Program Announcement for the Defense Health Agency

Peer Reviewed Medical Research Program

Lifestyle and Applied Health Research Award

Funding Opportunity Number: HT942526PRMRPLAHRA

Pre-Application Due: July 23, 2026

Application Due: August 6, 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) Lifestyle and Applied Health Research Award supports clinical research and/or clinical trials using a combination of scientific disciplines including occupational science, psychology, psychometrics, biostatistics and epidemiology, surveillance, implementation science, and population health. Applications must address and provide a solution to one of the congressionally directed FY26 PRMRP topic areas and one of the FY26 PRMRP strategic goals.

Distinctive Features: This funding opportunity requires patient advocate participation. The patient advocate will be a person living with, or a family member or caretaker of someone with, a disease or condition addressed in one of the congressionally directed FY26 PRMRP topic areas. **Animal research is not allowed.**

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly $16.8M to fund approximately four Lifestyle and Applied Health Research Award applications with total cost caps of $4.2M per award. The maximum period of performance is 4 years. 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 (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern Time (ET), July 23, 2026
- **Application Submission Deadline:** 11:59 p.m. ET, August 6, 2026
- **End of Application Verification Period:** 5:00 p.m. ET, August 13, 2026
- **Peer Review:** October/November 2026
- **Programmatic Review:** February/March 2027

Announcement Type: Initial

Funding Opportunity Number: HT942526PRMRPLAHRA

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 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

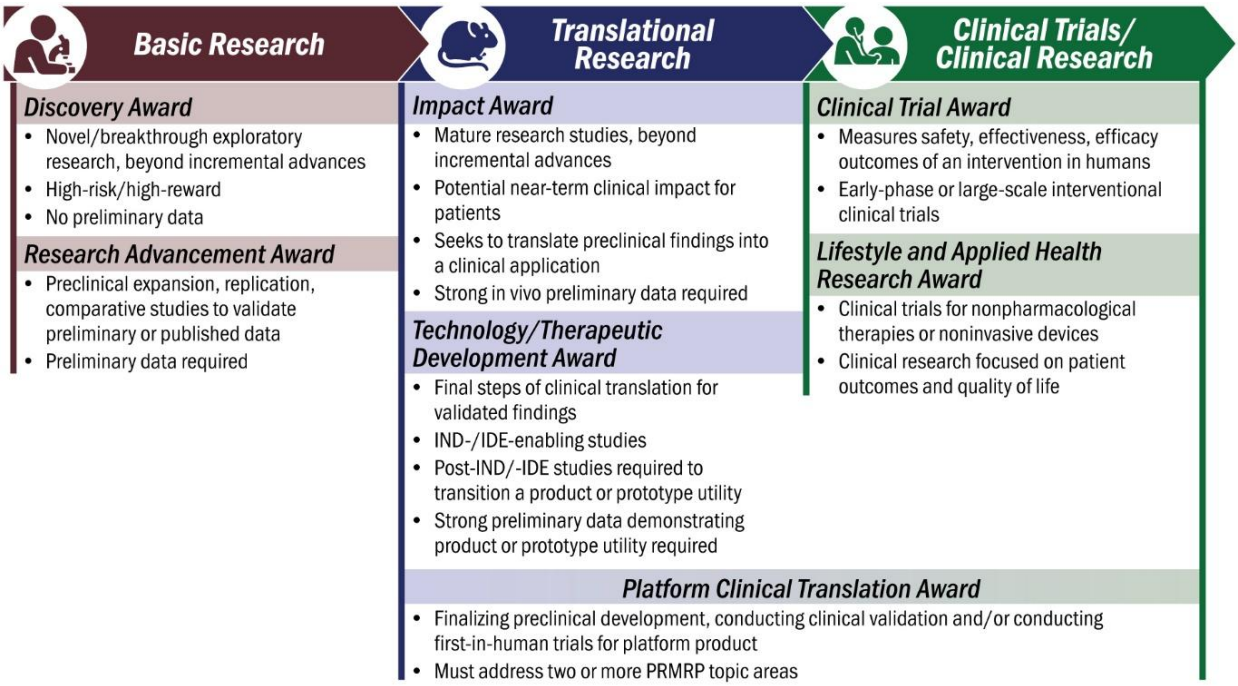
Awards are made to eligible ***organizations***, not to individuals. Refer to the GAI for additional recipient qualification requirements.

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 offered the Lifestyle and Behavioral Health Research Award mechanism in FY23 and FY24. For FY26, this mechanism was renamed to the Lifestyle and Applied Health Research Award.

