

# **I. OVERVIEW OF THE FUNDING OPPORTUNITY**

**Program Announcement for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Peer Reviewed Medical Research Program**

**Focused Program Award**

**Announcement Type: Initial**

**Funding Opportunity Number: HT9425-23-PRMRP-FPA**

**Assistance Listing Number: 12.420 Military Medical  
Research and Development**

## **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), April 12, 2023
- **Invitation to Submit an Application:** May 26, 2023
- **Application Submission Deadline:** 11:59 p.m. ET, July 19, 2023
- **End of Application Verification Period:** 5:00 p.m. ET, July 24, 2023
- **Peer Review:** September 2023
- **Programmatic Review:** November 2023

*This program announcement must be read in conjunction with the General Application Instructions, version 800. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”*

## TABLE OF CONTENTS

<b>I. OVERVIEW OF THE FUNDING OPPORTUNITY.....</b>	<b>1</b>
<b>II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY.....</b>	<b>3</b>
II.A. Program Description.....	3
II.A.1. FY23 PRMRP Topic Areas and Strategic Goals.....	3
II.B. Award Information .....	10
II.C. Eligibility Information.....	15
II.C.1. Eligible Applicants .....	15
II.C.2. Cost Sharing.....	16
II.C.3. Other .....	16
II.D. Application and Submission Information.....	16
II.D.1. eBRAP and Grants.gov.....	16
II.D.2. Content and Form of the Application Submission .....	17
II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM).....	39
II.D.4. Submission Dates and Times.....	39
II.D.5. Funding Restrictions.....	40
II.D.6. Other Submission Requirements .....	41
II.E. Application Review Information .....	41
II.E.1. Criteria .....	41
II.E.2. Application Review and Selection Process.....	48
II.E.3. Integrity and Performance Information.....	49
II.E.4. Anticipated Announcement and Federal Award Dates.....	49
II.F. Federal Award Administration Information .....	49
II.F.1. Federal Award Notices.....	49
II.F.2. Administrative and National Policy Requirements.....	50
II.F.3. Reporting.....	51
II.G. Federal Awarding Agency Contacts.....	52
II.G.1. eBRAP Help Desk.....	52
II.G.2. Grants.gov Contact Center .....	52
II.H. Other Information.....	52
II.H.1. Program Announcement and General Application Instructions Versions.....	52
II.H.2. Administrative Actions.....	52
II.H.3. Application Submission Checklist.....	55
<b>APPENDIX 2: DOD AND VA WEBSITES.....</b>	<b>59</b>

## **II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY**

### **II.A. Program Description**

Applications to the Fiscal Year 2023 (FY23) Peer Reviewed Medical Research Program (PRMRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC). The PRMRP was initiated in 1999 to support medical research projects of clear scientific merit and direct relevance to military health. Appropriations for the PRMRP from FY99 through FY22 totaled \$3.45 billion. The FY23 appropriation is \$370 million (M).

The vision of the PRMRP is to improve the health, well-being, and care of all military Service Members, Veterans, and Beneficiaries, 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 Beneficiaries. The PRMRP challenges the scientific and clinical communities to address the FY23 PRMRP Topic Areas with original ideas that foster new directions along the entire spectrum of research and patient care. The program seeks applications in laboratory, clinical, behavioral, epidemiological, and other areas of research to advance knowledge in disease etiology; improve prevention, detection, diagnosis, treatment, and quality of life for those affected by a relevant disease or condition; and develop and validate clinical practice or public health guidelines.

***The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.***

#### **II.A.1. FY23 PRMRP Topic Areas and Strategic Goals**

***All applications for FY23 PRMRP funding must specifically address one of the FY23 PRMRP Topic Areas as directed by the U.S. Congress and have direct relevance to military health.***

Additionally, the PRMRP implements a portfolio-driven approach by grouping related Topic Areas with Strategic Goals as a framework within which to address critical gaps in major research areas. ***All applications must address one of the FY23 PRMRP Strategic Goals as it relates to the portfolio-assigned FY23 PRMRP Topic Area.*** If the proposed research does not specifically address one FY23 PRMRP Topic Area and one FY23 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 FY23 PRMRP Topic Areas and Strategic Goals are listed in each PRMRP portfolio category below.

## **FY23 PRMRP Portfolio Categories with Associated FY23 PRMRP Topic Areas and FY23 PRMRP Strategic Goals**

### **Autoimmune Disorders and Immunology**

#### **Topic Areas**

- Celiac Disease
- Eczema
- Food Allergies
- Guillain-Barre Syndrome
- Inflammatory Bowel Disease
- Neuroinflammatory Responses to Emerging Viral Diseases
- Proteomics
- Rheumatoid Arthritis
- Scleroderma

#### **Strategic Goals**

##### **Foundational Studies**

- Identify factors, to include environmental exposures, lifestyle triggers, genetic risk factors, dietary practices, and past medical history, impacting the onset and progression of associated immune-mediated diseases
- Elucidate and prevent neurological, psychiatric, and psychosocial impact of associated immune-mediated diseases
- Determine the impact of the microbiome and/or gut-mediated inflammation on associated immune-mediated diseases

##### **Diagnosis**

- Develop innovative noninvasive methods for diagnosis and continuous monitoring of inflammation
- Identify biomarkers, including multi-omics approaches, to diagnose or predict onset and/or progression of associated immune-mediated diseases
- Develop tools to assess cognitive dysfunction associated with neurological implications of associated immune-mediated diseases

##### **Treatment**

- Develop and test therapeutic interventions to promote tissue healing
- Develop and test new treatments and/or refine existing treatment strategies to minimize toxicity, and mitigate the inflammatory, immune, and/or allergic disease state

##### **Epidemiology**

- Conduct patient-centered research on onset, exacerbation, outcomes, and treatment preferences for associated immune-mediated diseases
- Conduct population-based studies to identify risk factors that contribute to onset and progression associated immune-mediated diseases and comorbidities
- Conduct patient-centered research to decrease disease burden for military families

### **Cardiovascular Health**

#### **Topic Areas**

- Familial Hypercholesterolemia
- Hypercholesterolemia
- Proteomics
- Vascular Malformations

## Strategic Goals

### Prevention

- Elucidate and prevent the impact of cardiovascular conditions on the heart, brain, arteries, and additional target organs across a patient's life span

### Diagnosis

- Develop strategies to enable detection of associated cardiovascular conditions before clinical symptoms are apparent

### Treatment

- Develop novel therapeutics or advance treatment regimens for associated cardiovascular conditions that address sex/gender, ethnic, and/or racial differences

### Epidemiology

- Identify risk factors that contribute to associated cardiovascular conditions in civilian and/or military populations
- Conduct population-based or outcomes-based research to identify sex, gender, ethnic, racial, psychosocial, and/or quality of life long-term impacts of associated cardiovascular conditions

## Hemorrhage Control and Blood Products

### Topic Areas

- Hemorrhage Control
- Trauma
- Proteomics

## Strategic Goals

### Diagnosis

- Develop strategies or innovative technologies (to include wearable devices) for early detection of internal bleeding, trauma-induced coagulopathy, or hypovolemic shock

### Treatment

- Develop smart or automated tourniquets or battlefield hemostatic dressings with antimicrobial and/or analgesic effects
- Develop innovative damage control capabilities and solutions for control of non-compressible torso hemorrhage, especially interventions that can be used in austere environments
- Develop and evaluate regulatory-compliant strategies to improve the manufacture of whole blood and blood components with advantages in efficiency and timeliness over current manufacturing methods
- Develop and evaluate strategies to improve blood and blood product shelf life and transport, to minimize waste, and to reduce the logistical footprint

## **Epidemiology**

- Evaluate the effects of current combat blood product transfusion guidelines on immunological status and clinical outcomes
- Determine physiological impacts of blood loss (e.g., walking donors) on the ability to sustain performance in extreme environments

## **Infectious Diseases**

### **Topic Areas**

- Hepatitis B
- Malaria
- Neuroinflammatory Responses to Emerging Viral Diseases
- Proteomics
- Tuberculosis

### **Strategic Goals**

#### **Foundational Studies**

- Elucidate and prevent long-term complications following infections, including comorbidities

#### **Prevention**

- Develop or optimize vaccine strategies, vaccine platforms, or compounds of any preventive type, to include active or passive immunoprophylaxis
- Develop strategies to eliminate/reduce mother-to-child 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 or improve existing next-generation tools based on patient sample that are readily available for easier diagnosis (e.g., urine, sweat, biometrics)

