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

Technology/Therapeutic Development Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-22-PRMRP-TTDA

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 29, 2022
- **Application Submission Deadline:** 11:59 p.m. ET, May 27, 2022
- **End of Application Verification Period:** 5:00 p.m. ET, June 2, 2022
- **Peer Review:** August 2022
- **Programmatic Review:** December 2022

This program announcement must be read in conjunction with the General Application Instructions, version 701. 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 2022 (FY22) 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 2358 (10 USC 2358). 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 FY21 totaled $3.08 billion. The FY22 appropriation is $370 million (M).

The vision of the FY22 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 military health care. The PRMRP challenges the scientific and clinical communities to address the FY22 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. FY22 PRMRP Topic Areas and Strategic Goals

All applications for FY22 PRMRP funding must specifically address one of the FY22 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 FY22 PRMRP Strategic Goals as it relates to the portfolio-assigned FY22 PRMRP Topic Area.*** If the proposed research does not specifically address one FY22 PRMRP Topic Area and one FY22 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 FY22 PRMRP Topic Areas and Strategic Goals are listed in each PRMRP portfolio category below:

FY22 PRMRP Portfolio Categories with Associated FY22 PRMRP Topic Areas and FY22 PRMRP Strategic Goals

Autoimmune Disorders and Immunology

Topic Areas

- Food Allergies
- Guillain-Barré Syndrome
- Inflammatory Bowel Disease
- Rheumatoid Arthritis
- Sustained Release Drug Delivery

Strategic Goals

Foundational Studies

- Identify factors, to include environmental exposures, lifestyle triggers, and past medical history, impacting the onset and progression of associated immune-mediated diseases
- Determine the impact of the microbiome on associated immune-mediated diseases

Diagnosis

- Develop innovative noninvasive methods for continuous monitoring of inflammation
- Identify biomarkers to predict onset and/or progression 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 and/or allergic disease state

Epidemiology

- Conduct patient-centered research on onset, exacerbation, outcomes, and treatment preferences for associated immune-mediated diseases

Cardiovascular Health

Topic Areas

- Cardiomyopathy
- Congenital Heart Disease
- Familial Hypercholesterolemia
- Hypercholesterolemia
- Hypertension
- Vascular Malformations
- Women's Heart Disease
- Sustained Release Drug Delivery

Strategic Goals

Prevention

- Predict and prevent potential impact of extreme environments, posttraumatic stress disorder, and/or infections on cardiovascular health
- 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 an affordable genetic testing panel for accurate early detection of associated cardiovascular conditions

- 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 or ethnic/racial differences
- Develop less-invasive treatment technologies for associated cardiovascular conditions
- Advance engineered tissue technology for the treatment of associated cardiovascular conditions

Epidemiology
- Identify risk factors that contribute to associated cardiovascular conditions in civilian and/or military populations, particularly those who have sustained combat injuries
- Conduct population-based or outcomes-based research to identify sex/gender or ethnic/racial long-term impacts of associated cardiovascular conditions

Hemorrhage Control and Blood Products

Topic Areas
- Hemorrhage Control
- Pathogen-Inactivated Blood Products
- Platelet-Like Cell Production
- Sustained Release Drug Delivery
- Trauma

Strategic Goals

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

Treatment
- Develop smart/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 test novel or engineered blood products that add physiological, logistical, and cost advantages over current products

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
- Sustained Release Drug Delivery
- Viral Diseases

- Plant-Based Vaccines

Strategic Goals

Foundational Studies

- Improve understanding of long-term complications of infections (e.g., long COVID [coronavirus disease], myalgic encephalomyelitis/chronic fatigue syndrome [ME/CFS], sequelae from combat wounds)

Prevention

- Develop or optimize vaccine strategies, platforms, or compounds, to include active or passive immunoprophylaxis, especially for Dengue, Lassa, and Crimean-Congo Hemorrhagic fever viruses, and beta-coronaviruses

Diagnosis

- Develop diagnostics for early/pre-symptomatic detection of viral diseases, such as novel host-based biomarkers or other predictors of early/pre-symptomatic infection
- Develop strategies for rapid prediction of protective antigens/epitopes
- Identify testable correlates of protection, especially for Dengue, Lassa, and Crimean-Congo Hemorrhagic Fever viruses

