

Program Announcement for the Department of Defense Defense Health Program

# Peer Reviewed Medical Research Program

# Technology/Therapeutic Development Award

Funding Opportunity Number: HT942525PRMRPTTDA

Pre-Application Due: June 9, 2025

Application Due: July 21, 2025

# Content

	Before You Begin	3
1	Basic Information Contains a <u>summary of the funding opportunity</u> , <u>funding details</u> , and <u>submission/review dates</u>	4
2	Eligibility Details the factors that determine applicant organization and Principal Investigator eligibility	5
3	Program Description  Describes the program mission and intent of the Technology/Therapeutic Development  Award, provides key award information and considerations, and outlines funding restrictions	6
4	Application Contents Introduces the two-step <u>application process</u> and provides instructions for preparing a <u>preapplication</u> and <u>full application</u>	17
5	Submission Requirements Provides <u>locations for application packages</u> , instructions for submitting <u>pre-applications</u> and <u>full applications</u> , and describes <u>application verification</u>	26
6	Application Review Information Outlines the processes associated with application <u>compliance review</u> , <u>pre-application</u> and <u>full application</u> selection/notification, and <u>risk assessment</u> . Also details the complete review criteria for <u>pre-application screening</u> and both tiers of the CDMRP's application review process, <u>Peer Review</u> and <u>Programmatic Review</u>	29
7	Federal Award Notices Outlines what a successful applicant can expect to receive if recommended for funding	34
8	Post-Award Requirements References <u>policy requirements</u> for funded research, outlines <u>reporting requirements</u> , and restrictions related to <u>Principal Investigator changes</u> or <u>institutional award transfers</u>	35
9	Other Information Outlines criteria for administrative actions including application <u>rejection</u> , <u>modification</u> , <u>withdrawal</u> and <u>withhold</u>	37
	Appendix 1 Includes a checklist for all full application components to facilitate application submission	39
	Appendix 2 Acronym List	40
	Appendix 3 DOD and VA Websites	42

# **Before You Begin**

- Active SAM.gov, eBRAP.org, and Grants.gov registrations are required for application submission. User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- Read the funding opportunity announcement in the order it is written before beginning to prepare application materials. It is the responsibility of the applicant to determine whether the proposed research meets the intent of the funding opportunity and that all parties meet eligibility requirements.

# Who to Contact for Support

# eBRAP Help Desk

301-682-5507 help@eBRAP.org

Questions regarding funding opportunity submission requirements, as well as technical assistance related to pre-application or intramural application submission.

# **Grants.gov Contact Center**

800-518-4726 International: 1-606-545-5035 support@grants.gov

> Questions regarding Grants.gov registration and Workspace.

This document uses internal links; you can go back to where you were by pressing Alt + left arrow key (Windows) or command + left arrow key (Macintosh) on your keyboard.

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

# 1. Basic Information About the Funding Opportunity

**Summary:** The fiscal year 2025 (FY25) Peer Reviewed Medical Research Program (PRMRP) Technology/Therapeutic Development Award (TTDA) is a product-driven award mechanism intended to provide support for the translation of promising preclinical findings into products for clinical applications, including prevention, detection, diagnosis, treatment, or quality of life, for a disease or condition related to one of the FY25 PRMRP topic areas and one of the FY25 PRMRP strategic goals. Products can be tangible items, such as drugs or devices, or can be knowledge products, such as clinical decision making tools or practice guidelines. Products in development should be responsive to the health care needs of military Service Members, Veterans, and their Families.

**Distinctive Features:** For the PRMRP TTDA, the program expects the research proposed will take an already established proof-of-concept or prototype through the final stages of preclinical development. The PRMRP also expects that the research outcome will be a regulatory filing or translation of findings into clinical practice, as applicable.

**Funding Details:** The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$41.25 million (M) to fund approximately 12 Technology/Therapeutic Development Award applications with total cost caps of \$3.5M. The maximum period of performance is 4 years. It is anticipated that awards made from this fiscal year 2025 (FY25) funding opportunity will be funded with FY25 funds, which will expire for use on September 30, 2031. Awards supported with FY25 funds will be made no later than September 30, 2026.

# **Submission and Review Dates and Times**

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

**Announcement Type:** Modified

Funding Opportunity Number: HT942525PRMRPTTDA

**Assistance Listing Number: 12.420** 

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

# 2. Eligibility Information

# 2.1. Eligible Applicants

# 2.1.1. Organization

Extramural and intramural organizations are eligible to apply, *including foreign and domestic organizations, for-profit and non-profit organizations, and public or private entities*.

**Extramural Organization:** An eligible non-Department of Defense (DOD) organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

**Intramural DOD Organization:** Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

# 2.1.2. Principal Investigator

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

Industry titles may not be analogous to the faculty hierarchy in academia. For industry, investigators at or above an independent scientist level may be named by the company as the PI on the application.

Each investigator may be named on only one FY25 PRMRP application as a PI, which includes the FY25 PRMRP TTDA and the FY25 PRMRP Clinical Trial Award (HT942525PRMRPCTA). If more than one Letter of Intent (LOI) is submitted by the PI to the FY25 PRMRP, the first submission will be accepted, and the second will be administratively withdrawn.

