

# **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**

**Lifestyle and Behavioral Health Interventions Research Award**

**Announcement Type: Initial**

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

**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 19, 2023
- **Application Submission Deadline:** 11:59 p.m. ET, May 31, 2023
- **End of Application Verification Period:** 5:00 p.m. ET, June 5, 2023
- **Peer Review:** August 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.”*

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

### **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 Lifestyle and Behavioral Health Interventions Research Award (LBIRA) supports clinical research and/or clinical trials using a combination of scientific disciplines including behavioral health, psychology, psychometrics, biostatistics and epidemiology, surveillance, and public health. Applications are required to address and provide a solution to

one of the congressionally directed FY23 PRMRP Topic Areas and FY23 PRMRP Strategic Goals.

The overall intent of the FY23 PRMRP LBIRA mechanism is to promote evidence-based and patient-centered approaches to improve health and/or disease-related outcomes and enhance the patient experience in defined populations. Research ideas may include, but are not limited to:

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

***The FY23 PRMRP LBIRA mechanism is meant to support clinical research or clinical trials for non-pharmacological interventions or non-invasive devices. Studies involving clinical trials for pharmacological interventions, clinical trials for devices that are implants or attached to the subject, or studies involving animal use are not appropriate for the LBIRA mechanism. If animal studies are proposed, the application may be withdrawn.***

***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. Principal Investigators (PIs) seeking funding for a clinical trial involving pharmacological interventions or devices should apply to the FY23 PRMRP Clinical Trial Award mechanism (Funding Opportunity Number HT9425-23-PRMRP-CTA).***

Funded trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219.

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

***For the purposes of this funding opportunity Regulatory Agency refers to the U.S. Food and Drug Administration or any relevant international regulatory agency, unless otherwise noted.***

***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.

***Key aspects of the FY23 PRMRP LBIRA:***

- **Impact:** The FY23 PRMRP LBIRA is intended to support impactful research that will transform patient outcomes within the context of the FY23 PRMRP Topic Areas and FY23 PRMRP Strategic Goals. Research should challenge paradigms with respect to potential impact on patient care or population health, minimizing disease risk, increasing patient quality-of-life, and improving clinical decision-making. Proposed projects may include translational or clinical research, including clinical trials. Impactful research will accelerate the movement of promising ideas into clinical applications, generate knowledge to improve clinical guidelines, or significantly advance behavioral, cognitive, and/or social functioning as related to the targeted patient population.
- **Study Design:** Applications should clearly articulate the chosen design of the study. The rationale should support the chosen study design with statistical evaluation to back the design. Studies entailing retrospective or prospective recruitment should define the type of architecture of the study (e.g., descriptive, correlational, field experimental, meta-analyses). Studies may integrate case, control, cohort, or other population science study designs (including the use of biospecimens and data from established databases and ongoing clinical trials), provided the proposed sample is of sufficient size to generate findings with ample statistical power. Study populations should be clearly defined. Questionnaires should be described in sufficient detail to justify interpretation of potential results. ***Clinical trials testing pharmacological interventions or devices or research involving animal studies are not considered appropriate for the FY23 PRMRP LBIRA mechanism.***
- **Preliminary Data:** The FY23 PRMRP LBIRA will require preliminary data for all studies that propose the active (prospective) recruitment of human subjects for clinical trials. Studies not proposing active recruitment of human subjects are not required to present preliminary data, but they should be supported by sound reasoning and relevant literature.
- **Patient Advocate Participation:** Applications to the FY23 PRMRP LBIRA funding opportunity are recommended to include patient advocates. The ideal research team will include at least one patient advocate who will be integral throughout the planning and

implementation of the research project. The patient advocate will be a person living with, or a family member or caretaker of someone with, a disease or condition addressed in one of the congressionally directed FY23 PRMRP Topic Areas. As a lay representative, the patient advocate should be active in an advocacy organization. The patient advocate should be involved in the development of the research question, project design, oversight, and evaluation, as well as other significant aspects of the proposed project. Interactions with other team members should be well integrated and ongoing, not limited to attending seminars and semi-annual meetings. The role of the patient advocate should be focused on providing objective input on the research and its potential impact for individuals with, or at risk for, a disease or condition addressed in one of the congressionally directed FY23 PRMRP Topic Areas.