#### **Treatment**

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

#### **Epidemiology**

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

## Internal Medicine

### Topic Areas

- Endometriosis
- Focal Segmental Glomerulosclerosis
- Interstitial Cystitis
- Lymphatic Disease
- Lymphedema
- Nephrotic Syndrome
- Pancreatitis
- Polycystic Kidney Disease
- Pressure Ulcers
- Proteomics

### Strategic Goals

#### Foundational Studies

- Improve understanding of long-term complications and comorbidities of associated diseases and conditions

#### Prevention

- Develop and test strategies to prevent associated diseases or comorbidities

#### Diagnosis

- Develop tools or technologies for early detection, accurate diagnosis, or tracking of disease progression, including non-invasive methods, of associated diseases and conditions
- Develop tools to reduce time between presentation of symptoms and required specialized care for associated disease or condition management

#### Treatment

- Develop and test novel treatments, and/or improve upon existing treatments for associated diseases and conditions, which may include lifestyle interventions to improve psychosocial functioning and quality of life

#### Epidemiology

- Elucidate factors (e.g., medication toxicity, genetic predisposition, infections) that influence development, progression, and outcomes (including psychosocial functioning and quality of life) of associated diseases and conditions
- Develop surrogate endpoints to accelerate approval of new treatments for associated diseases and conditions
- Conduct patient-centered research to decrease disease burden for military families

## Neuroscience

### Topic Areas

- Eating Disorders
- Maternal Mental Health
- Myalgic Encephalomyelitis/  
Chronic Fatigue Syndrome
- Neuroactive Steroids
- Neuroinflammatory Responses to  
Emerging Viral Diseases
- Non-Opioid Therapy for Pain Management
- Peripheral Neuropathy
- Proteomics
- Sleep Disorders and Restriction
- Suicide Prevention
- Trauma

## Strategic Goals

### Foundational Studies

- Identify mechanisms underlying neurological diseases and/or psychological conditions including potential relationships to environmental or neurotoxic exposures, injury, stress, or infections

### Prevention

- Test efficacy of methods (e.g., screening, education programs, counseling) to prevent associated conditions or comorbidities

### Diagnosis

- Improve and validate diagnostic criteria for neurological health, psychological health, and/or cognitive assessment, which may include development and testing of personalized clinical decision-making tools or development of objective diagnostic criteria
- Develop strategies, such as predictive analytics or artificial intelligence, to provide early identification of associated neurological disease or psychological conditions, with the goal of providing early intervention

### Treatment

- Develop and evaluate novel treatments, strategies, or therapeutic targets for associated neurological diseases and psychological conditions, which may include repurposing existing drugs
- Develop capabilities to monitor, and therapies or countermeasures to maintain, optimal cognitive functioning and mental resilience in occupational environments or under sleep restriction (e.g., shift work, insufficient sleep, jet lag)
- Develop and test pain therapies that will not affect the cardiorespiratory system and cognitive abilities for use in trauma, battlefield, or resource-limited environments

### Epidemiology

- Conduct population-based studies to identify risk factors (e.g., military-specific lifestyle) that contribute to onset and progression of associated neurological diseases and psychological conditions

## Orthopaedic Medicine

### Topic Areas

- Arthritis
- Orthopaedics
- Proteomics
- Trauma

## Strategic Goals

### Foundational Studies

- Understand mechanisms underlying the pathobiology of associated musculoskeletal disorders
- Determine factors that lead to accelerated degeneration following joint injuries



## **Prevention**

- Develop orthopaedic strategies for improved point of injury care to mitigate risk of secondary complications
- Develop and test strategies to prevent infections caused by severe fractures or trauma

## **Diagnosis**

- Develop novel tools/technologies for early and precision diagnosis of associated musculoskeletal disorders

## **Treatment**

- Advance intra-articular treatments for joint injuries
- Develop and test strategies to increase quality of life or halt/slow disease progression, which may include regenerative medicine approaches and biologics for associated musculoskeletal disorders
- Develop and test strategies for rehabilitation regimens to allow Service Members to return to duty

## **Epidemiology**

- Conduct patient-reported outcomes research to inform treatment guidelines and improve exercise recommendations to optimize joint longevity

## **Rare Diseases and Conditions**

### **Topic Areas**

- Dystonia
- Ehlers-Danlos Syndrome
- Epidermolysis Bullosa
- Fibrous Dysplasia/McCune-Albright Syndrome
- Fragile X
- Frontotemporal Degeneration
- Hereditary Ataxia
- Hydrocephalus
- Mitochondrial Disease
- Myotonic Dystrophy
- Proteomics
- Sickle-Cell Disease
- Von Hippel-Lindau Syndrome Benign Manifestations

### **Strategic Goals**

#### **Foundational Studies**

- Identify biological mechanisms underlying disease onset, disease progression, or phenotype/symptomatic heterogeneity

#### **Diagnosis**

- Identify and validate biomarkers to predict onset or progression of disease
- Develop and validate improved diagnostic criteria and screening tools for early detection or to track disease progression

### **Treatment**

- Develop and test novel treatments or improve upon existing treatment regimens, especially those ready to progress rapidly to the clinical, which may include repurposing drugs or non-prescription treatment options
- Develop and test tissue engineering, gene therapy, or protein replacement strategies for associated diseases and conditions

### **Epidemiology**

- Population-based studies to identify risk or protective factors that influence onset, progression, and/or outcomes of associated diseases and conditions
- Conduct natural history/longitudinal studies to understand incidence, prevalence, and progression of associated diseases and conditions

## **Respiratory Health**

### **Topic Areas**

- Proteomics
- Pulmonary Fibrosis
- Respiratory Health
- Trauma

### **Strategic Goals**

#### **Foundational Studies**

- Determine how airborne hazards, toxins, or nanomaterial exposure cause respiratory injury/disease

#### **Prevention**

- Prevent lung injury caused by trauma, transfusion, mechanical ventilation, infection, or hemorrhagic shock

#### **Diagnosis**

- Develop and validate sensors to assess environmental and/or physiological levels of exposure to airborne hazards or toxins
- Develop a fieldable toolset to monitor lung dysfunction/failure
- Improve early detection for interstitial lung disease

#### **Treatment**

- Develop and test novel treatments, including precision medicine approaches, to slow progression or reverse lung injury/disease
- Develop improved fieldable devices to treat traumatic/acute lung injury in far forward settings, including toolsets to enable correct airway placement, oxygenation in austere settings, or miniature and/or semi-automated ventilator

## **II.B. Award Information**

The FY23 PRMRP Focused Program Award (FPA) is intended to optimize research and accelerate solutions to a critical question related to one of the congressionally directed FY23 PRMRP Topic Areas and one of the FY23 PRMRP Strategic Goals through a synergistic, multidisciplinary research program.

***Key aspects of this award include:***

**Overarching Challenge:** FPA applications must describe a unifying, overarching challenge that will be addressed by a set of research projects. The overarching challenge must be relevant to a critical problem or question in the field of research and/or patient care in one of the FY23 PRMRP Topic Areas and one of the FY23 PRMRP Strategic Goals.

**Research Projects:** Applications shall include multiple, distinct research projects led by individual project leaders that address complementary aspects of the overarching challenge. Applicants are strongly encouraged to submit **a minimum of four research projects**; additional studies are allowed. While individual projects must be capable of standing on their own high scientific merits, they must also be interrelated and synergistic with the other proposed projects and advance a solution beyond what would be possible through individual efforts. The exploration of multiple hypotheses or viewpoints of the same line of questioning is encouraged. ***This award mechanism is not intended to support a series of research projects that are dependent on the success of one of the other projects.*** Each project should propose a unique approach to addressing the overarching challenge and be capable of producing research findings with potential to impact the field and/or patient care. Individual research projects may range from exploratory, hypothesis-developing studies through small-scale clinical trials (i.e., up to and including phase 2 or equivalent). There should be a clear intent to progress toward translational/clinical work over the course of the effort. If an Investigational New Drug (IND) or Investigational Device Exemption (IDE) will be required to support a project that includes some preclinical work to be completed prior to an early-phase (pilot, phase 1, phase 2, or equivalent) clinical trial, then a proposed submission date of the IND or IDE application to the U.S. Food and Drug Administration (FDA) should be included in the application (including in the Statement of Work [SOW], see [Attachment 5](#)). A detailed plan describing how FDA requirements and filings will be met and completed is required; see [Attachment 8, Transition Plan and Regulatory Strategy](#), for more information.