3.2. Intent of the Lifestyle and Applied Health Research Award

The FY26 PRMRP Lifestyle and Applied Health Research Award (LAHRA) supports clinical research and/or clinical trials using a combination of scientific disciplines including occupational science, psychology, psychometrics, biostatistics and epidemiology, surveillance, implementation science, and population health. Applications are required to address and provide a solution to one of the congressionally directed FY26 PRMRP Topic Areas and one of the FY26 PRMRP Strategic Goals.

The FY26 PRMRP LAHRA mechanism intends to promote evidence-based and patient-centered approaches to improve health and/or disease-related outcomes and enhance the patient experience in defined populations. Research ideas may include, but are not limited to:

- Development and testing for efficacy of lifestyle interventions and symptom management approaches to minimize disease risk and/or maximize quality of life.
- Studies to investigate the impact of prevention, diagnostics, treatment, or health care delivery approaches on health outcomes.
- Studies to assess the relationship(s) between behavioral, cognitive, and/or social functioning in relation to disease or condition initiation, progression, detection, treatment and rehabilitation.
- Studies to examine and improve quality of life or decision-making.
- Population-focused studies to identify behavioral and lifestyle predictors of disease and/or disease progression.

The FY26 PRMRP LAHRA mechanism is meant to support clinical research or clinical trials for nonpharmacological interventions, noninvasive devices, and other types of interventions that are not regulated by the U.S. Food and Drug Administration (FDA) or other equivalent regulatory agency. Studies involving clinical trials for pharmacological interventions, clinical trials for devices that are implants or attached to the participant, or studies involving animal use are not appropriate for the LAHRA mechanism. If animals studies or clinical trials testing regulated interventions are proposed, the application may be withdrawn.

Applicants seeking funding for a clinical trial for an intervention that is regulated by the FDA, or other equivalent regulatory agency, should apply to the FY26 PRMRP Clinical Trial Award mechanism (HT942526PRMRPCTA).

The FY26 PRMRP LAHRA is further intended to support research that will make a near-term improvement in patient quality of life. Applicants seeking funding for basic or preclinical research should consider one of the other FY26 PRMRP program announcements being offered. For information about these award mechanisms, see information contained in the FY26 PRMRP Research Development Pipeline.

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. The FY26 PRMRP strategic goals for each portfolio are aligned to the categories of the continuum of care (foundational studies, epidemiology, prevention, diagnosis and treatment). 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 one topic area and one 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 one topic area and one 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 <u>one</u> topic area and <u>one</u> 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 <u>one</u> topic area and <u>one</u> 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 one topic area and one 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 one topic area and one 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 Lifestyle and Applied Health Research Award

- **Impact:** The LAHRA intends to support impactful research that will transform patient quality of life within the context of the congressionally directed FY26 PRMRP Topic Areas and FY26 PRMRP Strategic Goals. Research should challenge paradigms with respect to potential impact on patient care or population health, minimizing disease risk, enhancing patient outcomes, and improving clinical decision-making. Proposed projects should include clinical research and may include clinical trials. Impactful research will accelerate the movement of promising ideas into clinical applications, generate knowledge to improve clinical guidelines, or significantly advance behavioral, cognitive, and/or social functioning as

related to the targeted patient population. The anticipated outcomes of the research should be expected to have a positive impact on the lives of the relevant patient population(s) in the short term.

- **Study Design:** Applications should clearly articulate the chosen design of the study. The rationale should support the chosen study design with statistical evaluation to back the design. Studies entailing retrospective or prospective recruitment should define the type of architecture of the study (e.g., descriptive, correlational, field experimental, meta-analyses). Studies may integrate case, control, cohort, or other population science study designs (including the use of biospecimens and data from established databases and ongoing clinical trials), provided the proposed sample is of sufficient size to generate findings with ample statistical power. Study populations should be clearly defined. Questionnaires should be described in sufficient detail to justify interpretation of potential results. ***Clinical trials testing interventions that are regulated, such as pharmacological interventions or invasive devices, or research involving animal studies, are not considered appropriate for the FY26 PRMRP LAHRA mechanism.***
- **Preliminary Data:** The FY26 PRMRP LAHRA will require preliminary data for all studies that propose interventional clinical trials. Studies proposing non-interventional clinical research or retrospective clinical research studies are not required to present preliminary data, but they should be supported by sound reasoning and relevant literature.
- **Patient Advocate Participation:** Applications to the FY26 PRMRP LAHRA funding opportunity are required to include patient advocates. The research team must include at least one representative of the patient community who will be integral throughout the planning and implementation of the research project. The patient advocate will be a person living with, or a family member or caretaker of someone with, a disease or condition addressed in one of the congressionally directed FY26 PRMRP Topic Areas. As a lay representative, the patient advocate should be active in an advocacy organization. The patient advocate should be involved in the development of the research question(s), project design, oversight, and evaluation, as well as other significant aspects of the proposed project. Interactions with other team members should be well-integrated and ongoing, not limited to attending seminars and semi-annual meetings. The role of the patient advocate should be focused on providing objective input on the research and its potential impact for individuals with, or at risk for, a disease or condition addressed in one of the congressionally directed FY26 PRMRP Topic Areas.
- **Relevance to Military Health:** The program expects awards to address relevance to the health care needs of military Service Members, Veterans and their Families. The PRMRP encourages applicants 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.
    - PIs are encouraged to integrate and/or align their research projects with DOW and/or U.S. Department of Veterans Affairs (VA) research laboratories and programs.