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 Department of Defense (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 Lifestyle and Behavioral Health Interventions Research Award will not exceed \$3M. 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 \$22.5M to fund approximately five FY23 PRMRP Lifestyle and Behavioral Health Interventions Research 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, and beneficiaries is a key feature of this award. Investigators are

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

- Explanation of how the project addresses an aspect of the target disease/condition/technology that has direct relevance to the health of military Service Members, Veterans, and/or other Military Health System beneficiaries.
- Description of how the knowledge, information, products, or technologies gained from the proposed research could be implemented in a dual-use capacity to benefit the civilian population and also address a military need.
- Use of military or Veteran populations, samples, or datasets in the proposed research, if appropriate.
- Collaboration with DOD or Department of Veterans Affairs (VA) investigators or consultants.

Applicants are encouraged to integrate and/or align their research projects with DOD and/or VA research laboratories and programs. Collaboration with the DOD or VA is also encouraged. Potential for future development partnerships with the U.S. Army Medical Materiel Development Activity (<https://usamma.health.mil/>) may be available depending on the maturity and impact of the product on the military. 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 and FY23 PRMRP Strategic Goals can be found in [Appendix 2](#).

**Use of DOD or VA Resources:** If the proposed research involves access to active-duty military or 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.

## **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**

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

Each investigator may be named on only one FY23 PRMRP LBIRA pre-application or 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>).

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 applicants 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 (including the patient advocate, if applicable) 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**

**Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the PRMRP Portfolio, FY23 PRMRP Topic Area, and FY23 PRMRP Strategic Goal under which the application will be submitted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions. An invitation to submit is *not* required.

- **Tab 6 – Submit Pre-Application**

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

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

*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-LBIRA 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-LBIRA 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><br/>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><br/>An application may be submitted through Workspace by clicking the “Sign and Submit” 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</p>                           | <p><b>Submit package components to eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</b></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 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</i></b></p>   |

| Extramural Submissions  | Intramural DOD Submissions  |
|---|---|
| <p>to correct any potential technical issues that may disrupt the application submission.</p> <p><b>Note:</b> 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>Do not password protect any files of the application package, including the Project Narrative.</b></p> | <p><b><i>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 (15-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.

- **Background:** Describe how the proposed project addresses an FY23 PRMRP Topic Area. Additionally, describe how the proposed research project relates to an FY23 PRMRP Strategic Goal. Describe in detail the scientific rationale for the study. Provide a literature review and analysis. Describe the preliminary studies and/or preclinical data (if applicable) in support of the idea. Describe how the proposed research may have a major impact on patient outcomes. Articulate how the study will assess the relationship(s) between behavioral health and outcomes related to the disease or condition addressed. State the area of lifestyle or behavioral health science to be studied (e.g., basic behavioral, quality of life, decision making and/or cognitive function, educational interventions, symptom management).

If a clinical trial is proposed, include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications (as applicable). If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical

- trial and declare the source of prior funding. Specifically identify the portions of the study that will be supported with funds from this award.
- **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.
  - **Research Strategy and Feasibility:** Describe the study design, methods, and analyses in sufficient detail for evaluation including availability of resources (if applicable). Studies entailing retrospective or prospective recruitment should define the type of study (e.g., descriptive, correlational, field experimental, meta-analyses). Study populations should be defined. Address potential problem areas and potential pitfalls, and present alternative methods and approaches. If using psychometric measures, describe their reliability and validity. If use of a biorepository, patient medical files, or meta-analysis is proposed, describe the data to be collected and the process or methodology to collect the samples (i.e., for biorepositories – the standardization of procedures for collection). If human subjects or human anatomical samples will be used, include a plan for the recruitment of subjects or the acquisition of samples and document the experience of the PI and/or key collaborators in recruiting human subjects for similar projects. Basic studies should demonstrate the research strategy, feasibility, and how the study relates to the human experience with the disease or condition addressed.
  - **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. If applicable, specify the approximate number of human subjects to be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

If applicable, describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects.