**Implementation:** The research strategy to address the overarching challenge must be supported by a detailed implementation plan that identifies critical milestones and outlines the knowledge, resources, and technical innovations that will be utilized to achieve the milestones. A robust statistical plan and statistical expertise should be included where applicable. A plan for assessing individual project performance and progress toward addressing the overarching challenge must be included in the implementation plan. Plans to include an External Advisory Board (EAB) are encouraged; however, applicants must be careful to avoid potential conflicts of interest during review of the application by ensuring no contact with, recruiting of, or naming of specific EAB members in the application. For multi-institutional collaborations, plans for communication and data transfer among the collaborating institutions, as well as how data, specimens, and/or products obtained during the study will be handled, must be included. An intellectual and material property plan agreed to by participating organizations is required in the application's supporting documentation.

**Research Team:** The overall effort will be led by a Principal Investigator (PI) with demonstrated success in leading large focused projects. The PI is required to devote a minimum of 20% effort to this award. The PI should create an environment that fosters and supports collaboration and innovation in a way that engages all members of the team in all aspects of the

research plan. The research team assembled by the PI should be highly qualified and multidisciplinary, with identified project leaders for each of the complementary and synergistic research projects. The resources and expertise brought to the team by each project leader should combine to create a robust, synergistic collaboration. The PRMRP Science Officer assigned to a resulting award should be invited to participate in research team meetings (e.g., annual meetings of the entire research team). The plan for such meetings should be noted in the application.

**Milestone Meeting:** The PI will be required to present an update on progress toward accomplishing the goals of the award at a Milestone Meeting after the conclusion of year 2 of the period of performance. The PI may bring up to three additional members of the research team to the meeting. The Milestone Meeting will be attended by members of the PRMRP Programmatic Panel, CDMRP staff, the USAMRAA Grants Officer, and other Department of Defense (DOD) stakeholders.

The types of awards made under the program announcement will be assistance agreements. An assistance agreement is appropriate when the federal government transfers a “thing of value” to a “state, local government,” or “other recipient” to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the DOD during project performance is the key factor in determining whether to award a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The anticipated direct costs budgeted for the entire period of performance for an FY23 PRMRP Award will not exceed **\$7.2M**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2024. For additional information refer to [Section II.F.1, Federal Award Notices](#).

***The CDMRP expects to allot approximately \$54.0M to fund approximately 5 Focused Program Award applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY23 funding opportunity will be funded with FY23 funds, which will expire for use on September 30, 2029.***

**Relevance to Military Health:** Relevance to the health care needs of military Service Members, Veterans, military beneficiaries, and/or the American public is a key feature of this

award. Investigators are encouraged to consider the following characteristics as examples of how a project may demonstrate relevance to military health:

- Explanation of how the project addresses an aspect of the target disease/condition/technology that has direct relevance or is unique to the health of military Service Members, Veterans, or beneficiaries
- Explanation of how the project addresses an aspect of the target disease/condition/technology that has relevance or is unique to the military or family readiness of Service Members
- 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 or datasets, if appropriate to the proposed research

Applicants are strongly encouraged to integrate and/or align their research projects with DOD and/or Department of Veterans Affairs (VA) research laboratories and programs. Collaboration with DOD or VA investigators is also encouraged. 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 FY23 PRMRP Topic Areas can be found in [Appendix 2](#).

**Use of DOD or VA Resources:** If the proposed research involves access to active-duty military and Veteran patient populations and/or DOD or VA 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. Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

**Research Involving Human Data, Human Anatomical Substances, Human Subjects, or Human Cadavers:** All DOD-funded research involving new and ongoing research with human data, human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of application submission is *not* required; however, local IRB/EC approval is necessary prior to OHRO review. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of *all required and complete* documents to the OHRO. Refer to the General Application Instructions, Appendix 1, and the OHARO web page [https://mrhc.health.mil/index.cfm/collaborate/research\\_protections/hrpo](https://mrhc.health.mil/index.cfm/collaborate/research_protections/hrpo) for additional information.

As of January 20, 2020, U.S. institutions engaged in non-exempt cooperative research *must* rely on a single IRB to review and approve the portion of the research conducted at domestic sites in accordance with Code of Federal Regulations, Title 45, Part 46.114(b) (45 CFR 46.114[b]). If the proposed, non-exempt research involves more than one U.S.-based institution, a written plan

for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

*A clinical trial is defined* 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.

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

***Clinical research*** encompasses research with patient samples, data, and interaction with patients that may or may not be considered a clinical trial. ***For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research.*** Clinical research is observational in nature and includes: (1) Research that does not seek to evaluate the effects of interventions. Research conducted with human subjects (or on material of human origin such as data, tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects, but does not seek to assess the effects of an intervention, qualifies as clinical research. Patient-oriented research 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 study 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 tissues that cannot be linked to a living individual. ***Note:*** Studies that meet the requirements for exemption under [§.104\(d\)\(4\) of the Common Rule](#) are not considered clinical research as defined by CDMRP. Exemption category 4 refers to secondary research for which consent is not required.

**Research Involving Animals:** All research funded by the FY23 PRMR FPA involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHARO Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is ***not*** required. ***Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

## **II.C. Eligibility Information**

### **II.C.1. Eligible Applicants**

**II.C.1.a. Organization:** All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.

**Government Agencies Within the United States:** Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this program announcement may be submitted by extramural and intramural organizations, these terms are defined below.

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

**Intramural DOD Organization:** A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission:*** An application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.

**The USAMRAA makes awards to eligible organizations, not to individuals.**

### **II.C.1.b. Principal Investigator**

- The PI named by the organization on the application must be an independent investigator at or above the level of Full Professor (or equivalent).
  - Project leaders for each of the complementary and synergistic research projects must be at or above the level of Assistant Professor (or equivalent).
  - The PI is required to devote a minimum of 20% effort to this award.

Each investigator may be named on only one FY23 PRMRP FPA application as a PI.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by or affiliated with an eligible organization.

The CDMRP strongly encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at <https://orcid.org/>.

## **II.C.2. Cost Sharing**

Cost sharing/matching is not an eligibility requirement.

## **II.C.3. Other**

Organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to [Section II.H.2, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

## **II.D. Application and Submission Information**

*Submission of applications that are essentially identical or 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).*

### **II.D.1. eBRAP and Grants.gov**

The **electronic Biomedical Research Application Portal (eBRAP)** (<https://ebrap.org>) is a secure web-based system that allows PIs to submit their pre-applications, view and verify extramural full applications submitted to Grants.gov (<https://grants.gov>), receive communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission.

**Grants.gov** is a federal system required to be utilized by agencies to receive and process extramural grant applications. Full applications may only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Contact information for the eBRAP Help Desk and the Grants.gov Contact Center can be found in [Section II.G, Federal Awarding Agency Contacts](#).

#### ***Extramural Submission:***

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at Grants.gov.



### ***Intramural DOD Submission:***

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at eBRAP.org.

***Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.***

## **II.D.2. Content and Form of the Application Submission**

Submission is a two-step process requiring both ***pre-application*** (eBRAP.org) and ***full application*** (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to [Table 1, Full Application Guidelines](#)).

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

### **II.D.2.a. Step 1: Pre-Application Submission Content**

***During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required during the full application submission process.***

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the eBRAP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507 to request a change in designation.

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

The applicant organization and associated PI identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the eBRAP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

PIs with an ORCID identifier should enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B, for additional information on pre-application submission):

- **Tab 1 – Application Information**

Submission of application information includes assignment of primary and secondary research classification codes, which may be found at <https://ebrap.org/eBRAP/public/Program.htm>. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

Select the FY23 PRMRP Portfolio addressed by the proposed research.

Select the FY23 PRMRP Topic Area addressed by the proposed research.

Select the FY23 PRMRP Continuum of Care category addressed by the proposed research.

Select the FY23 PRMRP Strategic Goal addressed by the proposed research.

- **Tab 2 – Application Contacts**

Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 Research & Related Form), and click on “Add Organizations to this Pre-application.” The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

Enter the name, organization, and role of all collaborators and key personnel associated with the application.