Collaboration with the DOW and/or VA is also encouraged. 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 Lifestyle and Applied Health Research Award

Clinical trials and clinical research are allowed within this funding opportunity. *Applicants seeking funding for a clinical trial involving pharmacological interventions or devices should apply to the FY26 PRMRP Clinical Trial Award mechanism (HT942526PRMRPCTA).* 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.

This funding mechanism supports two different application categories:

- **Clinical Research** applications should select the **Lifestyle and Applied Health Research Award.**
- **Clinical Trial** applications should select the **Lifestyle and Applied Health Research Award** with a **Clinical Trial Option.**

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

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 **$4.2M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

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

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

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

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for up to two 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 FY26 PRMRP Lifestyle and Applied Health Research Award.

Must not be requested for:

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

4. Application Contents and Format

4.1. Application Overview

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

Intramural 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.

Letter of Intent (one-page limit): Provide a brief description of the research to be conducted. 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.

4.3. Full Application Components

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

(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov submissions only)*:

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 (15-page limit): Upload as "ProjectNarrative.pdf".**

  Describe the proposed project in detail using the outline below.

  - **Background:** Describe how the proposed project addresses a congressionally directed FY26 PRMRP Topic Area. Additionally, describe how the proposed research project relates to an FY26 PRMRP Strategic Goal. Describe in detail the scientific rationale for the study. Provide a literature review and analysis. Describe the preliminary studies and/or preclinical data (if applicable) in support of the idea. Describe how the proposed research will make important scientific advances in the relevant field of research, patient care, population health, quality of life, or clinical decision-making. Articulate how the study will assess the relationship(s) between

lifestyle and outcomes related to the disease or condition addressed. State the area of lifestyle or applied health science to be studied (e.g., basic behavioral, quality of life, decision-making and/or cognitive function, educational interventions, symptom management).

If a clinical trial is proposed, include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications (as applicable). Describe how the study would be expected to make an impact on the lives of relevant patient populations in the short term and or long term. If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically identify the portions of the study that will be supported with funds from this award.

- **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/ hypotheses.
- **Research Strategy and Feasibility:** Describe the study design, methods, and analyses in sufficient detail for evaluation including availability of resources (if applicable). Studies entailing retrospective or prospective recruitment should define the type of study (e.g., descriptive, correlational, field experimental, meta-analyses). Study populations should be defined. Address potential problem areas and potential pitfalls, and present alternative methods and approaches. If using psychometric measures, describe their reliability and validity. If use of a biorepository, patient medical files, or meta-analysis is proposed, describe the data to be collected and the process or methodology to collect the samples (i.e., for biorepositories – the standardization of procedures for collection). If human participants or human anatomical samples will be used, include a plan for the recruitment of participants or the acquisition of samples and document the experience of the PI and/or key collaborators in recruiting human participants for similar projects. Studies not including a clinical trial or active recruitment of human participants should demonstrate the research strategy, feasibility, and how the study relates to the human experience with the disease or condition addressed. Consult appropriate guidelines to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.
  - If the proposed research will use existing datasets (e.g., clinical databases, genomic databases, or other datasets), describe the dataset(s) including the data source, sample size, variables available, quality control procedures, and evidence of access.
- **Inclusion of Women and Minorities:** 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 Institutional Review Board [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.

- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. If applicable, specify the approximate number of human participants to be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

- **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 (required): 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.