- **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.
- **Letter of Patient Advocate Commitment (if applicable):** Provide a letter from the patient advocate confirming their commitment to the research project.
- **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 and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. 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.
- **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 and Lay Abstracts (two-page limit): Upload as “Abs.pdf”.** The technical and lay abstracts are 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.

**Technical Abstract (one-page limit):** Programmatic reviewers typically do not have access to the full application and rely on the technical abstract for appropriate description of the project’s key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

- **Background:** Present the ideas and rationale on which the proposed work is based.
- **Relevance to Topic Area:** State the relevance of the project to one of the FY23 PRMRP Topic Areas. Additionally, describe how the proposed research project addresses one of the FY23 PRMRP Strategic Goals.
- **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design, including appropriate controls.
- **Impact:** Briefly describe how the proposed project will have an impact on research and patient care in the specified disease(s)/condition(s).
- **Relevance to Military Health:** Describe the study’s relevance to the health care needs of military Service Members, Veterans, and/or beneficiaries.

**Lay Abstract (one-page limit):** Lay abstracts should be written using the outline below. *Do not duplicate the technical abstract.*

- Clearly describe the objectives and rationale for the proposed study in a manner readily understood by readers without a background in science or medicine.
- Explain if the proposed research expands on or is a new idea generated from the prior work, and how the outcomes from the original funded research relate to this proposed research effort.
- State the FY23 PRMRP Topic Area addressed by the proposed research project. Additionally, describe how the proposed research project addresses one of the FY23 PRMRP Strategic Goals.
- Describe the ultimate applicability and impact of the research.
  - What types of patients will it help, and how will it help them?
  - What are the potential clinical applications and benefits?
- **Attachment 4: Statement of Work (SOW) (three-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 LBIRA mechanism, refer to either the “*Suggested SOW Strategy for Clinical Research and/or Clinical Trials*” document for guidance on preparing the SOW 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 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 of research subjects 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.
- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

- **Attachment 5: Impact and Relevance to Military Health Statement (three-page limit): Upload as “Impact.pdf”.**
  - Describe how the proposed study will address an FY23 PRMRP Topic Area and an FY23 PRMRP Strategic Goal. Identify the volunteer population(s) that will participate in the proposed lifestyle or behavioral intervention, describe how they represent the target population that would benefit from the intervention, and describe the potential impact and anticipated outcomes of the proposed study on the lives and health of the target population with regard to the FY23 PRMRP Topic Area addressed.
  - Describe how the proposed research project will make important scientific advances in the relevant field of research, patient care or population health, quality of life, or clinical decision making.
  - ***Describe the short-term impact:*** Detail the anticipated outcomes that will be directly attributed to the results of the proposed study and how they will provide/improve short-term benefits for individuals.
  - ***Describe the long-term impact:*** Explain the long-range vision for implementation of the intervention in the clinic or field, and describe the anticipated long-term benefits for the targeted population, including impacts on patient care and/or quality of life.
  - Describe any relevant controversies or treatment issues that will be addressed by the proposed study.
  - Describe any potential issues that might limit the impact of the proposed study.
  - Describe how the lifestyle or behavioral intervention compares with currently available interventions and/or standards of care.
  - Describe how the proposed study is responsive to the health care needs of military Service Members, Veterans, and/or beneficiaries. Provide information about the incidence and/or prevalence of the disease or condition in the general population as well as in military Service Members, Veterans, and/or beneficiaries.
  - If active-duty military, military families, and/or Veteran population(s) or datasets will be used in the proposed research project, describe the population(s)/dataset(s) and the appropriateness of the population(s)/dataset(s) for the proposed study. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., military Service Members, Veterans, and/or beneficiaries).
  - If applicable, show how the proposed research project aligns with DOD and/or VA areas of research interests. Provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to benefit the civilian population and address a military need, as appropriate.