[FY23 PRMRP Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the eBRAP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

List all individuals other than collaborators and key personnel who may have a conflict of interest in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Tab 5 – Pre-Application Files**

*Note: Upload documents as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.*

- **Preproposal Narrative (six-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.
  - **Overarching Challenge:** Describe how the proposed research program addresses a unifying challenge or question and how it is relevant to an FY23 PRMRP Topic Area and an FY23 PRMRP Strategic Goal. Additionally, describe how the unifying challenge or question is relevant to a critical problem or question in the field of research and/or patient care in the FY23 PRMRP Topic Area addressed. Clearly articulate the rationale for the overarching challenge; include relevant preliminary data and literature citations.
  - **Research Strategy:** The FY23 PRMRP FPA strongly encourages a **minimum of four individual but complementary research projects** addressing the overarching challenge. For each proposed project, state the hypothesis to be tested, the specific aims, and the objectives to be reached. Briefly describe the experimental approach. Describe how the projects are interrelated to and synergistic with each other and align with the overarching challenge to advance a solution beyond what would be possible through individual efforts.
  - **Impact:** Explain how the research program addresses an FY23 PRMRP Topic Area and an FY23 PRMRP Strategic Goal. Describe the potential short-term and long-term impact of the proposed research on a critical problem or question in the field of research and/or patient care in the FY23 PRMRP Topic Area addressed. Explain how the effort is relevant to the health care needs of military Service Members, Veterans, and/or beneficiaries.
  - **Research Team:** Briefly describe the composition, expertise, and organization of the research team. Identify the project leaders and describe each team member's role in and commitment to the projects, with additional emphasis on the leadership role and commitment of the PI. Briefly describe how these features will facilitate the success of the key aspects of the projects.

- **Clinical Trial (if applicable):** If one or more of the proposed research projects include a clinical trial, briefly state the clinical intervention(s), subject population(s), and the type and phase of the clinical trial(s). Describe the objectives of the clinical trial(s), how it addresses the overarching challenge, and how it complements the other proposed projects.
- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* and are limited to the following:
  - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
  - **Key Personnel Biographical Sketches (five-page limit per individual):** *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **Tab 6 – Submit Pre-Application**

This tab must be completed for the pre-application to be accepted and processed.

### **Pre-Application Screening**

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the Defense Health Program (DHP) and the FY23 PRMRP, pre-applications will be screened based on the following criteria:

- **Overarching Challenge:** How well the unifying challenge or question addresses one of the FY23 PRMRP Topic Areas and one of the FY23 PRMRP Strategic Goals. How well the unifying challenge or question addresses a critical problem or question in the field of research and/or patient care in the FY23 PRMRP Topic Area addressed. How well the rationale supports the overarching challenge.
- **Research Strategy:** How well a hypothesis and specific aims are defined for each proposed project and to what extent each project’s approach will address them. How well the proposed projects complement each other and synergistically address the overarching challenge to advance a solution beyond what would be possible through individual efforts.

- **Impact:** To what degree the research program addresses an FY23 PRMRP Topic Area and an FY23 PRMRP Strategic Goal. Whether the potential short-term and long-range outcome(s)/product(s) (intellectual and/or material) of the proposed research, if successful, will impact a critical problem or question in the field of research and/or patient care in the FY23 PRMRP Topic Area addressed. To what degree the project is relevant to the health care needs of military Service Members, Veterans, and/or beneficiaries.
- **Research Team:** To what degree the background, expertise, and commitment of the PI, project leaders, and key personnel are appropriate with respect to their abilities to successfully complete the projects and the extent to which the PI is well prepared and committed to lead the research team and proposed projects.
- **Notification of Pre-Application Screening Results**

Following the pre-application screening, PIs will be notified as to whether they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated in [Section I, Overview of the Funding Opportunity](#). Invitations to submit a full application are based on the Pre-Application Screening Criteria.

#### **II.D.2.b. Step 2: Full Application Submission Content**

Applications will not be accepted unless notification of invitation has been received.

*The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.*

Each application submission must include the completed full application package for this program announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines.

#### **II.D.2.b.i. Full Application Guidelines**

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the **same version** of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further

information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

*Do not password protect any files of the application package, including the Project Narrative.*

**Table 1. Full Application Submission Guidelines**

Extramural Submissions	Intramural DOD Submissions
<b>Application Package Location</b>	
<p>Download application package components for HT9425-23-PRMRP-FPA from Grants.gov (<a href="https://grants.gov">https://grants.gov</a>) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.</p>	<p>Download application package components for HT9425-23-PRMRP-FPA from eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</p>
<b>Full Application Package Components</b>	
<p><b>SF424 Research &amp; Related Application for Federal Assistance Form:</b> Refer to the General Application Instructions, Section III.A.1, for detailed information.</p>	<p><b>Tab 1 – Summary:</b> Provide a summary of the application information.</p> <p><b>Tab 2 – Application Contacts:</b> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">Research &amp; Related Subaward Budget Attachment(s) Form</a></li> </ul>	<p><b>Tab 3 – Full Application Files:</b> Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Key Personnel</a></li> <li>• <a href="#">Budget</a></li> <li>• <a href="#">Performance Sites</a></li> </ul> <p><b>Tab 4 – Application and Budget Data:</b> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>
<b>Application Package Submission</b>	
<p><b>Create a Grants.gov Workspace.</b> Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p><b>Submit a Grants.gov Workspace Package.</b> An application may be submitted through Workspace by clicking the “Sign and Submit”</p>	<p><b>Submit package components to eBRAP</b> (<a href="https://ebrap.org">https://ebrap.org</a>).</p> <p><b>Tab 5 – Submit/Request Approval Full Application:</b> After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and</p>

Extramural Submissions	Intramural DOD Submissions
<p>button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package <b>at least 24-48 hours prior to the close date</b> to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p><i>Note:</i> If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p>	<p>press the “Submit Full Application” button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p>
<b><u>Application Verification Period</u></b>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <b><i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i></b></p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <b><i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i></b> Your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>
<b>Further Information</b>	
<p><b>Tracking a Grants.gov Workspace Package.</b> After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

#### **II.D.2.b.ii. Full Application Submission Components**

- **Extramural Applications Only**

**SF424 Research & Related Application for Federal Assistance Form:** Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications**

**Attachments:**

*Each attachment to 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 4.*

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 megabytes (MB), and the file size for the entire full application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (40-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 to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Overall Program:** Provide a description of the comprehensive effort using the following outline. Applicants are strongly encouraged to submit **a minimum of four research projects**; additional studies are allowed. Emphasize areas of synergy throughout the narrative.
  - **Overarching Challenge:** Describe the unifying, overarching challenge or question to be addressed and how it is relevant to an FY23 PRMRP Topic Area and an FY23 PRMRP Strategic Goal. Additionally, describe how the proposed research program addresses a critical problem or question in the field of research and/or patient care in the FY23 PRMRP Topic Area addressed. Clearly articulate the rationale for the overarching challenge; include relevant literature citations. Clearly describe how the proposed research projects are not dependent upon each other but are interrelated and synergistic and will advance toward a solution



through a multidisciplinary research program. Describe how each project will address the overarching challenge in a unique but complementary way and how the combined efforts of the projects will address the overarching challenge more effectively than if the projects were conducted independently.

- **Leadership:** Describe how the PI's research experience, leadership skills, and commitment to making an impact in their field of research and/or patient care demonstrate substantial qualifications to coordinate this collaborative effort. Describe the PI's demonstrated success in leading large focused projects and outline the PI's responsibilities during the conduct of the proposed research effort. The PI is required to devote a minimum of 20% effort to this award. Discuss the qualifications of the research team being brought together by the PI and how the assembled expertise will create a robust, synergistic collaboration necessary to address the overarching challenge and enable the success of the proposed research.
- **Implementation Plan and Environment:** Provide an overall strategic implementation plan for completing the proposed projects that identifies critical milestones and explain how these milestones will be achieved. Outline the knowledge, expertise, and technical innovations that the investigative team will utilize to make decisions, allocate resources, and accomplish the milestones. Describe and/or provide evidence that the research can be initiated without delay once the award is made. Present an overall management plan to facilitate a consistent and intensive flow of ideas and information among all team members, including aspects such as adherence to regulatory requirements, administrative support, and oversight to accelerate translation of the projects' outcomes to patients and/or for clinical use. Describe the research environment and how the facilities and resources will support the research requirements and the collaboration. Outline shared resources and/or cores that will be created and/or leveraged through the award. Describe plans for communication, data transfer among the collaborating institutions, and how data, specimens, and/or imaging products obtained during the study will be handled. If applicable, describe how Standard Operating Procedures will be created, reviewed, implemented, and modified during the course of the award. Describe how individual project performance will be assessed during the course of the award, including progression toward defined milestones, realization of study objectives, and addressing the overarching challenge. If an EAB is to be utilized, describe the role of the board and the expertise to be sought in its members. To avoid potential conflicts of interest in the review of the application, potential candidates for an EAB should not be contacted, recruited, or named during the application process.
- **Research Plan:** Provide the following details for each proposed research project, organizing each project clearly and separately. *Start each project on a new page.*
  - **Title:** Provide a title for each project.