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

# 2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

# 2.3. Other

Awards are made to eligible *organizations*, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

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

# 3. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP at the U.S. Army Medical Research and Development Command (USAMRDC) is the program office managing this FY25 funding opportunity as part of the PRMRP. Congress initiated the PRMRP in 1999 to support medical research projects of clear scientific merit and direct relevance to military health. Appropriations for the PRMRP from FY99 through FY24 totaled \$4.19 billion. The FY25 appropriation is \$150M.

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

# 3.1. Technology/Therapeutic Development Award History

The PRMRP first offered the TTDA mechanism in FY08. In FY21, the TTDA was offered with two funding levels based on the scope of research. In FY24, the PRMRP released the TTDA with only supported research in the final stages of preclinical development, previously referred to as Funding Level 2, and will continue to do so for FY25.

# 3.2. Intent of the Technology/Therapeutic Development Award

The PRMRP TTDA is a product-driven award mechanism intended to provide support for the translation of promising preclinical findings into products for clinical applications, including prevention, detection, diagnosis, treatment, or quality of life, for a disease or condition related to one of the FY25 PRMRP topic areas and one of the FY25 PRMRP strategic goals. The proposed experiments may be hypothesis or milestone driven. Products in development should be responsive to the health care needs of military Service Members, Veterans, and their Families. The product(s) to be developed under the FY25 PRMRP TTDA mechanism may be a tangible item, such as a pharmacologic agent (drugs or biologics) or device, or a knowledge-based product. (A "knowledge product" is a non-material product that addresses an identified need in a topic area, is based on current evidence and research, aims to transition into medical practice, training, tools, or to support material solutions [systems to develop, acquire, provide, and sustain medical solutions and capabilities], and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.)

# 3.2.1. FY25 Topic Areas and Strategic Goals

To meet the intent of the funding opportunity, all applications for FY25 PRMRP funding must specifically address one of the FY25 PRMRP topic areas as directed by the U.S. Congress and have direct relevance to military health. Additionally, the PRMRP implements a portfoliodriven approach by grouping related topic areas with strategic goals as a framework within which to address critical gaps in major research areas. All applications must address one of the FY25 PRMRP strategic goals as it relates to the portfolio-assigned FY25 PRMRP topic area. If the proposed research does not specifically address one FY25 PRMRP topic area and

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

one FY25 PRMRP strategic goal, then the government reserves the right to administratively withdraw the application. The government reserves the right to reassign the application's topic area if submitted to an incorrect topic area. The section below lists the FY25 PRMRP topic areas and strategic goals in each PRMRP portfolio category.

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

# **AUTOIMMUNE DISORDERS AND IMMUNOLOGY**

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

#### TOPIC AREAS

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

# STRATEGIC GOALS

#### Prevention

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

# **Diagnosis**

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

## **Treatment**

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

## **Epidemiology**

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

## **CARDIOVASCULAR HEALTH**

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

## **TOPIC AREAS**

Cardiac Health

- Proteomics
- Congenital Heart Disease

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

#### STRATEGIC GOALS

#### Prevention

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

# **Diagnosis**

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

#### **Treatment**

• Develop and evaluate novel therapeutics or improved treatment regimens.

# **Epidemiology**

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

# INFECTIOUS DISEASES

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

#### **TOPIC AREAS**

- Congenital Cytomegalovirus
- Far-UVC Germicidal Light
- Hepatitis B
- Malaria

- Post-Acute Sequelae of SARS CoV-2 Infection
- Proteomics
- Tick-Borne Disease
- Tuberculosis

# STRATEGIC GOALS

#### Prevention

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

#### Diagnosis

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

#### Treatment

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

## **Epidemiology**

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

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

#### INTERNAL MEDICINE

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

#### **TOPIC AREAS**

- Endometriosis
- Focal Segmental Glomerulosclerosis
- Interstitial Cystitis
- Menopause
- Nephrotic Syndrome

- Pancreatitis
- Polycystic Kidney Disease
- Proteomics
- Reconstructive Transplantation
- Vision

#### STRATEGIC GOALS

#### Prevention

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

# Diagnosis

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

#### **Treatment**

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

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

## **Epidemiology**

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

## NEUROSCIENCE AND BEHAVIORAL HEALTH

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

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

#### **TOPIC AREAS**

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

## STRATEGIC GOALS

#### Prevention

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

# **Diagnosis**

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

#### Treatment

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

## **Epidemiology**

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

#### ORTHOPAEDIC MEDICINE

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

#### **TOPIC AREAS**

- Orthotics and Prosthetics Outcomes
- Proteomics

# STRATEGIC GOALS

## Prevention

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

#### **Diagnosis**

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

#### **Treatment**

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

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

# **Epidemiology**

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

## **RARE DISEASES AND CONDITIONS**

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

#### TOPIC AREAS

- Angelman Syndrome
- Ehlers-Danlos Syndrome
- Epidermolysis Bullosa
- Fibrous Dysplasia/McCune-Albright Syndrome
- Fragile X
- Frontotemporal Degeneration
- Hereditary and Acquired Ataxia
- Hermansky-Pudlak Syndrome

- Mitochondrial Disease
- Myotonic Dystrophy
- Neurofibromatosis
- Proteomics
- Rett Syndrome
- Sickle-Cell Disease
- Tuberous Sclerosis Complex
- Von Hippel-Lindau Disease