- **Attachment 6: Clinical Trial Strategy (if applicable; no page limit): Upload as “Clinical.pdf”.** *If funds for a clinical trial are requested, this attachment is required.*
  - Describe the rationale for the proposed clinical trial. Demonstrate how the proposed clinical trial is supported by strong preliminary data and relevant literature citations.
  - Provide a description of the intervention and the endpoints to be measured.
  - Articulate the type of clinical trial to be performed (e.g., randomized, cohort, case-control, cross-sectional) and outline the proposed methodology in sufficient detail to show a clear course of action. Provide detailed plans for initiating the clinical study within the first year.
  - Define the study population and indicate the access to the study population, recruitment plans, and inclusion/exclusion criteria, including a justification for the plans and alternatives strategies if issues arise. Describe potential challenges and alternative strategies where appropriate.
  - Describe how the clinical trial will inform the correlative clinical research, if applicable.
  - **Regulatory Considerations (if applicable):** For investigator-sponsored regulatory exemptions (e.g., IND, IDE) provide evidence of institutional support. Provide evidence that the clinical trial does not require an IND/IDE. *If an IND/IDE is required for the proposed intervention, apply to the Clinical Trial Award mechanism (Funding Opportunity Number HT9425-23-PRMRP-CTA).* If the clinical trial will be conducted at international sites, provide equivalent information relevant to the host country(ies) regulatory requirements.
- **Attachment 7: Study Population (no page limit): Upload as “StudyPop.pdf”.** The Study Population attachment should include the components listed below.
  - **Study Population (required for all applications):** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn; required for all applications). Provide a table of anticipated enrollment counts at each study site (if applicable). Demonstrate that the research team has access to the proposed study population at each site, and describe the efforts that will be made to achieve accrual goals. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous studies (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention (if applicable). Identify ongoing studies that may compete for the same patient population and how they may impact enrollment progress (if applicable). Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender (if applicable). *For studies proposing to include military personnel, refer to the General Application Instructions, Appendix 1, for more information.*

- **Inclusion/Exclusion Criteria (if applicable):** List the inclusion and exclusion criteria for the proposed study. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.
  
- **Women and Minorities in the Study (if applicable):** 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 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 Public Health Service (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>.
  
- **Description of the Recruitment Process (if applicable):** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care provider identification).
  - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
  - If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan.
  - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.
  
- **Description of the Informed Consent Process (if applicable):** Specifically describe the plan for obtaining informed consent from human subjects.
  - *For the proposed study, provide a draft, in English, of the Informed Consent Form.*
  - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects’ questions will be addressed during the consent process and throughout the trial.
  - Include information regarding the timing and location of the consent process.
  - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such

as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.

- Address how privacy and time for decision-making will be provided and whether the potential human subject will be allowed to discuss the study with anyone before making a decision.
  - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
  - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. *Note:* In compliance with 10 USC 980 (<https://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf>), the application must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial. If applicable, refer to the General Application Instructions, Appendix 1, for more information.
  - *Assent:* If minors or other populations that cannot provide informed consent are included in the proposed study, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.
- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. *Note:* Some screening procedures may require a separate consent or a two-stage consent process.
  - **Risks/Benefits Assessment:**
    - **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Study risks include any risks that the human subject is exposed to as a result of participation in the study. Consider psychological, legal, social, and economic risks as well as physical risks. Consider how the proposed study might affect the daily lives of the individual human subjects participating in the study. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.

- **Risk management and emergency response:**
  - ❖ Appropriate to the study’s level of risk, describe how safety monitoring and reporting to the IRB and Regulatory Agency (if applicable) will be managed and conducted.
  - ❖ Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
  - ❖ Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the cost of such care.
  - ❖ Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).
  - ❖ Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
- **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.
- **Attachment 8: Data Management (no page limit): Upload as “Data\_Manage.pdf”.** The Data Management attachment should include the components listed below.
  - **Data Management:** Describe the data to be gathered and all methods used for collection, including the following:
    - **Data:** The types of data, software, or other materials to be produced.
    - **Acquisition and processing:** How the data will be acquired, including the time and location of data acquisition, if scientifically pertinent. If use of existing data resources is proposed, describe the origin of the dataset. Provide an account of the standards to be used for data and metadata format and content. Explain how the data will be processed.
    - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.