Treatment

- Establish new, and expand upon current, clinical networks for therapeutic drug testing to prevent transmission, resistance, or severe/chronic disease

Epidemiology

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

Internal Medicine

Topic Areas

- Ehlers-Danlos Syndrome
- Endometriosis
- Epidermolysis Bullosa
- Focal Segmental Glomerulosclerosis
- Interstitial Cystitis
- Nephrotic Syndrome
- Pancreatitis
- Polycystic Kidney Disease
- Pressure Ulcers
- Sustained Release Drug Delivery

Strategic Goals

Foundational Studies

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

Diagnosis

- Develop tools for early and accurate diagnosis, including non-invasive methods for associated diseases and conditions
- Develop technologies for tracking progression 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 non-surgical treatment options or optimize surgical techniques that improve fertility and reduce endometriosis symptoms/progression
- Develop and test therapeutics or dressings that enhance wound healing
- Advance engineered tissue technology to improve wound healing and transplant outcomes
- Develop and test novel treatments, and/or improve upon existing treatments for associated diseases and conditions

Epidemiology
- Elucidate factors (e.g., medication toxicity, genetic predisposition, infections) that influence development, progression, and outcome 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
- Dystonia
- Eating Disorders
- Fragile X
- Friedreich's Ataxia
- Frontotemporal Degeneration
- Hydrocephalus
- Myalgic Encephalomyelitis/Chronic Fatigue Syndrome
- Myotonic Dystrophy
- Non-Opioid Therapy for Pain Management
- Peripheral Neuropathy
- Rett Syndrome
- Sleep Disorders and Restriction
- Suicide Prevention
- Sustained Release Drug Delivery
- Trauma

Strategic Goals

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

Prevention
- Develop strategies, including predictive analytics and artificial intelligence, to provide early identification of associated neurological diseases and psychological conditions, with the goal of providing early intervention
- Develop tools to reduce complications of physical and/or psychological trauma

Diagnosis
- Improve diagnostic and/or develop objective diagnostic criteria (e.g., diagnostic biomarkers) for ME/CFS

Treatment

- Develop and evaluate novel treatments, strategies or therapeutic targets, including research to repurpose existing drugs, for associated neurological diseases and psychological conditions
- 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
- Develop and test treatment strategies to manage symptoms and improve quality of life for those affected by associated neurological and psychological conditions

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

Nutrition and Metabolism

Topic Areas

- Diabetes
- Mitochondrial Disease
- Nutrition Optimization
- Sustained Release Drug Delivery

Strategic Goals

Foundational Studies

- Understand correlations between nutrition and disease susceptibility (e.g., infectious, autoimmune, neurological, metabolic, cardiac)
- Develop and test novel nutrition-based approaches for recovery from injury/illness or to enhance performance in operational environments, extreme climates, or resource-limited settings

Prevention

- Develop evidence-based diet and exercise recommendations to decrease obesity, improve nutrition, and optimize energy balance to prevent metabolic diseases

Diagnosis

- Develop improved diagnostics for metabolic diseases
- Develop tools, devices, and/or strategies to monitor and optimize real-time nutritional intake at the individual level

Treatment

- Develop and test strategies to decrease the burden of treatment regimens, including improved insulin formulations or delivery methods, or smart/automated glucose-monitoring or implantable biosensor systems
- Develop and test novel treatment strategies for mitochondrial diseases, especially those ready to progress to the clinic, including repurposing existing drugs or non-prescription treatment options
- Treat obesity and develop strategies for weight management, especially for Veterans

Orthopaedic Medicine

Topic Areas

- Arthritis
- Fibrous Dysplasia
- Musculoskeletal Disorders (related to acute and chronic bone conditions and injuries)
- Sustained Release Drug Delivery

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 strategies for improved care at point of injury to prevent musculoskeletal disorder onset

Diagnosis

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

Treatment

- Develop and test novel and improved intra-articular treatments for joint injuries
- Develop and test strategies to increase quality of life or halt/slow disease progression, including regenerative medicine approaches and biologics for associated musculoskeletal disorders