## STRATEGIC GOALS

## Diagnosis

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

#### **Prevention**

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

#### **Treatment**

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

# **Epidemiology**

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

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

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

## **RESPIRATORY HEALTH**

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

#### **TOPIC AREAS**

- Burn Pit Exposure
- Proteomics

- Pulmonary Fibrosis
- Respiratory Health

#### STRATEGIC GOALS

#### Prevention

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

## **Diagnosis**

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

## **Treatment**

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

#### **Epidemiology**

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

# 3.2.2. Key Elements for the Technology/Therapeutic Development Award

- **Impact:** The PRMRP TTDA intends to support research that is in the final stages of preclinical development with potential for near-term clinical development. It is expected that the next step after completion of the proposed work would be either a clinical trial or translation into clinical practice, as appropriate for the product under development. The proposed study should demonstrate how the research will lead to the development of a product that will improve patient outcomes in one of the FY25 PRMRP topic areas and address one of the FY25 PRMRP strategic goals.
- **Preliminary Data:** Proof of concept demonstrating the potential utility of the proposed product, or a prototype/preliminary version of the proposed product, should already be

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

established. Applications must include relevant data that support the rationale for the proposed study. These data may be unpublished and/or from the published literature. Unpublished data should originate from the laboratory of the PI or a member of the research team.

Applications supported by this award must begin with lead compounds in hand, a device prototype, or appropriate proof of concept for knowledge products and must include preliminary data relevant to the phase of development, such as:

- Proof of identity and purity.
- Selectivity for the intended target over closely related targets.
- Availability of primary and secondary in vitro bioactivity assays for optimization or structure-activity relationship studies.
- Availability of clear efficacy data in at least one relevant model system, with adequate power and methods.
- Demonstration of diagnostic or prognostic prediction in at least one relevant disease model.
- Demonstration of initial phases of prototype development and/or software development.
- Demonstration of access to data or tools needed to generate a knowledge product that will inform patient care.
- Product Development: Award recipients are expected to submit or obtain an
  Investigational New Drug/Investigational Device Exemption (IND/IDE) application to the U.S.
  Food and Drug Administration (FDA), or must transition the product to clinical practice or to
  the intended end user, within the period of performance. Examples of the type of activity
  expected for this stage of product development include, but are not limited to:
  - Confirming efficacy and/or safety of therapeutic modalities (agents, delivery systems, and chemical modification of lead compounds) using established or validated preclinical systems.
  - Implementing full-scale Good Manufacturing Practice (GMP) production of therapeutics and/or delivery systems for use in advanced preclinical and initial clinical trials.
  - Validating pharmacologic agents through absorption, distribution, metabolism, excretion, and toxicity studies.
  - Developing pharmacologic agents to IND stage for initiation of phase 1 clinical trials.
  - Developing prototype devices to IDE stage or abbreviated IDE stage for initiation of clinical trials.
  - Optimizing diagnostic or treatment devices for field deployment.
  - Performing retrospective clinical studies to inform clinical care.
  - Developing clinical decision making tools to the clinical testing stage.
- Relevance to Military Health: Relevance to the health care needs of military Service Members, Veterans, and their Families is a key feature of this award. Investigators are encouraged to consider the following characteristics as examples of how a project may demonstrate relevance to military health:

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

- Explanation of how the project addresses an aspect of the target disease/condition/ technology that has direct relevance to the health of military Service Members, Veterans, and their Families.
- Description of how the knowledge, information, products, or technologies gained from the proposed research could be implemented in a dual-use capacity to benefit the civilian population and also address a military need.
- Use of military or Veteran populations, samples, or datasets in the proposed research, if appropriate.
- Collaboration with DOD or U.S. Department of Veterans Affairs (VA) investigators or consultants. A list of websites that may be useful in identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration within the FY25 PRMRP topic areas can be found in <u>Appendix 3</u>.

# 3.2.3. Other Important Considerations for the Technology/Therapeutic Development Award

Applications to the FY25 PRMRP TTDA must support product development and may not support clinical trials.

**A clinical trial is defined** in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. An **intervention** includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

- (1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does **not** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease; (b) diagnostic or detection studies (e.g., biomarker or imaging); (c) health disparity studies; and (d) development of new technologies.
- (2) Epidemiologic and behavioral studies that do **not** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.
- (3) Outcomes research and health services research that do not fit under the definition of clinical trial.

Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research. The

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

standards are described in <u>SC Landis et al.</u>, "A call for transparent reporting to optimize the <u>predictive value of preclinical research," Nature 490 (2012): 187-191, https://doi.org/10.1038/nature11556.</u> While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies.

Applications from investigators within the DOD and applications involving multidisciplinary collaborations among academia, industry, the DOD, the VA, and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. If the proposed research relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

# 3.3. CDMRP-wide Encouragements

The following encouragements are broadly applicable across many CDMRP programs, including the PRMRP. Investigators are encouraged to consider addressing these areas in their applications if doing so is appropriate for their line of research and meets the intent of this funding opportunity.

Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of Service Members, Veterans and their Families is encouraged. Such research could improve diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

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

# 3.4. Funding Instrument

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

# 3.5. Funding Details

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

**Cost Cap:** The application's total costs budgeted for the entire period of performance should not exceed **\$3.5M**. 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.

