

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

Investigator-Initiated Research Award

Announcement Type: Initial

Funding Opportunity Number: HT942524PRMRPIIRA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern time (ET), May 6, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, May 23, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, May 29, 2024
- **Peer Review:** July 2024
- **Programmatic Review:** September 2024

This program announcement must be read in conjunction with the General Application Instructions, version 900. 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

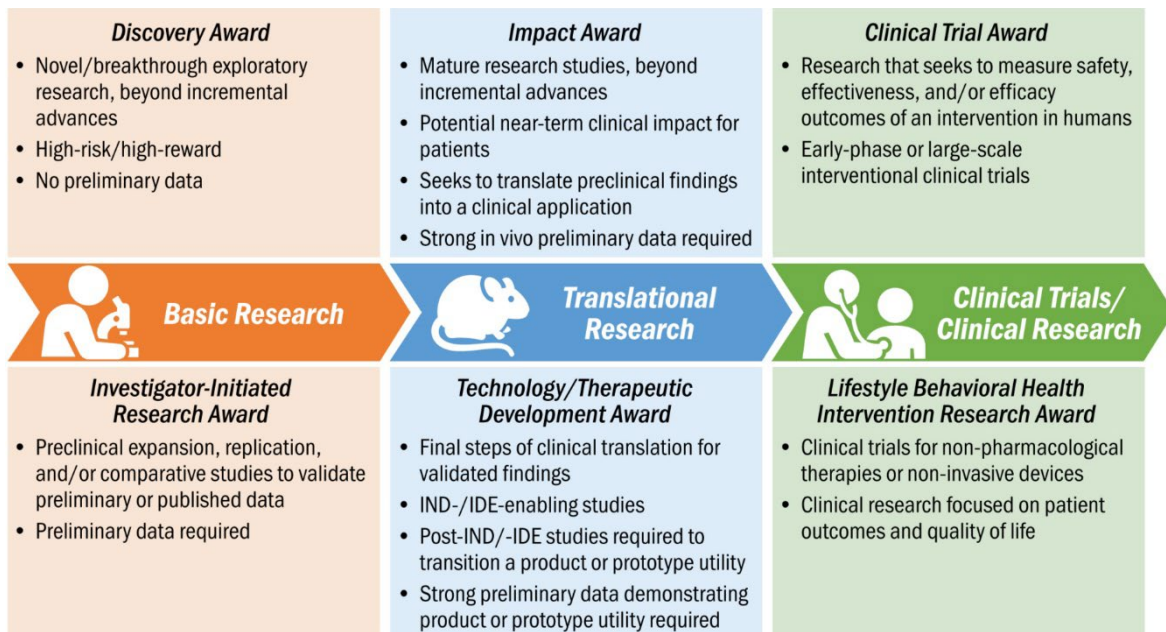
II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Peer Reviewed Medical Research Program (PRMRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the PRMRP in 1999 to support medical research projects of clear scientific merit and direct relevance to military health. Appropriations for the PRMRP from FY99 through FY23 totaled \$3.82 billion (B). The FY24 appropriation is \$370 million (M).

The vision of the PRMRP is to improve the health, care, and well-being of all military Service Members, Veterans, and their Families, and its mission is to encourage, identify, select, and manage medical research projects of clear scientific merit that lead to impactful advances in health care of Service Members, Veterans, and their Families. The PRMRP challenges the scientific and clinical communities to address the congressionally mandated FY24 PRMRP Topic Areas with original ideas that foster new directions along the entire spectrum of research and patient care.

II.A.1. FY24 PRMRP Research Development Pipeline

To address the congressionally mandated FY24 PRMRP Topic Areas in a bench-to-bedside fashion, the FY24 PRMRP award mechanisms are aligned to different phases of the research development pipeline illustrated below.



The **Basic Research** phase represents novel, exploratory research aimed at generating preliminary data and/or preclinical research that is ready for validation through expansion, replication, or comparative studies. Applicants seeking support for research aligning to the Basic Research phase may consider:

- FY24 PRMRP Discovery Award (HT942524PRMRPDA) for novel, high-risk, high-reward research projects with the potential to yield high-impact findings and new avenues of investigation
- FY24 PRMRP Investigator-Initiated Research Award (HT942524PRMRPIIRA) for preclinical research ready for validation

The **Translational Research** phase seeks to transition scientific outcomes toward diagnostic, treatment, and/or preventive strategies. Research projects are expected to have significant near-term impact on patients' lives. Examples of projects in the Translational Research phase include clinical translation of concepts previously validated through expansion, replication, or comparative studies and product/device development. Applicants seeking support for research aligning to the Translational Research phase may consider:

- FY24 PRMRP Impact Award (HT942524PRMRPIPA) for mature research products that have moved beyond the realm of basic laboratory research and demonstrate potential for near-term clinical impact
- FY24 PRMRP Technology/Therapeutic Development Award (HT942524PRMRPTTDA) for development of tangible products (drugs or biologics), knowledge-based products, and/or devices