- **Intellectual and Material Property Plan *(if applicable)*:** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Inclusion Enrollment Report *(required for all applications except those utilizing human biospecimens or datasets that cannot be linked to a specific individual, ethnicity, or race)*:** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the "Public Health Service (PHS) Inclusion Enrollment Report", a three-page fillable PDF form, that can be downloaded from eBRAP. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex, race and ethnicity.
- **Sex as a Biological Variable Strategy (two-page limit):** Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. If needed, provide a strong rationale for proposing a single-sex study, based on justification from scientific literature, preliminary data or other relevant considerations. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.
- **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 research participants. Include the name of the repository(ies) where scientific data and resources arising from the proposed study 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.

- **Attachment 3: Technical and Lay Abstracts (two-page limit): Start each abstract on a new page. Combine into one document and upload as "Abstracts.pdf".**

  Technical Abstract (one-page limit): Write the technical abstract using the outline below. Clarity and completeness within the space limits are highly important.

  - **Background:** Present the scientific rationale behind the proposed research project.
  - **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 hypothesis to be tested and/or objective(s) to be reached.
  - **Specific Aims:** State the specific aims of the study. If a clinical trial is proposed, include a description of the type of trial to be conducted, the phase of trial (if applicable), and the primary projected outcome(s) of the trial.
  - **Study Design:** Describe the study design, including appropriate controls.
  - **Impact:** Briefly describe how the proposed project will have a near-term impact on research and patient care in the specified disease(s)/condition(s).
  - **Relevance to Military Health:** Describe how the study is relevant to military health.

  Lay Abstract (one-page limit): 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 research.
  - What population will the research help, and how will it help them?
  - What are the potential applications, benefits, and risks of the anticipated outcomes?
  - What are the likely contributions of the proposed research project to advancing research, patient care and/or quality of life?
  - What is the potential benefit of the proposed study and the anticipated outcomes to Service Members, Veterans and/or their Families?

- **Attachment 4: Statement of Work (three-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the Suggested SOW Format.

  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 5: Impact Statement (two-page limit): Upload as "Impact.pdf".** The impact statement summarizes the potential short- and long-term impact of the proposed research. **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.**
  - Explain how the proposed research project will address a critical problem or question in one of the congressionally directed FY26 PRMRP topic areas. Additionally, describe how the project addresses one of the FY26 PRMRP strategic goals.
  - Describe how the proposed research project will make important scientific advances in the relevant field of research, patient care, population health, quality of life, or clinical decision-making.
  - **Describe the short-term impact:** Detail the anticipated outcomes that will be directly attributed to the results of the proposed study and how they will provide/ improve short-term benefits for individuals. Describe any relevant controversies, treatment issues or health disparities that will be addressed by the proposed study. If the proposed research 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 implementation of the intervention or clinical care knowledge in the clinic or field, and describe the anticipated long-term benefits for the targeted population, including impacts on patient care and/or quality of life.
    - Describe any potential issues that might limit the impact of the proposed study.
    - If a clinical trial is proposed, describe how the lifestyle or applied intervention compares with or will complement currently available interventions and/or standards of care.
    - If the proposed research 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.
    - If a clinical research study is proposed, describe the population- or patient-based data that will be collected and how it will be used to improve quality of life for the target population.
    - If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes
- **Attachment 6: Relevance to Military Health Statement (one-page limit): Upload as "MilRel.pdf". Attachment 6 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 active-duty military, military Families, and/or Veteran population(s) or datasets 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 interests. Provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to benefit the civilian population and address a military need, as appropriate.

- **Attachment 7: Clinical Strategy Statement, *required for applications selecting the Clinical Trial option* (no page limit): Upload as "Clinical.pdf".**
  - Describe the rationale for the proposed clinical trial. Provide a description of the intervention and the endpoints to be measured. Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.
  - If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically, identify the portions of the study that would be supported with funds from this award.
  - Provide detailed plans for initiating the clinical study within the first year, including FDA Investigational New Drug/Investigational Device Exemption (IND/IDE) application submission plans within 60 days of the award, if applicable. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
  - **Regulatory Considerations *(if applicable)*:** For investigator-sponsored regulatory exemptions (e.g., IND, IDE) provide evidence of institutional support. Provide evidence that the clinical trials does not require an IND/IDE. If the clinical trial will be conducted at international sites, provide equivalent information relevant to the regulatory requirements of the host country(ies).

    If an IND/IDE is required for the proposed intervention, applicants are encouraged to consider the PRMRP Clinical Trial Award mechanism (HT942526PRMRPCTA). For information about this award mechanism, see the FY26 PRMRP Research Development Pipeline.