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

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 FY25 PRMRP TTDA.

Must not be requested for:

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

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

# 4. Application Contents and Format

# 4.1. Application Overview

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

Intramural DOD organizations submitting a full application should follow instructions for submission through eBRAP.

Extramural organizations submitting a full application must follow instructions for submission through Grants.gov.

# 4.2. Step 1: Pre-Application Components

Pre-application submissions must include the following components.

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

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

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

# 4.3. Step 2: Full Application Components

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

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

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

## (b) Attachments:

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

Attachment 1: Project Narrative (18-page limit): Upload as "ProjectNarrative.pdf". The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair

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

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

Describe the proposed project in detail using the outline below.

- Background: Describe the product to be developed. The application must provide sound scientific rationale behind the proposed work, including relevant literature citations. Describe previous experience most pertinent to the project to demonstrate feasibility. Include relevant preliminary data and/or promising preclinical findings that demonstrate proof of concept of the product or a prototype/preliminary version of the product. Preliminary data should be appropriate for the proposed stage of development and include the following as appropriate: proof of identity and purity, demonstrate selectivity, demonstrate availability and/or feasibility of assays, show efficacy in an appropriate model system, etc. The data may be unpublished or from the published literature. Unpublished preliminary data should originate from the laboratory of the PI or a member of the study team.
- Hypothesis/Objective: State the hypothesis to be tested and/or the objective(s) to be reached. State which <u>FY25 PRMRP Topic Area</u> the proposed research addresses. Additionally, describe how the proposed research project addresses one of the <u>FY25 PRMRP Strategic Goals</u>.
- Specific Aims: Concisely explain the project's specific aims. These aims should agree with the primary aims and associated tasks described in the Statement of Work (SOW). If the proposed work is part of a larger study, present only the aims that this DOD award would fund.
- Research Strategy and Feasibility: Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Provide a well-developed, well-integrated research strategy that supports the translational feasibility and promise of the approach. Define the specific study outcomes and how they will be measured. Address potential problem areas and present alternative methods and approaches. Describe how data will be collected and handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, and identification of primary endpoints/outcomes.
- If animal studies are proposed, briefly describe the key elements of the study/studies as they relate to the overall project. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology. Describe the randomization and blinding procedures for the study and any other measures to be taken to minimize effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- If human subjects or human biological samples will be used, describe the study population and include a detailed plan for the recruitment of human subjects or the acquisition of samples. Describe the availability of the proposed study population and past successes in recruiting similar populations. If active-duty military, military Families, and/or Veteran population(s) or dataset(s) will be used in the proposed research project, describe the feasibility of accessing the population(s)/dataset(s). This award may not be used to conduct clinical trials.

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

- For all applications proposing clinical research describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex, racial, and ethnic group, and an accompanying rationale for the selection of subjects. If human subjects will be recruited, state the inclusion and exclusion criteria with sound rationale for the criteria. 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).
- Describe how the research project will be completed within the proposed period of performance.
- Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf". Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.

- References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Support (if applicable): Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOD collaborator(s) and/or access to military populations, databases, or DOD resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or individual designated by the VA Facility Director(s), confirming access to VA patients, resources, and/or VA research space.

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

- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Inclusion Enrollment Plan (only required if clinical research is proposed):
  Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form that can be downloaded from eBRAP at <a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.
- Sex as a Biological Variable Strategy: 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.
- Data and Research Resources Sharing Plan: Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe how data and resources generated during the period of performance will be shared with the research community and other affected communities. Include the name of the repository(ies) where scientific data and resources arising from the proposed clinical trial will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP's Policy on Data & Resources Sharing for more information about CDMRP's expectations for making data and research resources publicly available.
- Use of DOD Resources or VA Resources (if applicable): If the proposed research involves access to military and/or VA patient populations and/or DOD or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Also include a plan for obtaining any required data sharing, memorandum of understanding, or other agreements required to access and publish data. Refer to the General Application Instructions, Appendix 4, for additional considerations.
- Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf". The
  technical abstract is used by all reviewers. Abstracts of all funded research projects
  will be posted publicly. Use only characters available on a standard QWERTY
  keyboard; spell out all Greek letters, other non-English letters, and symbols. Graphics
  are not allowed.

Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

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

- Background: Present the scientific rationale behind the proposed research project.
- Relevance to Topic Area: First state both the <u>FY25 PRMRP Topic Area</u> and the <u>FY25 PRMRP Strategic Goal</u> addressed by the proposed project, and then state the relevance of the project to the topic area and strategic goal. The topic area and strategic goal must be the same as what was previously selected during preapplication submission.
- Hypothesis/Objective(s): State the hypothesis to be tested and/or objective(s) to be reached.
- Specific Aims: List the specific aims of the study.
- Study Design: Describe the study design, including appropriate controls.
- Impact: Briefly describe how the proposed project will have an impact on research and patient care in the specified disease(s)/condition(s).
- Relevance to Military Health: Describe the study's relevance to the health care needs of military Service Members, Veterans, and/or their Families.
- Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf". The lay abstract is used by all reviewers and addresses issues of particular interest to the affected community. Abstracts of all funded research projects will be posted publicly. Use only characters available on a standard QWERTY keyboard; spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. Do not duplicate the technical abstract.