Epidemiology

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

Respiratory Health

Topic Areas

- Pulmonary Fibrosis
- Respiratory Health
- Sustained Release Drug Delivery
- 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
- Develop novel delivery mechanisms and/or improved pharmaceuticals to prevent/treat high-altitude pulmonary edema (HAPE)

II.B. Award Information

The PRMRP Technology/Therapeutic Development Award (TTDA) is a product-driven award mechanism intended to provide support for the translation of promising preclinical findings into products for clinical applications, including prevention, detection, diagnosis, treatment, or quality of life, for a disease or condition related to one of the FY22 PRMRP Topic Areas and one of the FY22 PRMRP Strategic Goals. Products in development should be responsive to the healthcare needs of military Service Members, Veterans, and/or beneficiaries. ***This award mechanism may not be used to conduct clinical trials; however, non-interventional clinical research studies are allowed.***

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 placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. Interventions may be medical, surgical, pharmacological, or behavioral and outcomes may be biomedical or behavioral, measured through the collection of demographic, anthropometric, clinical, biochemical, molecular, or other data from the participants. ***Principal Investigators (PIs) seeking funding for a clinical trial should apply to the FY22 PRMRP Clinical Trial Award mechanism*** **(Funding Opportunity Number W81XWH-22-PRMRP-CTA).**

The product(s) to be developed under the PRMRP TTDA mechanism may be a tangible item such as a pharmacologic agent (drugs or biologics) or device, or a knowledge-based product. (A "knowledge product" is a non-materiel product that addresses an identified need in a topic area, is based on current evidence and research, aims to transition into medical practice, training, tools, or to support 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.) The Principal Investigator (PI) must provide a transition plan (including potential funding and resources, see Attachment 8, Transition Plan and Regulatory Strategy) showing how the product will progress to the next level of development (e.g., clinical trials, delivery to the military or civilian market) after the completion

of the PRMRP award. PIs are encouraged to develop relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development.

Proof of concept demonstrating the potential utility of the proposed product, or a prototype/ preliminary version of the proposed product, should already be established. ***Applications must include relevant data that support the rationale for the proposed study.*** These data may be unpublished and/or from the published literature. Investigators seeking to identify a product or demonstrate initial proof of concept should consider submitting to the FY22 PRMRP Investigator-Initiated Research Award (Funding Opportunity Number W81XWH-22-PRMRP-IIRA) or the FY22 PRMRP Discovery Award (Funding Opportunity Number W81XWH-22-PRMRP-DA), as appropriate.

Research proposed under this award mechanism may be at different stages of idea and research development. Two different funding levels, based on the scope of the research, are available under this program announcement. The applicant must select the funding level that is most appropriate for the research proposed.

- **Funding Level 1:** Research that is supported by significant preliminary data but has not advanced to the level of clinical translation. Anticipated direct costs of Funding Level 1 will not exceed **$2M**. Examples of the types of research that may be supported include, but are not limited to:
    - Collection and analysis of data for developing clinical guidance/guidelines for standard of care
    - Testing new therapeutic modalities (agents, delivery systems, and chemical modification of lead compounds) using established or validated preclinical systems
    - Designing pilot or full-scale Good Manufacturing Practice (GMP) production of therapeutics and/or delivery systems for use in advanced preclinical and initial clinical trials
    - Developing pharmacologic agents through absorption, distribution, metabolism, excretion, and toxicity studies
- **Funding Level 2:** Research that is in the final states of preclinical development with potential for near-term clinical development. Applications must provide relevant data that support the rationale for the proposed study. Funding Level 2 recipients must submit or obtain an Investigational New Drug/Investigational Device Exemption (IND/IDE) application to the U.S. Food and Drug Administration (FDA), or must transition the product to clinical practice, within the period of performance. Applications not meeting the requirements of Funding Level 2 will be reassigned to Funding Level 1. Anticipated direct costs of Funding Level 2 will not exceed **$4M**. Examples of the types of research that may be supported include, but are not limited to:

- Validating clinical guidance/guidelines for standard of care
- Confirming efficacy and/or safety of therapeutic modalities (agents, delivery systems, and chemical modification of lead compounds) using established or validated preclinical systems
- Implementing full-scale GMP production of therapeutics and/or delivery systems for use in advanced preclinical and initial clinical trials
- Validating pharmacologic agents through absorption, distribution, metabolism, excretion, and toxicity studies
- Developing pharmacologic agents to IND stage for initiation of phase 1 clinical trials
- Developing prototype devices to IDE stage or abbreviated IDE stage for initiation of clinical trials
- Optimizing diagnostic or treatment devices for field deployment

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 FY22 PRMRP Technology/Therapeutic Development Award will not exceed **$2M** for Funding Level 1 awards. The anticipate direct costs budgeted for the entire period of performance for an FY22 PRMRP Technology/Therapeutic Development Award will not exceed **$4M** for Funding Level 2 awards . Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards will be made no later than September 30, 2023. For additional information refer to Section II.F.1, Federal Award Notices.

The CDMRP expects to allot approximately $78M to fund approximately 20 FY22 PRMRP Technology/Therapeutic Development 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 FY22 funding opportunity will be funded with FY22 funds, which will expire for use on September 30, 2028.

Relevance to Military Health: Relevance to the healthcare needs of military Service Members, Veterans, military beneficiaries, and/or the American public is a key feature of this award. Investigators are encouraged to consider the following characteristics as examples of how a project may demonstrate relevance to military health:

- Explanation of how the project addresses an aspect of the target disease/condition/technology that has direct relevance or is unique to the health of military Service Members, Veterans, or beneficiaries
- Explanation of how the project addresses an aspect of the target disease/condition/technology that has relevance or is unique to the military or family readiness of Service Members
- Description of how the knowledge, information, products, or technologies gained from the proposed research could be implemented in a dual-use capacity to benefit the civilian population and also address a military need
- Use of military or Veteran populations or datasets in the proposed research, if appropriate to the proposed research project

Applicants are encouraged to integrate and/or align their research projects with DOD and/or Department of Veterans Affairs (VA) research laboratories and programs. Collaboration with DOD or VA investigators is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration within the FY22 PRMRP Topic Areas can be found in Appendix 2.

Use of DOD or VA Resources: If the proposed research involves access to active-duty military 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 Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Research Protections (ORP), Human Research Protection Office (HRPO), 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 submission is ***not*** required. Allow up to 3 months to complete the HRPO regulatory review and approval process following submission of ***all required and complete*** documents to the HRPO. Refer to the General Application Instructions, Appendix 1, and the Human Research Protections Office Resources and Overview document available on the

electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

If the proposed research involves more than one 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.

Research Involving Animals: All research funded by the FY22 PRMRP TTDA involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is ***not*** required. ***Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

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

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

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

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

II.C.1.b. Principal Investigator

PIs 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 FY22 PRMRP TTDA 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

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 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 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 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 FY22 PRMRP Portfolio addressed by the proposed research.

  Select the FY22 PRMRP Topic Area addressed by the proposed research.

  Select the FY22 PRMRP Continuum of Care category addressed by the proposed research.

  Select the FY22 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 associated with the application.

FY22 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 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, FY22 PRMRP Topic Area, and FY22 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
Application Package Location	
Download application package components for W81XWH-22-PRMRP-TTDA from Grants.gov (https://grants.gov) 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.	Download application package components for W81XWH-22-PRMRP-TTDA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel • Budget • Performance Sites **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.**	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application

Extramural Submissions	Intramural DOD Submissions
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 **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission. ***Note:*** 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 ***prior to*** the application submission deadline. ***Do not password protect any files of the application package, including the Project Narrative.***	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. ***Do not password protect any files of the application package, including the Project Narrative.***
Application Verification Period	
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 ***with the exception of the Project Narrative and Research & Related Budget Form***.	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 ***with the exception of the Project Narrative and Research & Related Budget Form***. 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.
Further Information	
Tracking a Grants.gov Workspace Package. 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.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

Extramural Submissions	Intramural DOD Submissions
Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	

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 (18-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information 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 the product to be developed. Present the scientific rationale behind the proposed work. Cite relevant literature. Describe previous experience most pertinent to the project. Include relevant preliminary data and/or promising preclinical findings that demonstrate proof of concept of the product or a prototype/preliminary version of the product; these data may be unpublished or from the published literature.