- **Project Leader:** Identify the project leader and any key personnel, as appropriate, describing each person’s qualifications, specific contributions, and evidence of strong commitment to the project.
- **Background:** Briefly describe the ideas and scientific rationale on which the proposed work is based. Provide sufficient preliminary data to support the feasibility of work proposed. If the project is exploratory/hypothesis-developing, preliminary data are not required. For each project, the project leader must demonstrate logical reasoning and provide a sound scientific rationale for the proposed project as established through a critical review and analysis of published literature. If proposing translational or clinical research, it is important to describe the project showing proof of concept and, if applicable, efficacy in an in vivo system(s) to support the translational feasibility and promise of the approach.
- **Hypothesis/Objective:** State the hypothesis to be tested and/or the objective(s) to be reached.
- **Specific Aims:** Concisely explain each project’s specific aims. The specific aims should align with the overall goal of the program and associated tasks described in the SOW.
- **Research Strategy and Feasibility:** Describe the experimental design, methods, and analyses to achieve rigorous and reproducible results, in sufficient detail for analysis. Provide a description of how the study will be controlled and how the study variables will be measured. If the project is a clinical trial, define the primary and secondary or interim endpoints/outcome measures, why they were chosen, and how and when they will be assessed. Explain how the research strategy will address the overarching challenge and meet appropriate milestones. Address potential problem areas and present alternative methods and approaches.
  - ❖ If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines 2.0 ([The ARRIVE guidelines 2.0 | ARRIVE Guidelines](#)).
  - ❖ Justify how the model system or human subjects/samples are appropriate to the proposed research project.
  - ❖ 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 datasets will be used in the proposed research project, describe how access to the population(s)/dataset(s) will be obtained.
  - ❖ Describe the strategy for the inclusion of women and minorities in the clinical research appropriate to the objectives of the study, including a description of

the composition of the proposed study population in terms of sex/gender, race, and/or ethnicity, and an accompanying rationale for the selection of subjects. It is not expected that every study will include all genders and racial and ethnic groups. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this requirement. The Policy on Inclusion of Women and Minorities, and Frequently Asked Questions for the policy may be downloaded from eBRAP under “Resources and Reference Material” at <https://ebrap.org/eBRAP/public/Program.htm>.

- ❖ If applicable, describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA.
- ❖ Describe how the research project will be completed within the proposed period of performance.
- **Statistical Plan:** Clearly describe a statistical plan appropriate to the type of study; provide the rationale for the statistical methodology. Define the number of samples and/or subjects (animal and/or human) to be used, and include a power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and provide meaningful outcomes. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.
- **Impact:** Describe the anticipated outcome(s)/product(s) (knowledge and/or material) that will be directly attributed to the results of the proposed research and their impact(s) on patient care and/or quality of life of relevant patient populations. Explain the anticipated short-term and long-term gains from this research and how they address the identified overarching challenge. Compare to the information known/products currently available, if applicable.
- **Clinical Trial(s) (if applicable):** *Only small-scale (e.g., up to and including phase 2 or equivalent) clinical trials are allowed.* Provide detailed plans for initiating and conducting the clinical trial during the course of this award. As appropriate, outline a plan for applying for and obtaining IND/IDE status (or other FDA approvals) within 18 months of award. Regulatory milestones to achieve IND/IDE status must be clearly defined in the project SOW and will be finalized during negotiations. If necessary, the agreement to support clinical trial efforts(s) will be contingent upon (1) obtaining all necessary regulatory approvals; (2) the availability of funds; and (3) accomplishment of research milestones and goals as determined by the USAMRAA Grants Officer.
  - ❖ Describe the type of clinical trial to be performed (e.g., treatment, prevention, diagnostic), the phase of trial and/or class of device (as appropriate), and the

study model (e.g., single group, parallel, crossover). Provide preclinical and/or clinical evidence to support the safety of the intervention.

- ❖ Identify the intervention to be tested and describe the projected outcomes. Describe how the proposed intervention compares with currently available interventions and/or standards of care. Clearly delineate research procedures from routine clinical procedures. Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications (as appropriate).
- ❖ Describe the study population, and how the sample population represents the targeted patient population that might benefit from the proposed intervention. Explain the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random). Provide information on and justification for the inclusion and exclusion criteria. Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment.
- ❖ Describe the process for obtaining informed consent and any screening procedures required to determine eligibility for study participation. In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.
- ❖ Describe the degree to which the informed consent, screening, and retention processes for human subjects will meet the needs of the proposed clinical trial. Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
- ❖ Consider how the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study. If the risks are unknown, this should be stated. Appropriate to the study's level of risk, describe how safety monitoring and reporting to the IRB and FDA (if applicable) will be managed and conducted. Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
- ❖ Define each arm/study group of the proposed trial, if applicable. Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating

group, or other procedures). Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers). If multiple site studies are involved, state the approximate number of subjects to be enrolled at each site. Identify and provide justification for the inclusion of international sites, as appropriate.

- ❖ Outline the timing and procedures planned during the follow-up period. Estimate the potential for subject loss to follow-up, and how such loss will be handled/mitigated.
  - ❖ Provide evidence to document the availability of and access to all critical reagents, including the intervention itself, if applicable, for the duration of the proposed trial.
  - ❖ Describe how quality control will be addressed. Describe how compliance with current Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), and Good Clinical Practice (GCP) guidelines will be established, monitored, and maintained, as applicable.
  - ❖ Describe the composition of the clinical trial team. Provide details on how the team (including investigator(s), study coordinator, and statistician) possesses the appropriate expertise in conducting clinical trials.
  - ❖ If applicable, describe measures to ensure consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. 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 that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **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 Organizational Support:** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.
- **Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual or organization demonstrating that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.
- **Intellectual Property:** Information can be found in the 2 CFR 200.315, “Intangible Property.”
  - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Data Management Plan (2-page limit):** If there is a separate Data Management Plan attachment, then submission of the Data Management Plan under “Supporting Documentation” is not required. Describe the data management plan in accordance with Section 3.c. Enclosure 3, [DoD Instructions 3200.12](#).
  - For Extramural Applications: Refer to General Application Instructions, Section III.A.2, Attachments Form, Attachment 2, Supporting Documentation, for more detailed information.
  - For Intramural Applications: Refer to General Application Instructions, Section IV.A.1, Application Component – Attachments, Attachment 2, Supporting Documentation, for more detailed information.
- **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.

- **Use of VA Resources (if applicable):** Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **Attachment 3: Technical Abstract (no page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. **Do not include proprietary or confidential information.** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Clarity and completeness within the space limits of the technical abstract are highly important. ***Technical abstracts must be provided for the overall program, as well as each individual project, with the abstract for each project starting on a new page.***

Describe the proposed research effort of the overall project and each individual project, including the following elements:

- **Overarching Challenge:** Identify the unifying, overarching challenge or question that will be addressed by the research plan and describe how it relates to an FY23 PRMRP Topic Area and an FY23 PRMRP Strategic Goal. Additionally, also state how the unifying, overarching challenge or question addresses critical problem or question in the FY23 PRMRP Topic Area addressed.
- **Background:** Briefly articulate the rationale for the overarching challenge and the proposed research.
- **Research Plan:** Provide a brief description of the studies proposed, including hypotheses, objectives, and scientific approach.
- **Impact:** Briefly describe the potential short-term and long-term impact of the results of the proposed research on one of the FY23 PRMRP Topic Areas and its related research field(s) and patient population(s).
- **Relevance to Military Health:** Explain how the effort is relevant to the health care needs of military Service Members, Veterans, and/or beneficiaries.
- **Attachment 4: Lay Abstract (no page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. **Do not include proprietary or confidential information. Do not duplicate the technical abstract.** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

***Lay abstracts must be provided for the overall program, as well as each individual project, with the abstract for each project starting on a separate page.*** Describe how the proposed research program addresses one of the FY23 PRMRP Topic Areas and one of the FY23 PRMRP Strategic Goals. Include a comprehensive overview of the effort that can be ***readily understood by readers without a background in science or medicine.*** Clearly describe the critical problem or question to be addressed and the ultimate applicability and impact of the research. ***Do not duplicate the technical abstract.***

- **Attachment 5: Statement of Work (no page limit): Upload as “SOW.pdf”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>.