Lay abstracts should address the points outlined below *in a manner that will be readily understood by readers without a background in science or medicine*. Avoid overuse of scientific jargon, acronyms, and abbreviations.

- First state both the <u>FY25 PRMRP Topic Area</u> and the <u>FY25 PRMRP Strategic Goal</u> addressed by the proposed project, and then state the relevance of the project to the topic area and strategic goal.
- Summarize the objectives and rationale for the proposed 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?
- Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf". Refer to eBRAP for the "Suggested SOW Format".
  - For the TTDA, refer to the <u>"Example: Assembling a Generic Statement of Work"</u> for guidance on preparing the SOW.
- Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".
  - Explain why the proposed research project is important and relevant to developing improvements in prevention, detection, diagnosis, treatment, or quality of life in the FY25 PRMRP topic area that was previously selected during pre-application submission. Describe how the project addresses the FY25 PRMRP strategic goal that was previously selected during pre-application submission. Additionally, describe how the study will address a critical problem or question in the relevant topic area. If applicable, describe

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

how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.

- Describe the Short-Term Impact: Detail the anticipated outcome/product (knowledge and/or materiel) that will be directly attributed to the results of the proposed research.
- Describe the Long-Term Impact: Explain the anticipated long-term gains from this research. Compare the product being developed to information known/products currently available, if applicable. Describe the anticipated long-range impact of the anticipated research findings on the field of study and/or patient care.
- Attachment 7: Relevance to Military Health Statement (one-page limit): Upload as "MilRel.pdf".
  - Describe how the proposed study is responsive to the health care needs of military Service Members, Veterans, and/or 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/or their Families. If the planned use of the product is to support the Warfighter, explain how the product meets the needs and requirements for use in the deployed setting.
  - If active-duty military, military Families, and/or Veteran population(s) or dataset(s) will be used in the proposed research project, describe the population(s)/dataset(s) and the appropriateness of the population(s)/dataset(s) for the proposed study. If a nonmilitary population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., military Service Members, Veterans, and/or their Families).
  - If applicable, show how the proposed research project aligns with DOD and/or VA areas of research interest. Provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to benefit the civilian population and address a military need, as appropriate.
- Attachment 8: Statistical Plan and Data Analysis (five-page limit): Upload as
   "Stats.pdf". All applicants are required to submit a Statistical Plan and Data Analysis.
  - Describe the statistical methodology and plan including how it supports the stated hypothesis or objective.
  - Describe the power analysis and whether it determined population numbers; if not, justify why the power analysis is not essential to the statistical evaluation.
  - State whether the study will include univariate, bivariate, or multivariate analyses.
     State the variables to be used in the main analysis; include covariates and how the data will be adjusted to account for covariates, if applicable. Stratification of data, if applicable, should be described and justified.
  - Explain data capture, verification, disposition, if applicable. Describe how data will be evaluated for reproducibility and adjusted for confounding variables.
  - Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, or international regulatory agency, if applicable.
  - Articulate how large datasets will be evaluated, if applicable. For laboratory projects, describe the organization and maintenance of large datasets, if applicable.

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

Attachment 9: Post-Award Transition Plan (three-page limit): Upload as "Transition.pdf".

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

- Details of the funding strategy to transition to the next level of development and/or commercialization (e.g., specific industry partners, specific funding opportunities to be applied for). Include a description of collaborations and other resources that will be used to provide continuity of development.
- For knowledge products, a description of collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. (A "knowledge product" is a non-materiel product that addresses an identified need, topic area, or capability gap; is based on current evidence and research; aims to transition into medical practice, training, or tools or to support materiel solutions [systems to develop, acquire, provide, and sustain medical solutions and capabilities]; and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.)
- A brief schedule and milestones for transitioning the intervention to the next level of development (e.g., next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by a Regulatory Agency). Explain the regulatory strategy that will support the proposed product label, if applicable.
- Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government's ability to access such products or technologies in the future.
- A risk analysis for cost, schedule, manufacturability, and sustainability.
- Attachment 10: Prior Outcomes Statement (if applicable; one-page limit): Upload as "Outcomes.pdf". If applicable, list all of the PI's prior or in-progress CDMRP/PRMRP research projects/awards including resulting publications, abstracts, patents, or other tangible outcomes. Only research and outcomes directly relevant to this application should be listed. Attachment 10 will be available for programmatic review only.
- Attachment 11: Representations (Grants.gov submissions only): Upload as "RequiredReps.pdf". All extramural applicants must complete and submit the "Required Representations" document that is available on eBRAP. For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
- Attachment 12: Suggested Intragovernmental/Intramural Budget Form (if applicable): Upload as "IGBudget.pdf". If an intramural DOD organization will be a

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

collaborator in the performance of the project, complete a separate budget for that organization using the <u>"Suggested Intragovernmental/Intramural Budget"</u> form that is available for download on eBRAP. Refer to the General Application Instructions, Section V.B.(c), for instructions and considerations.