- **Confidentiality**
  - ❖ Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
  - ❖ Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of the DOD are eligible to review study records.
  - ❖ Address requirements for reporting sensitive information to state or local authorities.
  
- **Data capture, verification, and disposition:** Describe how data will be captured and verified, including the quality assurance and quality control measures taken during collection, analysis, and processing. Describe where data (both electronic and hard copy) will be stored; who will keep the data; how the data will be stored, if applicable; the file formats and the naming conventions that will be used; the process for locking the database at study completion; and the length of time that data will be stored, along with a justification for the time frame of preservation, which may include considerations related to the balance between the relative value of data preservation and other factors such as the associated cost and administrative burden of data storage. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. Describe the database lock process. For studies requiring Regulatory Agency oversight, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) is required.
  
- **Data reporting:** Describe how data will be reported.
  
- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether the results of screening and/or study participation will be shared with human subjects or their primary care provider, including results from any screening or diagnostic tests performed as part of the study. In cases of national security or controlled unclassified information concerns, include a statement that the data cannot be made available to the public (e.g., “This data cannot be cleared for public release in accordance with the requirements in DoD Directive 5230.09.”).
  
- **Laboratory Evaluations**
  - **Specimens to be collected, schedule, and amount:** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.

- **Evaluations to be made:** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
  - **Storage:** Describe specimen storage, including location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the plan to store specimens for future use, including considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.
  - **Labs performing evaluations and special precautions:** Identify the laboratory performing each evaluation, the applicable quality standard, and any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.
- **Attachment 9: Patient Advocate Involvement Statement (if applicable): Upload as “Advocate.pdf”.** The Patient Advocate Involvement Statement should be written by the PI. Provide the name of at least one patient advocate and their relationship with one of the FY23 PRMRP Topic Areas. Describe the integral role that the patient advocate will play in the planning, design, implementation, and evaluation of the research project. Describe how the patient advocate’s knowledge of current health issues in one of the FY23 PRMRP Topic Areas and how their background will contribute to the research project.
  - **Attachment 10: Study Personnel and Organization (no page limit): Start each document on a new page. Combine into one document and upload as “Personnel.pdf”.** The Study Personnel and Organization attachment should include the components listed below.
    - **Organizational Chart:** Provide an organizational chart that identifies key members of the study team and provides an outline of the governing structure for multi-institutional studies. Identify collaborating organizations, centers, and/or departments and name each person’s position on the project. Include any separate laboratory or testing centers. Identify the data and clinical coordinating center(s) and note any involvement from Contract Research Organizations, as appropriate. Identify and provide justification for the inclusion of international sites, as appropriate. If applicable, identify the Regulatory Agency sponsor and any external consultants or other experts who will assist with Regulatory Agency sponsor applications. While there is no specified format for this information, a table(s) or diagram is recommended. *Note:* This item may be made available for programmatic review.
    - **Study Personnel Description:** Briefly describe the composition of the study team, including roles of the individuals listed in the organizational chart on the project. Study coordinator(s) should be included. Describe how the levels of effort for each individual are appropriate to successfully support the proposed research. Describe