- **Attachment 8: Study Population Recruitment and Safety Plan, *required for applications selecting the Clinical Trial option* (no page limit): Upload as "StudyPopPlan.pdf".** Include the components listed below.
  - **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). Provide a table of anticipated enrollment counts at each study site. ***Demonstrate that the research team has access to the proposed study population at each site and describe the efforts that will be made to achieve accrual goals.*** Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex. ***For clinical trials proposing inclusion of military populations, refer to the GAI, Appendix 4, for more information.***

- **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. Provide detailed justification for exclusions.
- **Description of the Recruitment Process:** Explain methods for identification of potential human participants (e.g., medical record review, obtaining sampling lists, health care provider identification). Describe the recruitment process in detail. Address who will identify potential human participants, who will recruit them, and what methods will be used to recruit them. Address the availability of human participants for the clinical trial for each enrollment site. If human participants will be compensated for participation in the study, include a detailed description of and justification for the compensation plan. Describe the recruitment and advertisement materials. Discuss past efforts in recruiting human participants from the target population for previous clinical trials *(if applicable)*. Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention. Identify ongoing clinical trials that may compete for the same patient population and how they may impact enrollment progress.
- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human participants.
  - ***For the proposed study, provide a draft, in English, of the Informed Consent Form.***
  - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human participants' questions will be addressed during the consent process and throughout the trial.
  - Include information regarding the timing and location of the consent process.
  - Address issues relevant to the mental capacity of the potential human participant (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human participant age), if applicable.
  - Address how privacy and time for decision-making will be provided and whether the potential human participant will be allowed to discuss the study with anyone before making a decision.
  - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study, and describe any relevant procedures to assure continued consent.
  - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. ***Note:*** In compliance with 10 USC 980, the application must describe a clear intent to benefit for human participants who cannot give their own consent to participate in the proposed clinical trial.
  - ***Assent:*** If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.

- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/ suitability for study participation and the diagnostic criteria for entry.
- **Risks/Benefits Assessment:**
  - **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. If applicable, any potential risk to the study personnel should be identified.
  - **Risk management and emergency response:** Appropriate to the study's level of risk, describe how safety monitoring and reporting to the IRB and Regulatory Agency (if applicable) will be managed and conducted. Describe all safety measures to minimize and/or eliminate risks to human participants and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values. Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the cost of such care.
  - **Potential benefits:** Describe known and potential benefits of the study to the human 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 9: Patient Advocate Involvement Statement (two-page limit): Upload as "Advocate.pdf".**

  The Patient Advocate Involvement Statement should be written by the PI. Provide the name of at least one patient advocate and their relationship with one of the congressionally directed FY26 PRMRP Topic Areas. Describe the integral role that the patient advocate will play in the planning, design, implementation, and evaluation of the research project. Describe how the patient advocate's knowledge of current health issues in one of the congressionally directed FY26 PRMRP topic areas and how their background will contribute to the research project.

- **Attachment 10: Study Personnel and Organization (no page limit): Start each document on a new page. Combine into one document and upload as "Personnel.pdf".** The Study Personnel and Organization attachment should include the components listed below.
  - **Organizational Chart:** Provide an organizational chart that identifies key members of the study team and provides an outline of the governing structure for multi-institutional studies. Identify collaborating organizations, centers, and/or departments and name each person's position on the project. Include any separate laboratory or testing centers. Identify the data and clinical coordinating center(s) and note any involvement from Contract Research Organizations, as appropriate. Identify and provide justification for the inclusion of international sites, as appropriate. 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. ***Note:*** This item may be made available for programmatic review.

- **Study Personnel Description:** Briefly describe the composition of the study team, including roles of the individuals listed in the organizational chart on the project. Study coordinator(s) should be included. Describe how the levels of effort for each individual are appropriate to successfully support the proposed research. Describe relevant background and qualifications that demonstrate appropriate expertise to accomplish the proposed work, including previous interactions with the relevant Regulatory Agency, if applicable.
- **Study Management Plan:** Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed study involves more than one institution, clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. Provide a regulatory submission plan for the master protocol and master consent form by the lead institution. If the research involves more than one institution, a single IRB is required for all institutions located in the United States. 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.

- **Attachment 11: Questionnaires and Other Research Data Collection Instruments (*if applicable*; no page limit): Upload as "Data_Collection.pdf".**

  The Questionnaires and Other Research Data Collection Instruments attachment should include a copy of the most recent version of questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study. Describe how and when the instrument(s) will be administered. Describe how the instrument(s) will be adapted to the participant population, if applicable.