For the FY23 PRMRP FPA, refer to either the “***Suggested SOW Strategy for Clinical Research and/or Clinical Trials***” or “***Suggested SOW Strategy Generic Research***”, whichever format is most appropriate for the proposed effort, and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

- Include the name(s) of the key personnel and contact information for each study site/subaward site.
  - Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
  - If applicable, indicate timelines required for regulatory approvals relevant to human subjects research such as IRB or IACUC, USAMRDC OHARO OHRO or ACURO, and IND and IDE applications by the FDA or other government agency.
- **Attachment 6: Impact Statement (five-page limit): Upload as “Impact.pdf”.**

An Impact Statement **must** be included for the overall program ***and for each individual project***, and should:

- Describe how the program or project addresses an FY23 PRMRP Topic Area and an FY23 PRMRP Strategic Goal. Explain how the proposed overall program or project will make important scientific advances, will promote greater understanding of the causes and progression of the relevant disease(s) or condition(s), and/or will promote the development of improvements in prevention, detection, diagnosis, treatment, or quality of life in the FY23 PRMRP Topic Area addressed. For projects with clinical



trials, explain how the sample population represents the targeted patient population that might benefit from the proposed intervention and how the outcome(s) will ultimately be translated to patients.

- ***Describe the short-term impact:*** Detail the anticipated outcome(s)/product(s) (knowledge and/or materiel) that will be directly attributed to the results of the proposed research and their impact(s) on the lives of relevant patient populations.
- ***Describe the long-term impact:*** Explain the anticipated long-term gains from this research. Compare to the information known/products currently available, if applicable. Explain the long-range vision for how the research will impact the field of study and/or patient care for relevant patient populations.
- **Attachment 7: Relevance to Military Health Statement (one-page limit): Upload as “MilRel.pdf”.**
  - Describe how the proposed effort is responsive to the health care needs of military Service Members, Veterans, and/or beneficiaries. Provide information about the incidence and/or prevalence of the disease or condition to be studied in the general population as well as in military Service Members, Veterans, and/or beneficiaries.
  - If active-duty military, military families, and/or Veteran population(s) or dataset(s) will be used in the proposed research project, describe the population(s)/dataset(s) and the appropriateness of the population(s)/dataset(s) for the proposed study. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., military Service Members, Veterans, and/or beneficiaries).
  - If applicable, show how the proposed research project aligns with DOD and/or VA areas of research interest and/or patient care. 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: Transition Plan and Regulatory Strategy (three-page limit): Upload as “Transition.pdf”.**

Provide information on the methods and strategies proposed to move the product or knowledge outcomes of the program to the next phases of development and/or clinical use following the successful completion of the proposed effort. Articulate this information for the overall effort as well as the individual projects. Applicants are encouraged to work with their organization’s Technology Transfer Office (or equivalent) to develop the transition plan. The transition plan should include the components listed below, as appropriate:

- A description of the outcomes expected upon completion of the proposed research efforts. Outcomes should be specific and measurable and should include the intended end user.

- Details of the funding strategy that will be used to bring the outcomes to the next phase of development and/or delivery to market or incorporation into patient care (e.g., specific potential industry partners, specific funding opportunities to be applied for).
  - For knowledge outcomes, a description of how the knowledge will be further developed, disseminated, and incorporated into clinical/patient care.
  - Details of the development plan and FDA regulatory strategy that will support the planned product indication, to include considerations for compliance with current GMP, GLP, and GCP guidelines (if applicable). Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy.
  - A description of collaborations and other resources that will be used to provide continuity of development.
  - A brief schedule and milestones for bringing the outcomes to the next phase of development (e.g., further research, clinical trials, transition to industry, delivery to the market, incorporation into clinical practice, approval by the FDA). Include a potential risk analysis for cost, schedule, manufacturability, and sustainability.
  - If applicable, ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government’s ability to access such products or technologies in the future.
- **Attachment 9: Data and Research Resources Sharing Plan (one-page limit): Upload as “Sharing.pdf”.**
    - Describe how data and resources generated during the performance of the proposed research projects will be shared with the research community. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the proposed projects. Specifically describe a plan to make animal models, tissue samples, and other resources developed as part of the proposed research projects available to the scientific community. If there are limitations associated with a pre-existing agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data and/or research resource sharing plan. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
    - In preparing requested budgets, applicants may include anticipated costs associated with data and research resource sharing (i.e., making a large dataset available to the public or developing an important resource for the scientific community).
  - **Attachment 10: IND/IDE Documentation: *Only applicable for applications that include a clinical trial(s)*. If submitting multiple documents, start each document on**

**a new page. Combine and upload as a single file named “IND-IDE.pdf”.** If more than one clinical trial is proposed, provide the below information for each trial/intervention. The IND/IDE Documentation Form located on the eBRAP website may not be used in place of this information.

- State the product/intervention name.

***For products/interventions that do not require regulation by the FDA or an international regulatory agency:***

- For investigator-sponsored regulatory exemptions (e.g., IND, IDE) provide evidence of institutional support. Provide evidence that the clinical trial does not require regulation by the FDA. If the clinical trial will be conducted at international sites, provide equivalent information relevant to the regulatory requirements of the host country(ies). No further information for this attachment is required.

***For products that require regulation by the FDA and/or an international regulatory agency:***

- State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the United States.
- If the product is marketed in the United States, state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).
- If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification. Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor’s understanding of all sponsor responsibilities and commitment to oversee execution of the study.
- ***If an IND or IDE is required, the application must be submitted to the FDA prior to the FY23 PRMRP FPA [application submission deadline](#) (this includes clinical trials requesting exception from informed consent under 21 CFR 50.24).*** The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed clinical trial. Provide the date of submission, the application number, and a copy of the FDA letter acknowledging the submission. If there are any existing cross-references in place, provide the application number(s) and associated sponsor(s). Provide an explanation of the status of the application (e.g., past the critical 30-day period, pending response to questions raised by the FDA, on clinical hold, on partial clinical hold). If the IND or IDE application has been placed on clinical hold or partial hold, explain the conditions that must be met for release of the hold. Provide a summary of

any previous meetings with the FDA on development of this product. A copy of the Agency meeting minutes should be included if available. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application.

- If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.
- If an active IND or IDE for the investigational product is in effect, but an amendment is needed to include the proposed trial, describe the type and nature of the amendment(s) and the timeline for submission. Indicate whether the amendment increases the risk of the intervention.
- If the clinical trial will be conducted at international sites, provide equivalent information and supporting documentation relevant to the product indication/label and regulatory approval and/or filings in the host country(ies).
- Provide the current status for manufacturing development (e.g., manufacturer’s name, GMP-compliant lots available, status of stability testing), non-clinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support phase I testing, etc.), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).
- Describe the overall regulatory strategy and product development plan that will support the planned product indication/label. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy. Include considerations for compliance with current GMP, GLP, and GCP guidelines.
- **Attachment 11: Public Health Service (PHS) Inclusion Enrollment Report, if applicable: Upload as “PHS.pdf”.** For each proposed research project containing a clinical trial, provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and/or ethnicity. *All project enrollment reports should be uploaded as a single combined file.*

Consistent with the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects,” and congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Describe the strategy for the inclusion of women and minorities in the clinical trial appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The PHS Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.

- **Attachment 12: Outcomes Statement (if applicable; one-page limit): Upload as “Outcomes.pdf”.** If applicable, list all the PI’s prior or in-progress PRMRP research projects/awards including resulting publications, abstracts, patents, or other tangible outcomes. Only research and outcomes directly relevant to this application should be listed. **Attachment 12 will be available for programmatic review only.**
- **Attachment 13: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- **Attachment 14: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using “Suggested Collaborating DOD Military Facility Budget Format”, available for download on the eBRAP “Funding Opportunities & Forms” web page <https://ebrap.org/eBRAP/public/Program.htm>, including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] et seq.), the DOD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

**Research & Related Personal Data:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

**Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- **PI Biographical Sketch (five-page limit): Upload as “Biosketch\_LastName.pdf”.** The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health (NIH) Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

- PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.
  - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
  - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch\_LastName.pdf”.
  - Include a biographical sketch for each Project Leader.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.
  - Include previous/current/pending support for each Project Leader.
  - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
  - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

**Research & Related Budget:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

**Budget Justification (no page limit): Upload as “BudgetJustification.pdf”.** The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

**Project/Performance Site Location(s) Form:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

**Research & Related Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are

present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

- **Intramural DOD Collaborator(s):** Complete the “Suggested Collaborating DOD Military Facility Budget Format” and upload to Grants.gov attachment form as [Attachment 14](#). (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

### **II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)**

The applicant organization must be registered as an entity in SAM (<https://www.sam.gov/SAM/>) and receive confirmation of an “Active” status before submitting an application through Grants.gov. *As of April 2022, all federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI generated through SAM.gov.* Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

### **II.D.4. Submission Dates and Times**

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

### **Applicant Verification of Full Application Submission in eBRAP**

***For Both Extramural and Intramural Applicants:*** eBRAP allows an organization’s representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in an email to the PI and in the “Full Application Files” tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

***Extramural Submission:*** The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the

application verification period, the full application package, *with the exception of the Project Narrative and Budget Form*, may be modified.