- relevant background and qualifications that demonstrate appropriate expertise to accomplish the proposed work, including previous interactions with the relevant Regulatory Agency, if applicable.
- **Study Management Plan:** Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed study involves more than one institution, clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. Provide a regulatory submission plan for the master protocol and master consent form by the lead institution. If the research involves more than one institution, a single IRB is required for all institutions located in the United States. If applicable, describe how communication and data transfer between/among the collaborating institutions will occur, as well as how data, specimens, and/or imaging products obtained during the study will be handled and shared.
  - **Attachment 11: Questionnaires and Other Research Data Collection Instruments, if applicable (no page limit): Upload as “Data\_Collection.pdf”.** The Questionnaires and Other Research Data Collection Instruments attachment should include a copy of the most recent version of questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study. Describe how and when the instrument(s) will be administered. Describe how the instrument(s) will be adapted to the subject population, if applicable.
  - **Attachment 12: Transition Plan (three-page limit): Upload as “Transition.pdf”.** Describe/discuss the methods and strategies proposed to move the intervention to the next phase of development (clinical trials, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Applicants are encouraged to work with their organization’s Technology Transfer Office (or equivalent) to develop the transition plan. PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development. The post-award transition plan should include the components listed below.
    - Details of the funding strategy to transition the intervention to the next level of development and/or commercialization (e.g., specific industry partners, specific funding opportunities to be applied for). Include a description of collaborations and other resources that will be used to provide continuity of development.
    - For knowledge products, a description of collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. (A “knowledge product” is a non-materiel product that addresses an identified need, topic area, or capability gap; is based on current evidence and research; aims to transition into medical practice, training, or tools or to support materiel solutions [systems to develop, acquire,

- provide, and sustain medical solutions and capabilities]; and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.)
- A brief schedule and milestones for transitioning the intervention to the next level of development through a clinically meaningful outcome (e.g., next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by a Regulatory Agency).
  - Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government’s ability to access such products or technologies in the future.
  - A risk analysis for implementation of findings generated from the proposed research.
- **Attachment 13: Outcomes Statement (if applicable; one-page limit): Upload as “Outcomes.pdf”.** If applicable, list all of 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 13 will be available for programmatic review only.**
  - **Attachment 14: 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 15: 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 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”.
- Key Personnel 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.

**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 15](#). (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 **\$3.0M**. 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-sponsored meeting to be specified by the program office during award negotiations (e.g., the Military Health System Research Symposium)

- Travel costs for up to two 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 LBIRA.

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 listed in decreasing order of importance:

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

- **Impact**
  - To what extent the project impacts a critical problem or question in one of the FY23 PRMRP Topic Areas.
  - To what extent the proposed research project addresses one of the FY23 PRMRP Strategic Goals.
  - Whether the proposed research project will make important scientific advances in the relevant field of research, patient care or population health, quality of life, or clinical decision making.
  - To what degree the proposed project could make a significant impact on the lives of relevant patient populations in the short term and/or long term.

- **Research Strategy and Feasibility**

- How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, supporting data, and logical reasoning.
- How well the hypotheses, experimental design, and methods have been developed and how well they support completion of the aims.
- To what extent the data will be collected and analyzed in a manner consistent with the study aims.
- To what extent the power analysis demonstrates that the sample size is appropriate to test the hypothesis and allow a meaningful outcome.
- If applicable, the degree to which the plan to study patient populations is appropriate and feasible and whether the application provides evidence of availability of and access to the necessary study populations and/or resources.
- If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
- How well potential problems are identified and alternative methods or approaches are addressed.
- How well the study population or data set is described and whether it is appropriate to address the study objectives.
- How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.
- Whether the research can be completed within the proposed period of performance.

- **Transition Plan**

- Whether the identified next level of development and/or commercialization is realistic.
- Whether the follow-on funding strategy described to bring the findings from this award to the next level of development is reasonable and achievable (e.g., specific industry partners, specific funding opportunities to be applied for).
- For knowledge products, whether the proposed collaborations and other resources for providing continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications are established and/or achievable.
- Whether the schedule and milestones for bringing the intervention to the next level of development through to achieving a clinically meaningful outcome (next-phase clinical

trials, transition to industry, delivery to the market, and/or incorporation into standard practice) are achievable.

- Whether the potential risk analysis for implementation of findings generated from the proposed research is realistic and reasonable.
- How well the application identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent government access to products supported by this program announcement.

- **Personnel**

- Whether the background and expertise of the PI and other key personnel demonstrate their ability to perform the proposed work.
- Whether the levels of effort by the PI and other key personnel are appropriate to ensure the successful conduct of the project.
- How the PI's record of accomplishment demonstrates their ability to accomplish the proposed work.
- If applicable, to what extent the patient advocate will play an integral role in the planning, design, implementation, and evaluation of the research.
- If applicable, whether the patient advocate's knowledge of issues in one of the FY23 PRMRP Topic Areas and their background will contribute to the project.

