Population Recruitment and Safety Plan (Attachment 6) is missing.
- The Regulatory Strategy (Attachment 8) is missing.
- Funding Level Justification (Attachment 12) is missing.

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to reviewing 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 FY26 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.
- The application includes the name(s) of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY26, 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.
- The application from an extramural organization, including non-DOW federal agencies, is received through eBRAP.
- The federal government recipient organization (including an intramural DOW organization): (a) cannot accept and execute the entirety of the requested budget in FY26 funds; and/or (b) 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.
- The application includes URLs, with the exception of links in the References Cited and Publication and/or Patent sections.
- The application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- The same research project is submitted to different funding opportunities within the same program and fiscal year.
- The application fails to address one of the congressionally directed FY26 PRMRP Topic Areas.
- The application fails to address one of the FY26 PRMRP Strategic Goals.
- The proposed research is not a clinical trial.
- The PI does not meet the eligibility criteria.
- For clinical trials (Clinical Trial Only) 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 (Clinical Trial Only) regulated by a relevant regulatory agency, evidence that an IND or IDE application and/or international equivalent was submitted prior to the application submission deadline was not included with the application.
- The invited application proposes a different research project than that described in the pre-application.
- The investigator is named as PI on more than one application submitted to the FY26 PRMRP. If more than one pre-application is submitted naming the same PI to the FY26 PRMRP, the first submission will be accepted, and the remaining will be administratively withdrawn.
- The selected funding level does not align with the proposed trial design.

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 DHACA Grants Officer for a determination of the final disposition of the application.

9.2.5. Other Funding Opportunities

The PRMRP is committed to leveraging efforts with other funding organizations to accelerate progress in research. At the time of funding notifications, the PRMRP may inform highly rated, unfunded applicants about opportunities to provide their PRMRP applications and peer review summary statements to non-governmental and other governmental funders, who will determine the specific criteria for funding consideration.

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"	☐
Relevance to Military Health Statement – Attachment 7, upload as "MilRel.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 Statement – Attachment 11, upload as "Impact.pdf"	☐
Funding Level Justification – Attachment 12, upload as "FundJust.pdf"	☐
Prior Outcomes Statement ***(if applicable)*** **– Attachment 13, upload as "Outcomes.pdf"**	☐
Representations ***(Grants.gov submissions only)*** **– Attachment 14, upload as "RequiredReps.pdf"**	☐
Suggested Intragovernmental/Intramural Budget Form ***(if applicable)*** **– Attachment 15, upload as "IGBudget.pdf"**	☐
Additional Application Materials	
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach Biographical Sketch for Senior/Key Persons (Biosketch_LastName.pdf)	☐
Attach Current/Pending Support for Senior/Key Persons (Support_LastName.pdf)	☐
Research & Related Budget	☐
Project/Performance Site Location(s)	☐
Research & Related Subaward Budget Attachment(s) ***(if applicable)***	☐

Appendix 2. Acronym List

ARRIVE	Animal Research: Reporting of In Vivo Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CONSORT	Consolidated Standards of Reporting Trials
CTA	Clinical Trial Award
DHA	Defense Health Agency
DHA R&D	Defense Health Agency Research and Development
DHACA	Defense Health Agency Contracting Activity
DOD	U.S. Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DOW	U.S. Department of War
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
GAI	General Application Instructions
GCP	Good Clinical Practices
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
ORRC	Office of Research and Regulatory Compliance
PANDAS	Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcus
PANS	Pediatric Acute-Onset Neuropsychiatric Syndrome

PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
PRMRP	Peer Reviewed Medical Research Program
R&D	Research and Development
RPPR	Research Performance Progress Report
SAM	System for Award Management
SF424 R&R	Standard Form 424 (Application for Federal Assistance, Research & Related)
SOW	Statement of Work
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USC	United States Code
VA	U.S. Department of Veterans Affairs

Appendix 3. Application Category Summary

	Clinical Trial With Planning Phase	Clinical Trial Only
Award Information	• Supports the final phase of regulatory activity necessary to initiate a clinical trial • Includes planning for regulatory/ administrative approvals, developing the clinical protocol, establishing access to patients, and other preparatory activities • Expectation that recipients will submit an IND/IDE application to the FDA (or equivalent agency) and receive an acknowledgement letter (or equivalent communication) during period of performance • Not an assurance of funding for the proposed clinical trial • Includes option for clinical trial if regulatory submissions are achieved, federal funds are available, and the topic area is supported at that time	• Supports a clinical trial having either FDA (or equivalent agency) approval or exemption in place prior to award start. Applications for approvals or exemptions must be submitted prior to the application submission deadline.
Budget	• Up to $800,000 for the planning phase • Request budget for clinical trial based on phase of proposed trial: ○ Funding Level 1: Phase 0/1 or equivalent, $6M ○ Funding Level 2: Phase 2 or equivalent, $10M ○ Funding Level 3: Phase 3 or equivalent, $20M	• Request budget based on phase of proposed trial: ○ Funding Level 1: Phase 0/1 or equivalent, $6M ○ Funding Level 2: Phase 2 or equivalent, $10M ○ Funding Level 3: Phase 3 or equivalent, $20M
Period of Performance	• Up to 12 months for the planning phase • Up to 4 years for the proposed clinical trial	• Up to 4 years
Pre-Application Components	• Preproposal Narrative ○ Describes the proposed clinical trial • Pre-Application Supporting Documents ○ Includes an estimated budget for the planning phase and the proposed clinical trial ○ Funding level justification	• Preproposal Narrative ○ Describes the clinical trial • Pre-Application Supporting Documents ○ Includes an estimated budget for the clinical trial ○ Funding level justification

	Clinical Trial With Planning Phase	Clinical Trial Only
Full Application Components	• Project Narrative ○ 8-page limit for the planning phase ○ 20-page limit for the proposed clinical trial • Statement of Work ○ Includes two SOWs: one for the planning phase and one for the proposed clinical trial ○ Uploaded as one attachment; starts statement for the proposed clinical trial on a new page ○ 5-page limit • Budget ○ Includes two budgets: one for the planning phase and one for the proposed clinical trial • Study Population Recruitment and Safety Plan; Data Management; Regulatory Strategy; Study Personnel and Organization ○ Describes any missing or applicable aspects to be addressed during the planning phase ○ Requires resubmission if changed/ finalized when/if option for the proposed clinical trial is exercised	• Project Narrative ○ 20-page limit • Statement of Work ○ 3-page limit • Study Population Recruitment and Safety Plan; Data Management; Regulatory Strategy; Study Personnel and Organization ○ Requires submission in full