**Intramural DOD Submission:** After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, *with the exception of the Project Narrative and Budget Form*, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

**For All Submissions:** Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

#### **II.D.5. Funding Restrictions**

The maximum period of performance is **4** years.

The application's direct costs budgeted for the entire period of performance should not exceed **\$7.2M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate.

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

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Travel in support of multidisciplinary collaborations.
- Travel costs for the PI to disseminate project results at one DOD-supported meeting (e.g., the Military Health System Research Symposium).
- Costs for up to four investigators to travel to one scientific/technical meeting per year in addition to the optional meeting described above. The intent of travel costs to scientific/technical meetings is to disseminate project results from the FY23 PRMRP FPA.

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DOD or other federal agency is not allowed except under very limited circumstances. Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.



Refer to the General Application Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. *For federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.5.*

## **II.D.6. Other Submission Requirements**

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

## **II.E. Application Review Information**

### **II.E.1. Criteria**

#### **II.E.1.a. Peer Review**

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

- **Overall Impact**
  - To what extent the overarching challenge impacts a critical problem or question in the field of research and/or patient care in the FY23 PRMRP Topic Area addressed.
  - To what extent the overarching challenge addresses one of the FY23 PRMRP Strategic Goals.
  - To what degree the proposed program could make a significant impact on the lives of relevant patient populations in the short term or long term.
  - How well the research projects are described as distinct studies, not dependent upon each other but rather interrelated and synergistic, and advancing toward a solution through a multidisciplinary approach.
  - How well the research program will:
    - Make important scientific advances in the relevant field of research;
    - Promote greater understanding of the causes and progression of the relevant disease(s)/condition(s), or;
    - Promote the development of improvements in prevention, detection, diagnosis, treatment, or quality of life.

- **Implementation Plan**

- How well the proposed projects are supported by a detailed implementation plan that identifies critical milestones and explains how these milestones will be achieved.
- How well research resources and/or cores that will be created or leveraged will be utilized and shared.
- To what extent the plans to assess individual project performance during the course of the award are appropriate.
- How well the overall management plan will facilitate consistent and intensive interactions and communication by all team members.
- How the proposed plans for communication, data and specimen collection, data transfer, and periodic meetings are appropriate.
- To what extent the plans for creating, reviewing, implementing, and modifying Standard Operating Procedures are appropriate, if applicable.
- To what degree the scientific environment is appropriate for the proposed research.
- How well the research requirements are supported by the availability of and accessibility to facilities and resources (including patient populations, samples, and collaborative arrangements).
- To what degree the quality and extent of organizational support are appropriate for the proposed research.

- **Leadership**

- To what degree the PI is experienced in successfully leading large focused projects and is therefore well-positioned to lead the research team in achieving the overarching goal of the proposed effort.
- How well the PI demonstrates experience, leadership skills, and commitment to making an impact in the relevant field of research and/or patient care.
- Whether the PI will devote a minimum of 20% effort to this award.

- **Transition Plan and Regulatory Strategy**

- The degree to which the strategy proposed to bring the anticipated outcomes to the next phase of development and/or clinical use, including funding, milestones, and schedule, is realistic and achievable.
- Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.

- Whether the regulatory strategy and development plan are appropriate and well described.
- How well the application identifies intellectual property ownership and whether there is sufficient evidence of a plan to resolve intellectual and material property issues, if applicable.
- Whether the applicant has demonstrated they have access to all intellectual property rights necessary for development and commercialization, and evidence that the government has the ability to access such products or technologies, if applicable.
- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA and/or international equivalent.

***Scored Review Criteria for Individual Research Projects without a clinical trial:***

- **Impact**

- To what extent the individual project impacts the overarching challenge.
- To what degree the individual project could make a significant impact on the lives of relevant patient populations in the short term or long term.
- How well the individual project will make important scientific advances in the relevant field of research.

- **Research Strategy and Feasibility**

- How well the scientific rationale supports the research and its feasibility, as demonstrated by a critical review and analysis of the literature, the presentation of preliminary data (where applicable), and logical reasoning.
- How well the hypothesis, objectives, and aims are developed.
- To what degree the experimental design, methods, endpoints, and analyses support completion of the aims and are designed to achieve rigorous and reproducible results.
- How well the choice of model (animal, human subjects or samples, or other) is justified and whether it is appropriate.
- If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
- To what degree the statistical plan and power analysis, including sample size projections, are appropriate for the proposed project and will allow for a meaningful outcome.

- Whether there is sufficient evidence to support availability and accessibility of the populations, samples, or other resources required for the study, if applicable.
- How well potential problems are acknowledged and alternative approaches are addressed.
- **Personnel**
  - To what degree the project team's background and expertise are appropriate with respect to its ability to perform the proposed work, including whether there is evidence of sufficient expertise for all aspects of the work and whether there is evidence of strong commitment to the projects.
  - To what degree the levels of effort are appropriate for successful conduct of the proposed work.

***Scored Review Criteria for Individual Research Projects with clinical trials:***

- **Clinical Impact**
  - To what extent the individual project impacts the overarching challenge.
  - How well the individual project will make important scientific advances in the relevant field of research.
  - How well the sample population represents the targeted patient population that might benefit from the proposed intervention.
  - How the potential outcomes of the proposed clinical trial will provide/improve short-term benefits for individuals.
  - To what degree the long-term benefits for implementation of the intervention may impact patient care and/or quality of life.
- **Research Strategy and Feasibility**
  - How well the scientific rationale supports the research and its feasibility, as demonstrated by a critical review and analysis of the literature, the presentation of preliminary data (where applicable), and logical reasoning.
  - How well the hypothesis, objectives, and aims are developed.
  - To what degree the experimental design, methods, endpoints, and analyses support completion of the aims and are designed to achieve rigorous and reproducible results.
  - How well the choice of model (animal, human subjects or samples, or other) is justified and whether it is appropriate.
  - If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.

- To what degree the statistical plan and power analysis, including sample size projections, are appropriate for the proposed project, and will allow for a meaningful outcome.
- Whether there is sufficient evidence to support availability and accessibility of the populations, samples, or other resources required for the study, if applicable.
- How well potential problems are acknowledged and alternative approaches are addressed.
- **Intervention**
  - Whether there is evidence of support, indicating availability of the intervention from its source, for the duration of the proposed clinical trial (if applicable).
  - To what degree the intervention addresses the clinical need(s) described.
  - How the intervention compares with currently available interventions and/or standards of care.
  - To what degree the application includes preclinical and/or clinical evidence to support the safety and stability (as appropriate) of the intervention.
  - How well research procedures are clearly delineated from routine clinical procedures.
  - Whether measures are described to ensure the consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).
- **Regulatory Strategy and Transition Plan**
  - How the regulatory strategy and development plan to support the product indication or product label change, if applicable, are appropriate and well described.
  - How well the documentation provided supports the feasibility of acquiring an active IND or IDE (and/or international equivalent) covering the proposed trial, if applicable. Or, whether the application includes documentation that the study is exempt from FDA or other international agency regulation, or that the IND or IDE application (and/or international equivalent) has been deemed safe to proceed by the FDA and/or relevant international regulatory agency, as appropriate.
  - For investigator-sponsored regulatory exemptions (e.g., IND, IDE, or other international equivalent), whether there is evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the FDA or relevant international regulatory agency.
  - Whether plans to comply with GMP, GLP, and GCP guidelines are appropriate.
  - For knowledge products, whether the proposed collaborations and other resources are achievable to provide continuity of development.

- Whether the schedule and milestones for bringing the intervention to the next level of development (next-phase clinical trials, transition to industry, delivery to the market, incorporation into clinical practice, and/or approval by the FDA) are achievable.
- Whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
- **Recruitment, Accrual, and Feasibility**
  - How well the application addresses the availability of human subjects for the clinical trial and the prospect of their participation.
  - Whether the application demonstrates access to the proposed human subject population.
  - The degree to which the recruitment, informed consent, screening, and retention processes for human subjects will meet the needs of the proposed clinical trial.
  - How well the application identifies possible delays (e.g., slow accrual, attrition) and presents adequate mitigation plans to resolve them.
  - To what extent the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study.
  - Whether the strategy for the inclusion of women and minorities is appropriate to the objectives of the study.
  - Whether the distribution of the proposed enrollment on the basis of sex/gender, race, and/or ethnicity is appropriate for the proposed research.
- **Statistical Plan and Data Analysis**
  - To what degree the statistical model and data analysis plan are suitable for the planned study.
  - How the statistical plan, including sample size projections and power analysis, is adequate to meet the objectives of the study and all proposed correlative studies.
  - Whether the statistical plan compensates for the use of a subpopulation of a recruited sample population to ensure appropriate power can be achieved within the subpopulation study.
- **Ethical Considerations**
  - Whether the population selected to participate in the trial stands to benefit from the knowledge gained.
  - If applicable, how well the inclusion of international sites is justified.