- (c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a)
- (d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and senior/key person's current/pending support information must be attached to the individual's profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.
  - Biographical Sketch: Upload as "Biosketch LastName.pdf".
    - The CDMRP staff and reviewers use biosketches to evaluate whether research teams are equipped with the expertise necessary to carry out the proposed research.
    - Biosketches must conform to the federal-wide Biographical Sketch Common Form. To prepare their biosketch attachments, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in <a href="SciENcv">SciENcv</a> for the National Institutes of Health (NIH) or the U.S. National Science Foundation (NSF).
  - Current/Pending Support: Upload as "Support LastName.pdf".
    - Current and pending (other) support information are used to assess the capacity or any <u>conflicts of commitment</u> that may impact the ability of the individual to carry out the research effort as proposed. The information also helps to assess any potential scientific and budgetary overlap/duplication with the project being proposed.
    - Current and pending support documentation must conform to the federal wide format. To prepare their Current and Pending Support form, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in <a href="SciENcv">SciENcv</a> for NIH or NSF.
- (e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).
  - Budget Justification (no page limit): For instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c), Section L; for eBRAP submissions, refer to General Application Instructions, Section V.B.(c), Budget Justification Instructions.
- (f) Project/Performance Site Location(s) Form: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).
- (g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Grants.gov Submissions only): Refer to the General Application Instructions, Section IV.C.(e), for detailed information.

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

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

# 4.4. Other Application Elements

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

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

# 5. Submission Requirements

# 5.1. Location of Application Package

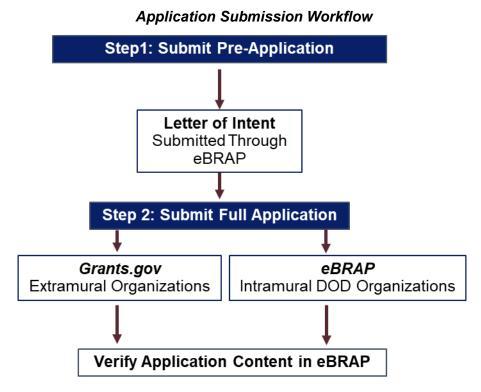
Download the application package components for HT942525PRMRPTTDA from <u>Grants.gov</u> or <u>eBRAP</u>, depending on which submission portal will be used.

# 5.2. Unique Entity Identifier and System for Award Management

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

## **5.3. Submission Instructions**

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



# 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

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

number, application title, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire preapplication and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at <a href="mailto:help@eBRAP.org">help@eBRAP.org</a> or 301-682-5507 prior to the application submission deadline.

Refer to the General Application Instructions, Section III.A, for considerations and detailed instructions regarding pre-application submission.

# 5.3.2. Full Application Submission

**Grants.gov Submissions:** Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding Grants.gov submissions.

**eBRAP Submissions:** Only intramural DOD organizations may submit full applications through eBRAP. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding eBRAP submissions.

#### 5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application" Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure the proper ordering as specified in the program announcement. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted through the appropriate portal prior to the full application submission deadline. Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

#### 5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. *The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant.* 

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

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

# 5.5. Intergovernmental Review

Not applicable for this funding opportunity.

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

# 6. Application Review Information

# 6.1. Application Compliance Review

Submitting applications that propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

While it is allowable to propose similar research projects to different programs within CDMRP or to other organizations, duplication of funding or accepting funding from more than one source for the same research is prohibited. See the <u>CDMRP's full position on research duplication</u>.

Including classified research data within the application and/or proposing research that may produce classified outcomes or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

Members of the FY25 PRMRP Programmatic Panel should not be involved in any preapplication or full application including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic panel members *may* provide <u>letters</u> to confirm <u>PI eligibility</u> and access to laboratory space, equipment, and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). *A list of the <u>FY25 PRMRP Programmatic Panel members can be found on the CDMRP website.</u>* 

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

#### 6.2. Review Criteria

## 6.2.1. Pre-Application Screening Criteria

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

#### 6.2.2. Peer Review Criteria

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

#### Impact

- To what extent the proposed research project addresses the applicant-selected <u>FY25</u> <u>PRMRP Topic Area</u>, and to what extent the proposed research impacts a critical problem or an important scientific question relevant to that topic area.
- To what extent the proposed research project addresses the applicant-selected <u>FY25</u> PRMRP Strategic Goal.
- How the proposed research project, if successful, will make important scientific advances in the relevant field of research or advance patient outcomes.
- If applicable, to what extent the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.

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

 To what degree the proposed project will make a significant impact on the lives of relevant patient populations in the short term and/or long term.

# 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, promising preclinical findings, sound scientific rationale, and demonstrated proof of concept.
- How well the hypotheses/objectives, experimental design, and methods have been developed and how well they support completion of the aims.
- o The degree to which the expected outcomes are specific and measurable.
- 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 is appropriate and feasible, and whether the application provides evidence of availability 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 distribution of proposed enrollment are appropriate for the proposed research.
- How well the study (or studies) is designed to achieve the objectives, including the choice of model, if applicable, and the endpoints/outcome measures to be used.
- How well potential problems are identified and alternative approaches are addressed.
- Whether the research can be completed within the proposed period of performance.
- If applicable, whether the inclusion and exclusion criteria for the subjects are sound.