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

- **Clinical Impact**

- How impactful the anticipated outcomes of the proposed clinical trial would be to the target population with regard to the FY23 PRMRP Topic Area and FY23 PRMRP Strategic Goal addressed.
- How well the sample population represents the targeted patient population that might benefit from the proposed intervention.
- How the anticipated outcomes of the proposed clinical trial will provide/improve short-term benefits for individuals.
- How significantly the long-term benefits for implementation of the behavioral or lifestyle intervention may impact patient care and/or quality of life.

- If applicable, to what extent the patient advocate will play an integral role in the planning, design, implementation, and evaluation of the research.
- If applicable, whether the patient advocate’s knowledge of issues in one of the FY23 PRMRP Topic Areas and their background will contribute to the project.
- **Research Strategy and Feasibility**
  - How well the scientific rationale for clinically testing the behavioral or lifestyle intervention is supported by the preliminary data, critical review and analysis of the literature, and/or laboratory/preclinical evidence.
  - How well the study aims, hypotheses and/or objective(s), experimental design, methods, data collection procedures, and analyses are designed to answer clearly the clinical objective.
  - How well the inclusion and randomization criteria meet the needs of the proposed clinical trial.
  - How well the exclusion criteria are justified.
  - How well plans to collect specimens and conduct laboratory evaluations are addressed, if applicable.
  - To what degree the data collection instruments (e.g., surveys, questionnaires), if applicable, are appropriate to the proposed study.
  - To what extent the data will be collected and analyzed in a manner consistent with the study aims.
  - Whether the research can be completed within the proposed period of performance.
- **Clinical Trial Strategy**
  - Whether the preliminary data and literature citations support the rationale for the proposed clinical trial.
  - To what degree the intervention and endpoints to be measured are described.
  - To what degree the proposed methodology shows a clear course of action and supports the initiation of the clinical study within the first year.
  - How well the study population is described, including recruitment plans and inclusion/exclusion criteria.
  - How well potential challenges and alternative strategies are described.
  - To what degree the clinical trial will inform correlative clinical research, if applicable.

- **Statistical Plan**
  - 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 for the study and all proposed correlative studies.
  - If applicable, whether the statistical plan compensates for the use of a subpopulation of a recruited sample population to ensure appropriate power can be achieved within the subpopulation study.
- **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 subjects 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 contingency 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 (e.g., will human subjects still be able to take their regular medications while participating in the clinical trial? Are human subjects required to stay overnight in a hospital?).
  - 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.
- **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 well the level of risk to human subjects is minimized and whether the safety monitoring and reporting plan is appropriate for the level of risk.
  - How well the evidence shows that the procedures are consistent with sound research design and, when appropriate, that these procedures are already in use for diagnostic or treatment purposes.

- To what degree privacy and confidentiality issues are appropriately considered.
- To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
- **Transition Plan and Regulatory Considerations**
  - For investigator-sponsored regulatory exemptions (e.g., IND, IDE), whether there is evidence of appropriate institutional support, including capabilities to ensure monitoring.
  - Whether the identified next level of development and/or commercialization is practical.
  - Whether the funding strategy described to transition the intervention to the next level of development (e.g., specific industry partners, specific funding opportunities to be applied for) is reasonable and achievable.
  - For knowledge products, whether the proposed collaborations and other resources for providing continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications are established and/or achievable.
  - Whether the schedule and milestones for transitioning the intervention to the next level of development through to a clinically meaningful outcome (next-phase clinical trials, transition to industry, delivery to the market, and/or incorporation into clinical practice) are achievable.
  - If applicable, whether the potential risk analysis for implementation is realistic and reasonable.
  - How well the application identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent government access to products supported by this program announcement.
- **Personnel and Communication**
  - Whether the composition of the study team (e.g., study coordinator, statistician) is appropriate.
  - To what degree the study team's background and expertise are appropriate to accomplish the proposed work (e.g., statistical expertise, expertise in the disease, and expertise in conducting clinical trials).
  - Whether the levels of effort of the study team members are appropriate for successful conduct of the proposed trial.