- **Attachment 12: 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, then describe the planned next steps necessary to make the product available to the target population.

- **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)		
iv. Research & Related Subaward Budget Attachment(s) *(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 HT942526PRMRPLAHRA from Grants.gov or eBRAP, depending on which submission portal will be used.

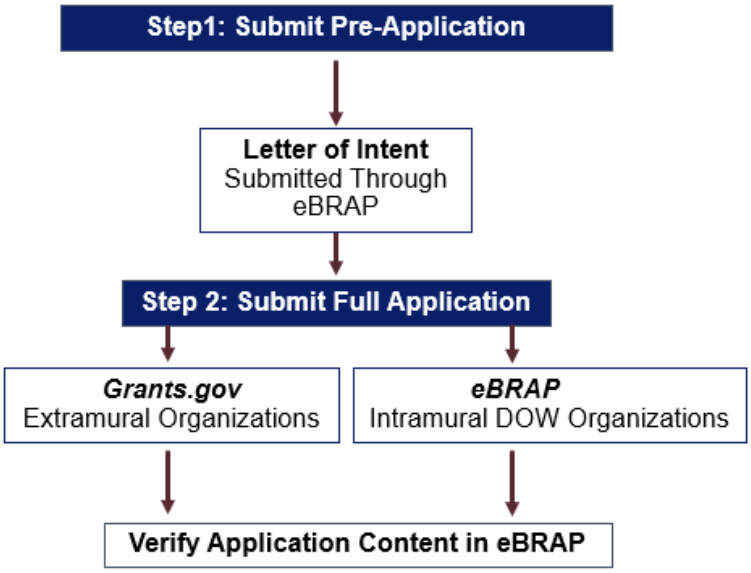
5.2. Unique Entity Identifier and System for Award Management

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 category:

- Clinical Research applications should select the Lifestyle and Applied Health Research Award option.
- Clinical Trial applications should select the Lifestyle and Applied Health Research Award with a Clinical Trial option.

Application Includes:	Select Mechanism Option:
Clinical Research Only (no clinical trial)	Lifestyle and Applied Health Research Award
Clinical Trial	Lifestyle and Applied Health Research Award – Clinical Trial Option

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

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

6.2.2. Peer Review Criteria

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

Scored review criteria for clinical research applications that do not include a proposed clinical trial:

- **Impact**
  - To what extent the project aligns to the applicant-selected congressionally directed FY26 PRMRP Topic Area.
  - To what extent the project impacts a critical problem or question in 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.

- Whether the proposed research project will make important scientific advances in the relevant field of research, patient care, population health, quality of life or clinical decision-making.
- To what degree the proposed project could make a significant impact on the lives of proposed patient population(s) in the short term.
- To what extent the proposed research will contribute to the implementation of clinical practice changes that will provide benefits to the targeted population, including impacts on quality of life.
- If applicable, to what extent the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.

- **Research Strategy and Feasibility**
  - How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, supporting data and logical reasoning.
  - How well the hypotheses, experimental design, and methods have been developed, and how well they support completion of the aims.
  - To what extent the data will be collected and analyzed in a manner consistent with the study aims.
  - If applicable, the degree to which the plan to study patient populations, specimens or data is appropriate and feasible; and whether the application provides evidence of availability of and access to the necessary study populations and/or resources.
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study or whether the justification for a single-sex study is sufficiently strong
  - If applicable, whether the strategy for the inclusion of women and minorities and the distribution of proposed enrollment are appropriate for the proposed research.
  - How well potential problems are identified and alternative methods or approaches are addressed.
  - How well the study population or dataset is described and whether it is appropriate to address the study objectives.
  - How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling, and endpoints/outcomes to be measured.
  - To what extent the proposed timeline for completion of the research is reasonable.
  - To what extent the plan for sharing of project data and research resources is appropriate and 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.
- **Transition Plan**
  - Whether the identified next level of development and/or commercialization is realistic.
  - Whether the follow-on funding strategy described to bring the findings from this award to the next level of development is reasonable and achievable (e.g., specific industry partners, specific funding opportunities to be applied for).

- For knowledge products, whether the proposed collaborations and other resources for providing continuity of development (including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications) are established and/or achievable.
- Whether the schedule and milestones for bringing the knowledge to the next level of development are reasonable and achievable.
- Whether the risk analysis for implementation of findings generated from the proposed research is realistic and reasonable.
- How well the application identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent government access to products supported by this program announcement.