## • Statistical Plan and Data Analysis/Management

- To what extent the power analysis demonstrates that the sample size is appropriate to allow a meaningful outcome or how well the application justified why a power analysis is not essential to the statistical evaluation, as applicable.
- o If human or animal studies are included, how well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.
- To what extent the statistical methodology and plan supports the stated hypothesis or objective.
- If applicable, how well the described dataset supports the aims of the project.
- Whether the application states if the analyses will be univariate, bivariate, or multivariate.
- How well the data management is described and justified to include all methods for data collection (e.g., identifiers, confidentiality).
- How well the application explains the data capture, verification, and disposition, if applicable.
- Whether there is a plan to organize, maintain, and/or evaluate large datasets, if applicable.

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

# Post-Award Transition Plan and Regulatory Strategy

- To what extent the anticipated outcomes will support the translation of promising preclinical findings to the next stage of development (clinical trials, commercialization, and/or delivery to the civilian or military market) after successful completion of the award.
- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
- Whether the identified next level of development and/or plans for commercialization is realistic.
- Whether the funding strategy described to bring the product to the next level of development (e.g., specific potential industry partners, specific funding opportunities to be applied for) is reasonable and realistic.
- Whether the regulatory strategy and the development plan to support the proposed product label, if applicable, are appropriate and well-described.
- If applicable, whether the proposed collaborations and other resources for providing continuity of development of knowledge products, 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 anticipated product to the next phase of development through to achieving a clinically meaningful outcome (clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice, or approval by the FDA) are achievable. Whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
- If applicable, to what degree the intellectual and material property plan is appropriate.

#### Personnel

- How appropriate the levels of effort are for successful conduct of the proposed work.
- How the background and expertise of the PI and other key personnel demonstrate their ability to perform the proposed work.
- How the PI's record of accomplishment demonstrates their ability to accomplish the proposed work.

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

# Budget

Whether the budget is appropriate for the proposed research.

#### Environment

- To what extent the scientific environment is appropriate for the proposed research project.
- How well the research requirements are supported by the availability of and accessibility to facilities and resources.

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

 To what extent the quality and level of institutional support are appropriate for the proposed research project.

# Application Presentation

 To what extent the writing, clarity, and presentation of the application components influence the review.

# 6.2.3. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the FY25 PRMRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Relative impact
  - Relevance to the FY25 PRMRP Topic Areas
  - Relevance to the <u>FY25 PRMRP Strategic Goals</u>
  - Relevance to military health
  - o 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 made to the Commanding General, USAMRDC. *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in <u>Section 6.2.3</u>, <u>Programmatic Review</u>. Additional information about the two-tier process used by the CDMRP can be found on the <u>CDMRP website</u>.* 

Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as

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

evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a <u>limited time period</u> based on the fiscal year of the funds.

# 6.4. Risk, Integrity, and Performance Information

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

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

In accordance with National Security Presidential Memorandum and all associated laws, all fundamental research funded by the DoD must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the <a href="DOD Component Decision Matrix">DOD Component Decision Matrix</a> must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

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

# 7. Federal Award Notices

For each full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the application receipt and review process for the PRMRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. No commitment on the part of the government should be inferred from discussions with any other individual. The award document signed by the Grants Officer is the official authorizing document (i.e., assistance agreement).

Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to *intragovernmental and intramural DOD organizations* will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For additional information about pre-award costs for Grants.gov submissions, refer to the General Application Instructions, Section I.D, Pre-Award Costs section; and for eBRAP submissions, refer to the General Application Instructions, Section 1.D, Pre-Award Costs section.

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

# 8. Post-Award Requirements

# 8.1. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this program announcement.

Refer to the General Application Instructions, Appendix 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest <u>DoD R&D Terms and Conditions</u> and the <u>USAMRAA Research</u> <u>Terms and Conditions</u>: Addendum to the <u>DoD R&D Terms and Conditions</u> for further information.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee (IACUC), IRB, or Ethics Committee (EC) review. Refer to the General Application Instructions, Appendix 6, for additional information.

# 8.2. Reporting

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

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

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

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

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

# 8.3. PI Changes and Award Transfers

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.

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

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

# 9. Other Information

# 9.1. Program Announcement and General Application Instructions Versions

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code CD25\_01d. The program announcement numeric version code will match the General Application Instructions version code CD25\_01.

## 9.2. Administrative Actions

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

# 9.2.1. Rejection

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

- Project Narrative is missing.
- Budget is missing.
- Pre-application (LOI) was not submitted.

#### 9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents.
- Documents not requested will be removed.

#### 9.2.3. Withdrawal

The following may result in administrative withdrawal of the full application:

- A member of the <u>FY25 PRMRP Programmatic Panel</u> is named as being involved in the development or execution of the research proposed or is found to have assisted in the preapplication or application processes.
- Applications that include names of personnel from either of the CDMRP peer or
  programmatic review companies for which conflicts cannot be adequately mitigated. For
  FY25, the identities of the peer review contractor and the programmatic review contractor
  may be found on the <u>CDMRP website</u>.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) if: (a) the organization cannot accept and execute the entirety of the requested budget in FY25 funds; and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.