- How well the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, standardization of procedures) meet the needs of the proposed clinical trial.
- For multi-site clinical trials, how well the lead site responsibilities and human research protections regulatory coordination are defined and planned for.

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

- **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, whether appropriate resources or support are available at each participating center or institution.

- **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 Defense Health Program and FY23 PRMRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Relative impact
  - Relevance to military health
  - Relevance to the FY22 PRMRP Topic Areas
  - Relevance to the FY22 PRMRP Strategic Goals

- 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**

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

Unless otherwise restricted, changes in PI will be allowed at the discretion of the Grants Officer, provided the intent of the award mechanism is met.

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

Refer to the General Application Instructions, Appendix 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.

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

***For applications including a proposed clinical trial:***

- Quarterly technical progress reports may be 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 application:

- Pre-application was not submitted.
- 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 Project Narrative.
- Documents not requested will be removed.

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

The following may result in administrative withdrawal of the 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 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 does not meet the eligibility criteria.
- The investigator is named as PI on more than one application submitted to the FY23 PRMRP LBIRA mechanism. Only the first application received per funding level will be accepted; additional applications will be administratively withdrawn.

- The proposed project includes animal research.
- The proposed intervention requires an IND/IDE or includes a pharmacological intervention or invasive device.
- Study Population ([Attachment 7](#)) is missing.
- Data Management ([Attachment 8](#)) is missing.

#### **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 and Lay Abstracts: Upload as Attachment 3 with file name "Abs.pdf"  |           |
|  | Statement of Work: Upload as Attachment 4 with file name "SOW.pdf"  |           |
|  | Impact and Relevance to Military Health Statement: Upload as Attachment 5 with file name "Impact.pdf"                       |           |
|  | Clinical Trial Strategy: Upload as Attachment 6 with file name "Clinical.pdf" if applicable                                 |           |
|  | Study Population: Upload as Attachment 7 with file name "StudyPop.pdf"  |           |
|  | Data Management: Upload as Attachment 8 with file name "Data_Manage.pdf"  |           |
|  | Patient Advocate Involvement Statement: Upload as Attachment 9 with the file name "Advocate.pdf"                            |           |
|  | Study Personnel and Organization: Upload as Attachment 10 with file name "Personnel.pdf"                                    |           |
|  | Questionnaires and Other Research Data Collection Instruments: Upload as Attachment 11 with file name "Data_Collection.pdf" |           |
|  | Transition Plan: Upload as Attachment 12 with file name "Transition.pdf"  |           |
|  | Outcomes Statement: Upload as Attachment 13 with file name "Outcomes.pdf"   |           |
| Representations (extramural submissions only): Upload as Attachment 14 with file name "RequiredReps.pdf" |   |           |

| Application Components   | Action   | Completed |
|--|--|-----------|
|  | Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 15 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 (extramural submissions only)              | Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field                           |           |
| Budget (intramural submissions only)                                 | 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   |
| 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  |
| FY       | Fiscal Year   |
| GCP      | Good Clinical Practice  |
| GLP      | Good Laboratory Practice  |
| GMP      | Good Manufacturing Practice   |
| ICH E6   | International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use |
| IDE      | Investigational Device Exemption  |
| IND      | Investigational New Drug  |
| IRB      | Institutional Review Board  |
| LAR      | Legally Authorized Representative   |
| LBIRA    | Lifestyle and Behavioral Health Interventions Research Award  |
| LOI      | Letter of Intent  |
| M        | Million   |
| MB       | Megabytes   |
| MIPR     | Military Interdepartmental Purchase Request   |
| OHARO    | Office of Human and Animal Research Oversight (previously Office of Research Protections)                             |
| OHRO     | Office of Human Research Oversight (previously Human Research Protection Office)                                      |
| 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                                   |
| VA      | Department of Veterans Affairs                       |

## 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/>