- **Personnel and Communication**
  - Whether the background, expertise, and record of accomplishment of the PI and other key personnel demonstrate their ability to perform the proposed work.
  - Whether the levels of effort by the PI and other key personnel are appropriate to ensure the successful conduct of the project.
  - If applicable, whether the inclusion of any external consultants is justified to ensure the successful completion of the project.
  - If applicable, whether the inclusion of any personnel working at international sites is adequately justified.
  - If applicable, whether communication and data transfer between/among the PI's research team and any collaborating institutions are adequately described.
  - To what extent the patient advocate will play an integral role in the planning, design, implementation, and evaluation of the research.
  - Whether the patient advocate's knowledge of issues in one of the congressionally directed FY26 PRMRP topic areas and their background will contribute to the project.

Scored review criteria for applications submitted with a proposed clinical trial:

- **Clinical Impact**
  - To what extent the project aligns to the applicant-selected congressionally directed FY26 PRMRP Topic Area and FY26 PRMRP Strategic Goal.
  - How impactful the anticipated outcomes of the proposed clinical trial would be to the target population with regard to the applicant-selected congressionally directed FY26 PRMRP topic area and FY26 PRMRP 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 behavioral or lifestyle intervention may impact patient care and/or quality of life.
- If applicable, to what extent the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.

- **Research Strategy and Feasibility**
  - How well the scientific rationale for clinically testing the lifestyle intervention is supported by the preliminary data, critical review and analysis of the literature, and/or laboratory/preclinical evidence.
  - How well the study aims, hypotheses and/or objective(s), experimental design, methods, data collection procedures, and analyses are designed to answer clearly the clinical objective, and to achieve reproducible and rigorous results.
  - How well plans to collect specimens and conduct laboratory evaluations are addressed, if applicable.
  - To what degree the data collection instruments (e.g., surveys, questionnaires), if applicable, are appropriate to the proposed study.
  - To what extent the data will be collected and analyzed in a manner consistent with the study aims.
  - Whether the research can be completed within the proposed period of performance.
  - To what extent the plan for sharing of project data and research resources is appropriate and 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.
  - How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, data handling, and endpoints/outcomes to be measured.
  - To what degree the statistical model and data analysis plan are suitable for the planned study.
  - Whether the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
  - If applicable, whether the statistical plan compensates for the use of a subpopulation of a recruited sample population to ensure appropriate power can be achieved within the subpopulation study.
- **Clinical Trial Strategy**
  - To what degree the intervention and endpoints to be measured are described.
  - To what degree the proposed methodology shows a clear course of action and supports the initiation of the clinical study within the first year.
  - How well potential challenges and alternative strategies are described.
  - To what degree the clinical trial will inform correlative clinical research, if applicable.
  - For investigator-sponsored regulatory exemptions (e.g., IND, IDE), whether there is evidence of appropriate institutional support, including capabilities to ensure monitoring.

- **Recruitment, Accrual and Feasibility**
  - How well the application addresses the availability of human participants for the clinical trial and the prospect of their participation.
  - Whether the application demonstrates access to the proposed human participants population.
  - The degree to which the recruitment, informed consent, screening, and retention processes for human participants will meet the needs of the proposed clinical trial.
  - How well the application identifies possible delays (e.g., slow accrual, attrition) and presents adequate contingency plans to resolve them.
  - To what extent the proposed clinical trial might affect the daily lives of the individual human participants participating in the study (e.g., will human participants still be able to take their regular medications while participating in the clinical trial? Are human participants required to stay overnight in a hospital?).
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study, or whether the justification for a single-sex study is sufficiently strong
  - Whether the strategy for the inclusion of women and minorities and the distribution of proposed enrollment are appropriate for the proposed research, including a description of the composition of the proposed study population in terms of sex, racial, and ethnic group, and an accompanying rationale for the selection of participants.
  - Whether an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race, and ethnicity is included.
  - For phase 3 clinical trials, whether the application describes plans for the valid analysis of group differences on the basis of sex, race, and/or ethnicity that are appropriate for the scientific goals of the study.
- **Ethical Considerations**
  - Whether the population selected to participate in the trial stands to benefit from the knowledge gained.
  - How well the level of risk to human participants is minimized, and whether the safety monitoring and reporting plan is appropriate for the level of risk.
  - How well the evidence shows that the procedures are consistent with sound research design and, when appropriate, that these procedures are already in use for diagnostic or treatment purposes.
  - To what degree privacy and confidentiality issues are appropriately considered.
  - To what degree the process for seeking informed consent is appropriate, and whether safeguards are in place for vulnerable populations.
- **Transition Plan**
  - Whether the identified next level of development and/or commercialization is practical.
  - Whether the funding strategy described to transition the intervention to the next level of development is reasonable and achievable.
  - For knowledge products, whether the proposed collaborations and other resources for providing continuity of development (including proposed development or modification of

clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications) are established and/or achievable.