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

- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application fails to address one of the congressionally directed FY25 PRMRP Topic Areas.
- The application fails to address one of the <u>FY25 PRMRP Strategic Goals</u>.
- The application describes studies on a topic area or strategic goal that is different from the <u>FY25 PRMRP Topic Area</u> and <u>FY25 PRMRP Strategic Goal</u> selected in the pre-application.
- The investigator is named as PI on more than one application submitted to the FY25 PRMRP. If more than one Letter of Intent is submitted by the same PI to the FY25 PRMRP, the first submission will be accepted, and the second will be administratively withdrawn.
- The PI does not meet the eligibility criteria.
- A clinical trial is proposed.

#### 9.2.4. Withhold

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

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

# **Appendix 1. Full Application Submission Checklist**

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

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

# **Appendix 2. Acronym List**

CDMRP Congressionally Directed Medical Research Programs

CFR Code of Federal Regulations
DOD U.S. Department of Defense

DoDGARs Department of Defense Grant and Agreement Regulations

eBRAP Electronic Biomedical Research Application Portal

EC Ethics Committee

ET Eastern Time

FAD Funding Authorization Document
FDA U.S. Food and Drug Administration

FY Fiscal Year

GMP Good Manufacturing Practice

IACUC Institutional Animal Care and Use Committee

IDE Investigational Device Exemption

IND Investigational New Drug
IRB Institutional Review Board

LOI Letter of Intent

M Million

MIPR Military Interdepartmental Purchase Request

NIH National Institutes of Health

NSF U.S. National Science Foundation

OHARO Office of Human and Animal Research Oversight (previously Office of

Research Protections)

OUSD R&E Office of the Under Secretary of Defense for Research and Engineering

PDF Portable Document Format

PHS Public Health Service
PI Principal Investigator

PRMRP Peer Reviewed Medical Research Program

QWERTY First six letters of the second row of a standard English-language keyboard

RPPR Research Performance Progress Report

SAM System for Award Management

SciENcv Science Experts Network Curriculum Vitae

SF424 Standard Form 424 (Application for Federal Assistance, Research & Related)

SOW Statement of Work

TTDA Technology/Therapeutic Development Award

UEI Unique Entity Identifier

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

URL Uniform Resource Locator

USAMRAA U.S. Army Medical Research Acquisition Activity

USAMRDC U.S. Army Medical Research and Development Command

USC United States Code

VA U.S. Department of Veterans Affairs

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

# Appendix 3. DOD and VA Websites

Air Force Office of Scientific Research <a href="https://www.afrl.af.mil/AFOSR/">https://www.afrl.af.mil/AFOSR/</a>

Air Force Research Laboratory <a href="https://www.afrl.af.mil/">https://www.afrl.af.mil/</a>

Armed Forces Radiobiology Research Institute

https://afrri.usuhs.edu/home

Combat Casualty Care Research Program <a href="https://cccrp.health.mil">https://cccrp.health.mil</a>

Congressionally Directed Medical Research Programs

https://cdmrp.health.mil/

Defense Advanced Research Projects Agency

https://www.darpa.mil/

Defense Health Agency <a href="https://www.dha.mil//">https://www.dha.mil//</a>

Defense Suicide Prevention Office <a href="https://www.dspo.mil/">https://www.dspo.mil/</a>

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

Defense Threat Reduction Agency <a href="https://www.dtra.mil/">https://www.dtra.mil/</a>

Military Health System Research Symposium <a href="https://mhsrs.health.mil/sitepages/home.aspx">https://mhsrs.health.mil/sitepages/home.aspx</a>

Military Infectious Diseases Research Program

https://midrp.health.mil/

Military Operational Medicine Research Program

https://momrp.health.mil/

Navy Bureau of Medicine and Surgery <a href="https://www.med.navy.mil/BUMED/Nurse-Corps/?faqs=med.navy.afpims.mil">https://www.med.navy.mil/BUMED/Nurse-Corps/?faqs=med.navy.afpims.mil</a>

Naval Health Research Center

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

Navy and Marine Corps Force Health Protection Command

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

Naval Medical Research Command <a href="https://www.med.navy.mil/Naval-Medical-Research-Command/">https://www.med.navy.mil/Naval-Medical-Research-Command/</a>

Office of Naval Research <a href="https://www.onr.navy.mil/">https://www.onr.navy.mil/</a>

Office of the Under Secretary of Defense for Acquisition and Sustainment <a href="https://www.acq.osd.mil/">https://www.acq.osd.mil/</a>

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

Uniformed Services University of the Health Sciences

https://www.usuhs.edu

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

U.S. Army Combat Capabilities Development Command <a href="https://www.army.mil/devcom">https://www.army.mil/devcom</a>

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

U.S. Army Medical Research and Development Command <a href="https://mrdc.health.mil/">https://mrdc.health.mil/</a>

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

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

U.S. Army Research Institute of Environmental Medicine

https://www.t2.army.mil/T2-Laboratories/Designated-Laboratories/US-Army-Research-Institute-of-Environmental-Medicine/

U.S. Army Research Laboratory <a href="https://www.arl.army.mil/">https://www.arl.army.mil/</a>

U.S. Army Directorate of Prevention, Resilience and Readiness <a href="https://www.armyresilience.army.mil/">https://www.armyresilience.army.mil/</a>

U.S. Department of Defense Blast Injury Research Program

https://blastinjuryresearch.health.mil/

U.S. Department of Veterans Affairs, Office of Research and Development <a href="https://www.research.va.gov/">https://www.research.va.gov/</a>