- How the level of risk to human subjects is minimized and how the safety monitoring and reporting plan is appropriate for the level of risk.
- How well the evidence shows that the procedures are consistent with sound research design and, when appropriate, that these procedures are already in use for diagnostic or treatment purposes.
- To what degree privacy and confidentiality issues are appropriately considered.
- To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
- **Personnel**
  - To what degree the project team's background and expertise are appropriate with respect to its ability to perform the proposed work, including whether there is evidence of sufficient expertise for all aspects of the work and whether there is evidence of strong commitment to the project.
  - How well the project leader has assembled an appropriate and robust clinical team with the combined backgrounds and expertise needed to enable successful conduct of the clinical trial.
  - To what degree the levels of effort are appropriate for successful conduct of the proposed work.

In addition, the following **unscored criteria** will also contribute to the overall evaluation of the application:

- **Data and Resource Sharing**
  - To what degree the plan for sharing of project data and research resources is appropriate and reasonable to facilitate use by the wider research community.
- **Budget**
  - Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.
  - Whether the budget is appropriate for the proposed research.
- **Environment**
  - If applicable, to what degree the intellectual and material property plan is appropriate.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

### II.E.1.b. 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 mission of the DHP and FY23 PRMRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Relative impact
  - Relevance to the FY23 PRMRP Topic Areas
  - Relevance to the FY23 PRMRP Strategic Goals
  - Relevance to military health
  - Program portfolio composition
  - Relative outcomes from the PI's previous PRMRP-funded research (if applicable)

### II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section II.E.1.b, Programmatic Review](#).* Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.health.mil/about/2tierRevProcess>. An information paper describing the funding recommendations and review process for the award mechanisms for the FY23 PRMRP will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise



the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

### **II.E.3. Integrity and Performance Information**

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

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a federal awarding agency previously entered and is currently available in FAPIIS.

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.

### **II.E.4. Anticipated Announcement and Federal Award Dates**

All application review dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

## **II.F. Federal Award Administration Information**

### **II.F.1. Federal Award Notices**

Awards supported with FY23 funds are anticipated to be made no later than September 30, 2024. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from the USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

**Pre-Award Costs:** An institution of higher education, hospital, or non-profit 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. Refer to the General Application Instructions, Section III.A.5.

***Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds.*** 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.**

**Federal Government Organizations:** Funding made to federal government organizations (to include intramural DOD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

#### **II.F.1.a. PI Changes and Award Transfers**

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

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

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

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

#### **II.F.2. 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 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the latest [DoD R&D General Terms and Conditions](#) and the [USAMRAA General Research Terms and Conditions: Addendum to the DoD R&D General Terms and Conditions](#) for further information.

Certification Regarding Disclosure of Funding Sources. The proposing entity must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI, Partnering PIs (if applicable), and all key personnel:

- Certify that the current and pending support provided on the application is current, accurate, and complete;
- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and
- Have been made aware of the requirements under Section 223(a)(1) of this Act.

False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (18 USC 1001).

### **II.F.3. Reporting**

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Annual progress reports as well as a final progress report will be required.

If the application includes a clinical trial, quarterly reports will be required.

The Award Terms and Conditions will specify if more frequent reporting is required.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template “Award Expiration Transition Plan,” available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) under the “Progress Report Formats” section. The Award Expiration Transition Plan must outline whether and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

PHS Inclusion Enrollment Reporting Requirement (***only required for clinical research studies and clinical trials***): Enrollment reporting on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in 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 FAPIIS 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 5, Section B).

## **II.G. Federal Awarding Agency Contacts**

### **II.G.1. eBRAP Help Desk**

Questions related to program announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the eBRAP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET (closed on most U.S. federal holidays). Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

### **II.G.2. Grants.gov Contact Center**

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. federal holidays). Note that the eBRAP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726; International 1-606-545-5035

Email: [support@grants.gov](mailto:support@grants.gov)

Sign up on Grants.gov for “send me change notification emails” by following the link on the “Synopsis” page for the program announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

## **II.H. Other Information**

### **II.H.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 800a. The program announcement numeric version code will match the General Application Instructions version code 800.

### **II.H.2. Administrative Actions**

After receipt of applications, the following administrative actions may occur:

### **II.H.2.a. Rejection**

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

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

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

### **II.H.2.b. Modification**

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.

### **II.H.2.c. Withdrawal**

The following may result in administrative withdrawal of the pre-application or application:

- An FY23 PRMRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the FY23 PRMRP Programmatic Panel members can be found at <https://cdmrp.health.mil/prmrp/panels/panels23>.*
- 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.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY23, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.health.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.

- 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 may be withdrawn.
- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The invited application proposes a different research project than that described in the pre-application.
- The application fails to address one of the congressionally directed FY23 PRMRP Topic Areas.
- The application fails to address one of the FY23 PRMRP Strategic Goals.
- The PI and/or project leaders do not meet the eligibility criteria.
- The investigator is named as PI on more than one application submitted to the FY23 PRMRP FPA mechanism.

#### **II.H.2.d. 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.

### II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance ( <b>extramural submissions only</b> )	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) ( <b>intramural submissions only</b> )	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Relevance to Military Health Statement: Upload as Attachment 7 with file name "MilRel.pdf"	
	Transition Plan and Regulatory Strategy: Upload as Attachment 8 with file name "Transition.pdf"	
	Data and Research Resources Sharing Plan: Upload as Attachment 9 with file name "Sharing.pdf"	
	IND/IDE Documentation: Upload as Attachment 10 with file name "IND-IDE.pdf" if applicable	
	Public Health Service Inclusion Enrollment Report: Upload as Attachment 11 with file name "PHS.pdf" if applicable	
	Outcomes Statement: Upload as Attachment 12 with file name "Outcomes.pdf" if applicable	
	Representations (extramural submissions only): Upload as Attachment 13 with file name "RequiredReps.pdf"	

Application Components	Action	Completed
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 14 with file name “MFBudget.pdf” if applicable	
Research & Related Personal Data	Complete form as instructed	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field	
Research & Related Budget ( <b>extramural submissions only</b> )	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field	
Budget ( <b>intramural submissions only</b> )	Suggested DOD Military Budget Format, including justification	
Project/Performance Site Location(s) Form	Complete form as instructed	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed	



## APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHP	Defense Health Program
DOD	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
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FPA	Focused Program Award
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
OHARO	Office of Human and Animal Research Oversight
OHRO	Office of Human Research Oversight
ORCID	Open Researcher and Contributor ID, Inc.
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
PRMRP	Peer Reviewed Medical Research Program
SAM	System for Award Management

SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
URL	Uniform Resource Locator
UEI	Unique Entity Identifier
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code

## APPENDIX 2: DOD AND VA WEBSITES

PIs are encouraged to integrate and/or align their research projects with DOD and/or VA research laboratories and programs. Collaboration with DOD or VA investigators is also encouraged. Below is a list of websites that may be useful in identifying additional information about DOD and VA areas of research interest, ongoing research, or potential opportunities for collaboration within the FY23 PRMRP Topic Areas.

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

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

Armed Forces Radiobiology Research Institute  
<https://afri.usuhs.edu/home>

Combat Casualty Care Research Program  
<https://cccrp.health.mil/Pages/default.aspx>

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

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

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

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

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

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

Military Health System Research Symposium  
<https://mhsrs.amedd.army.mil/SitePages/Home.aspx>

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

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

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

Naval Health Research Center  
<https://www.med.navy.mil/Naval-Medical-Research-Center/Naval-Health-Research-Center/>

Navy and Marine Corps Public Health Center  
<https://www.med.navy.mil/Navy-Marine-Corps-Public-Health-Center/>

Naval Medical Research Center  
<https://www.med.navy.mil/Naval-Medical-Research-Center/>

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

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

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

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

U.S. Air Force 59<sup>th</sup> Medical Wing  
<https://www.59mdw.af.mil/>

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

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

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

U.S. Army Medical Materiel Development  
Activity  
<https://usamma.health.mil/>

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

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

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

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

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

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

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

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

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