- Whether the schedule and milestones for transitioning the intervention to the next level of development through to a clinically meaningful outcome (next-phase clinical trials, transition to industry, delivery to the market, and/or incorporation into clinical practice) are achievable.
- If applicable, whether the risk analysis for implementation is realistic and reasonable.
- How well the application identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any potential impact of intellectual property issues on product development and subsequent government access to products supported by this program announcement.

- **Personnel and Communication**
  - Whether the composition of the study team (e.g., study coordinator, statistician) is appropriate.
  - To what degree the study team's background and expertise are appropriate to accomplish the proposed work (e.g., statistical expertise, expertise in the disease, and expertise in conducting clinical trials).
  - Whether the levels of effort of the study team members are appropriate for successful conduct of the proposed trial.
  - How well the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, standardization of procedures) meet the needs of the proposed clinical trial.
  - For multi-site clinical trials, how well the lead site responsibilities and the human research protections regulatory coordination are defined and planned for.
  - If applicable, whether the inclusion of any external consultants is justified to ensure the successful completion of the project.
  - If applicable, whether the inclusion of any personnel working at international sites is adequately justified.
  - If applicable, whether communication and data transfer between/among the PI's research team and any collaborating institutions are adequately described.
  - To what extent the patient advocate will play an integral role in the planning, design, implementation, and evaluation of the research.
  - Whether the patient advocate's knowledge of issues in one of the congressionally directed FY26 PRMRP Topic Areas and their background will contribute to the project.

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

- **Budget**
  - Whether the budget is appropriate for the proposed research.

- **Environment**
  - To what extent the scientific environment and level of institutional support is appropriate for the proposed research project.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources.
- **Application Presentation**
  - To what extent the writing, clarity and presentation of the application components influence the review.

6.2.3. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of 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 military health
  - Relevance to the congressionally directed FY26 PRMRP Topic Areas
  - Relevance to the FY26 PRMRP Strategic Goals
  - 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

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

6.3.2. Full Application

All applications are evaluated by scientists, clinicians and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are 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 the Code of Federal Regulations, Title 2, Part 200.1 (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.

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.

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.

8.2. Reporting

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

For applications including a proposed clinical trial: Quarterly and annual technical progress reports as well as final technical progress reports will be required. Technical reports must be prepared in accordance with the RPPR.

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

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

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal

contract, grant and cooperative agreement awards with a cumulative total value greater than $10M are required to provide information to 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

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

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

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_01d.

9.2. Administrative Actions

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

9.2.1. Rejection

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

- The Project Narrative is missing.
- The Budget is missing.
- The Pre-application was not submitted.
- The Project Narrative exceeds page limit.

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 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, then the first submission will be accepted, and the remaining will be administratively withdrawn.
- The PI does not meet the eligibility criteria.
- The proposed project includes animal research.
- The proposed intervention requires an IND/IDE or equivalent submission and oversight by a regulatory agency.
- For applications with the Clinical Trial option, the Study Population Recruitment and Safety Plan (Attachment 8) is missing.

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 and Lay Abstracts – Attachment 3, upload as "Abstracts.pdf"	☐
Statement of Work – Attachment 4, upload as "SOW.pdf"	☐
Impact Statement – Attachment 5, upload as "Impact.pdf"	☐
Relevance to Military Health – Attachment 6, upload as "MilRel.pdf"	☐
Clinical Strategy Statement ***(if applicable)*** **– Attachment 7, upload as "Clinical.pdf"**	☐
Study Population Recruitment and Safety Plan – Attachment 8, upload as "StudyPopPlan.pdf"	☐
Patient Advocate Involvement Statement – Attachment 9, upload as "Advocate.pdf"	☐
Study Personnel and Organization – Attachment 10, upload as "Personnel.pdf"	☐
Questionnaires and Other Research Data Collection Instruments ***(if applicable)*** **– Attachment 11, upload as "Data_Collection.pdf"**	☐
Post-Award Transition Plan – Attachment 12, upload as "Transition.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
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
IACUC	Institutional Animal Care and Use
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
LAHRA	Lifestyle and Applied Health Research Award
LAR	Legally Authorized Representative
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
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