- **Hypothesis/Objective:** State the hypothesis to be tested and/or the objective(s) to be reached. State which FY22 PRMRP Topic Area the proposed research addresses. Additionally, describe how the proposed research project addresses one of the FY22 PRMRP Strategic Goals.

- **Specific Aims:** Concisely explain the project's specific aims. These aims should agree with the primary aims and associated tasks described in the Statement of Work (SOW). If the proposed work is part of a larger study, present only aims that this DOD award would fund.

- **Research Strategy and Feasibility:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Provide a well-developed, well-integrated research strategy that supports the translational feasibility and promise of the approach. Define the specific study outcomes and how they will be measured. Address potential problem areas and present alternative methods and approaches. Describe how data will be collected and handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, and identification of primary endpoints/ outcomes. Clearly describe the statistical plan and the rationale for the statistical methodology. Provide a sample size estimate and the method by which it was derived, including power analysis calculation, if applicable. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, or international regulatory agency, if applicable.

- If animal studies are proposed, briefly describe the key elements of the study/studies as they relate to the overall project. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology. Describe the randomization and blinding procedures for the study and any other measures to be taken to minimize effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.

- If human subjects or human biological samples will be used, describe the study population and include a detailed plan for the recruitment of human subjects or the acquisition of samples (refer to Attachment 9, Public Health Service (PHS) Inclusion Enrollment Report, for additional details). Describe the availability of the proposed study population and past successes in recruiting similar populations. If active-duty military, military families, and/or Veteran population(s) or datasets will be used in the proposed research project, describe the feasibility of accessing the population(s)/dataset(s). ***This award may not be used to conduct clinical trials.***

- Describe how the research project will be completed within the proposed period of performance.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. 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 or not 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 that demonstrates that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- **Intellectual Property:** Information can be found in the Code of Federal Regulations, Title 2, Part 200.315 (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 Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***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.

  Programmatic reviewers typically do not have access to the full application and therefore 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. Describe the proposed research project, including the following elements:

  State the PRMRP Portfolio, FY22 PRMRP Topic Area, and FY22 PRMRP Strategic Goal addressed by the proposed research project. Clearly describe the proposed research, including the rationale, the overall goal, the hypothesis to be tested, innovative aspects of the research, the study design, the expected results, long-term and short-term impacts to the relevant research field and patient care, and how the results will be used as a foundation for future research projects.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information***. ***Do not duplicate the***

technical abstract. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Describe how the proposed research project addresses one of the FY22 PRMRP Topic Areas and one of the FY22 PRMRP Strategic Goals. Include a comprehensive overview of the proposed research project that can be ***readily understood by readers without a background in science or medicine.*** Clearly describe the critical problem or question to be addressed and the ultimate applicability and impact of the research. ***Do not duplicate the technical abstract***.

- **Attachment 5: Statement of Work (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 FY22 PRMRP TTDA mechanism, refer to the "***Suggested SOW Strategy Generic Research***" 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 outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

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

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".**

  Explain why the proposed research project is important and relevant to developing improvements in prevention, detection, diagnosis, treatment, or quality of life in the FY22 PRMRP Topic Area addressed. Describe how the project addresses one of the FY22 PRMRP Strategic Goals. Additionally, describe how the study will address a critical problem or question in the relevant Topic Area.

- ***Describe the short-term impact:*** Detail the anticipated outcome/product (knowledge and/or materiel) that will be directly attributed to the results of the proposed research.

- ***Describe the long-term impact:*** Explain the anticipated long-term gains from this research. Compare to the information known/products currently available, if applicable. Explain the long-range vision for how the research will impact the field of study and/or patient care.

- **Attachment 7: Relevance to Military Health Statement (one-page limit): Upload as "MilRel.pdf".**

  Describe how the proposed study is responsive to the healthcare 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 the planned use of the product is to support the Warfighter, explain how the product meets the needs and requirements for use in the deployed setting.

  If active-duty military, military families, and/or Veteran population(s) or 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 interest. Provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to benefit the civilian population and address a military need, as appropriate.

- **Attachment 8: Transition Plan and Regulatory Strategy (three-page limit): Upload as "Transition.pdf".**

  Describe the methods and strategies proposed to move the product or knowledge outcomes to the next phase of development (e.g., clinical trials, partnership with DOD advanced developers, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Outline the regulatory strategy. 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, DOD advanced developers, 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.

  - The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication (e.g., Target Product Profile). Describe in detail the FDA regulatory strategy, including the number and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings to be held, the submission filing strategy, and considerations for compliance

with GMP, Good Laboratory Practice, and Good Clinical Practice guidelines, if appropriate.

- Details of the funding strategy to transition the product(s) to the next level of development and/or commercialization (e.g., specific potential 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 detailed schedule and milestones for transitioning the product to the next phase of development through to achieving a clinically meaningful outcome (e.g., next-phase clinical trials, transition to industry, delivery to the civilian and/or military market, incorporation into clinical practice, and/or approval by the FDA).

- Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government's ability to access such products or technologies in the future.

- A risk analysis for cost, schedule, manufacturability, and sustainability.

- **Attachment 9: Public Health Service Inclusion (PHS) Enrollment Report, if applicable (non-interventional clinical research studies only): Upload as "PHS.pdf".** Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and/or ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this requirement.

  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 PHS Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

- **Attachment 10: 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 11: 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 11. (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 published in the Federal Register, July 10, 2019,

(https://www.federalregister.gov/documents/2019/07/10/2019-14665/unique-entity-id-standard-for-awards-management), the UEI for awards management generated through SAM will be used instead of the Data Universal Numbering System (DUNS) number as of April 2022. ***All federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI.*** USAMRDC will transition to use of the UEI beginning with FY22 announcements and utilize the latest SF424, which includes the UEI. The DUNS will no longer be accepted. Applicant organizations will not go to a third-party website to obtain an identifier. During the transition, your SAM registration will automatically be assigned a new UEI displayed in SAM. (For more information, visit the General Services Administration: https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/iae-information-kit/unique-entity-identifier-update.) Current SAM.gov registrants are assigned their UEI and can view it within SAM.gov. ***Authorized Organizational Representatives with existing eBRAP accounts should update their organizational profile to include the UEI prior to submission of the full application to Grant.gov (see below).*** 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 requested funding level should be based on the scope of the research proposed. The government reserves the right to fund an application at a lower funding level.

Funding Level 1: The anticipated direct costs budgeted for the entire period of performance will not exceed **$2M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the government exceeding **$2M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

Funding Level 2: The anticipated direct costs budgeted for the entire period of performance will not exceed **$4M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the government exceeding **$4M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

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

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

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

- Travel in support of multidisciplinary collaborations.
- Travel costs for the PI to disseminate project results at one DOD-supported meeting (e.g., the Military Health System Research Symposium).

- Costs for up to three investigators to travel to one scientific/technical meeting per year in addition to the meeting described above. The intent of travel costs to scientific/technical meetings is to disseminate project results from the FY22 PRMRP TTDA.

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:

- **Impact**
    - To what extent the proposed research project impacts a critical problem or an important scientific question relevant to one of the FY22 PRMRP Topic Areas.
    - To what extent the proposed research project addresses one of the FY22 PRMRP Strategic Goals.
    - How the proposed research project, if successful, will make important scientific advances in the relevant field of research.
    - 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, promising preclinical findings, sound scientific rationale, and demonstrated proof of concept.

- How well the hypotheses, experimental design, and methods have been developed and how well they support completion of the aims.
- The degree to which the expected outcomes are specific and measurable.
- To what extent the data will be collected and analyzed in a manner consistent with the study aims.
- 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 the study (or studies) is designed to achieve the objectives, including the choice of model, if applicable, and the endpoints/outcome measures to be used.
- How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.
- How well potential problems are identified and alternative approaches are addressed.
- Whether the research can be completed within the proposed period of performance.

- **Transition Plan and Regulatory Strategy**
  - To what extent the anticipated outcomes will support the translation of promising preclinical findings into a product for clinical application.
  - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
  - Whether the identified next level of development and/or plans for commercialization is realistic.
  - Whether the funding strategy described to bring the product to the next level of development (e.g., specific potential industry partners, specific funding opportunities to be applied for) is reasonable and realistic.
  - Whether the regulatory strategy and the development plan to support the proposed product label, if applicable, are appropriate and well described.
  - If applicable, whether the proposed collaborations and other resources for providing continuity of development of knowledge products, including proposed development or modification of clinical practice guidelines and recommendations, provider training

materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications are established and/or achievable.

- Whether the schedule and milestones for bringing the anticipated product to the next phase of development through to achieving a clinically meaningful outcome (clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice, or approval by the FDA) are achievable. Whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.

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

In addition, the following **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, to what degree the intellectual and material property plan is appropriate.
  - How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - How the quality and extent of organizational support are appropriate for the proposed research.
  - How the scientific environment is appropriate for the proposed research.
- **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 FY22 PRMRP, as evidenced by the following:
    - Adherence to the intent of the award mechanism
    - Relative impact
    - Relevance to the FY22 PRMRP Topic Areas
    - Relevance to the FY22 PRMRP Strategic Goals
    - Relevance to military health
    - Program portfolio composition

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.army.mil/about/2tierRevProcess. An information paper describing the funding recommendations and review process for the award mechanisms for the FY22 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 FY22funds are anticipated to be made no later than September 30, 2023. 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

Unless otherwise restricted, changes in PI or organization will be allowed at the discretion of the USAMRAA 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; the USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions; and the USAMRAA General Research Terms and Conditions with For-Profit Organizations, for further information.

New Requirement: 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 (218 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 more frequent reporting is required.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template "Award Expiration Transition Plan," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline if 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 non-interventional clinical research studies)***: 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. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: 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

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 701b. The program announcement numeric version code will match the General Application Instructions version code 701.

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 FY22 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 FY22 PRMRP Programmatic Panel members can be found at https://cdmrp.army.mil/prmrp/panels/panels22***.
- 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 FY22, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.army.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 FY22 PRMRP Topic Areas.
- The application fails to address one of the FY22 PRMRP Strategic Goals.
- The investigator is named as PI on more than one application submitted to the FY22 PRMRP TTDA mechanism.
- A clinical trial is proposed.

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 **(extramural submissions only)**	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) **(intramural submissions only)**	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Relevance to Military Health Statement: Upload as Attachment 7 with file name "MilRel.pdf"	
	Transition Plan and Regulatory Strategy: Upload as Attachment 8 with file name "Transition.pdf"	
	Public Health Service Inclusion Enrollment Report Format: Upload as Attachment 9 with file name "PHS.pdf" if applicable	
	Representations (extramural submissions only): Upload as Attachment 10 with file name "RequiredReps.pdf"	
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 11 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	

Application Components	Action	Completed
	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
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S Food and Drug Administration
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MB	Megabytes
ME/CFS	Myalgic Encephalomyelitis/Chronic Fatigue Syndrome
MIPR	Military Interdepartmental Purchase Request
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
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
TTDA	Technology/Therapeutic Development Award

UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	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 FY22 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://afrri.usuhs.edu/home

Combat Casualty Care Research Program
https://ccc.amedd.army.mil/Pages/default.aspx

Congressionally Directed Medical Research Programs
https://cdmrp.army.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.amedd.army.mil/

Military Operational Medicine Research Program
https://momrp.amedd.army.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 59th Medical Wing
https://www.59mdw.af.mil/

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

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

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

U.S. Army Medical Materiel Development Activity
https://www.usammda.army.mil/

U.S. Army Medical Research and Development Command
https://mrdc.amedd.army.mil/

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

U.S. Army Research Institute of Environmental Medicine
https://www.usariem.army.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.amedd.army.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://www.wrair.army.mil