The **Clinical Trials/Clinical Research** phase represents small- and large-scale confirmatory trials and/or applied clinical research that will revolutionize the clinical management of the diseases and conditions included in the congressionally mandated Topic Areas. Applicants seeking support for trials and studies aligned to the Clinical Trials/Clinical Research phase may consider:

- FY24 PRMRP Clinical Trial Award (HT942524PRMRPCTA) for projects focused on safety, effectiveness, and/or efficacy outcomes of pharmacological interventions, devices, and implants attached to the subject
- FY24 PRMRP Lifestyle and Behavioral Health Interventions Research Award (HT942524PRMRPLBIRA) for clinical trials and clinical research focused on effectiveness and/or outcomes of nonpharmacological interventions or noninvasive devices

NOTE: The scope of research proposed in applications in response to the FY24 PRMRP program announcements must align with the research phases outlined above. It is the responsibility of the applicant to select the award mechanism that aligns with the scope of the proposed research. The funding mechanism should be selected based on the research scope defined in the program announcement, and not on the amount of the budget. Applications

submitted under a mechanism that is not deemed appropriate for the scope of research proposed will not be funded.

II.A.2. FY24 PRMRP Topic Areas and Strategic Goals

To meet the intent of the funding opportunity, ***all applications for FY24 PRMRP funding must specifically address one of the FY24 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 FY24 PRMRP Strategic Goals as it relates to the portfolio-assigned FY24 PRMRP Topic Area.*** If the proposed research does not specifically address one FY24 PRMRP Topic Area and one FY24 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 FY24 PRMRP Topic Areas and Strategic Goals are listed in each PRMRP portfolio category below.

FY24 PRMRP Portfolio Categories with Associated FY24 PRMRP Topic Areas and FY24 PRMRP Strategic Goals

AUTOIMMUNE DISORDERS AND IMMUNOLOGY

All applications under this portfolio must be aligned to Autoimmune Disorders and Immunology by addressing one Topic Area and one Strategic Goal listed below:

TOPIC AREAS

- Celiac Disease
- Computational Biology for Precision Health
- Food Allergies
- Guillain-Barré Syndrome
- Inflammatory Bowel Disease
- Proteomics
- Scleroderma

STRATEGIC GOALS

Foundational Studies

- Identify triggers and/or risk factors impacting onset and progression of disease (e.g., environmental exposures, psychosocial stressors, climate change, lifestyle preferences, genetic risk factors, dietary practices, past medical history, sex and/or gender).
- Determine associations between the microbiome and gut-mediated inflammation.
- Develop preclinical models that recapitulate the phenotype of human disease.

Prevention

- Develop and test strategies to prevent the onset and/or progression of disease.

Diagnosis

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

Treatment

- Develop and test therapeutic and/or lifestyle interventions to reduce inflammation and inflammatory responses, improve or delay symptom onset, reduce the negative consequences of disease sequelae and/or promote tissue healing.
- Develop and test new treatments and/or refine existing treatment strategies to minimize toxicity and mitigate inflammatory, immune and/or allergic disease states.

Epidemiology

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

CARDIOVASCULAR HEALTH

All applications under this portfolio must be aligned to Cardiovascular Health by addressing one Topic Area and one Strategic Goal listed below:

TOPIC AREAS

- Computational Biology for Precision Health
- Congenital Heart Disease
- Proteomics
- Vascular Malformations

STRATEGIC GOALS

Prevention

- Develop and test strategies to prevent or reduce the impact of the disease/condition on the heart, brain, arteries, and additional target organs across an individual's life span.
- Develop strategies to understand and prevent disease onset based on sex, gender, ethnic and/or racial differences.

Diagnosis

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

Treatment

- Develop and evaluate novel therapeutics or advance treatment regimens, especially those that address sex, gender, ethnic and/or racial differences.

Epidemiology

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

INFECTIOUS DISEASES

All applications under this portfolio must be aligned to Infectious Diseases by addressing one Topic Area and one Strategic Goal listed below:

TOPIC AREAS

- Computational Biology for Precision Health
- Congenital Cytomegalovirus
- Far-UVC Germicidal Light
- Hepatitis B
- Malaria
- Proteomics

STRATEGIC GOALS

Foundational Studies

- Elucidate long-term complications following infections, including comorbidities.

Prevention

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

Diagnosis

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

Treatment

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

Epidemiology

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

INTERNAL MEDICINE

All applications under this portfolio must be aligned to Internal Medicine by addressing one Topic Area and one Strategic Goal listed below:

TOPIC AREAS

- | | |
|--|-----------------------------|
| • Accelerated Aging Processes Associated with Military Service | • Lymphedema |
| • Computational Biology for Precision Health | • Nephrotic Syndrome |
| • Focal Segmental Glomerulosclerosis | • Pancreatitis |
| • Interstitial Cystitis | • Polycystic Kidney Disease |
| | • Proteomics |

STRATEGIC GOALS

Foundational Studies

- Improve understanding of molecular underpinnings, progression, comorbidities and long-term complications of the disease/condition.
- Develop improved research tools to translate preclinical findings to more efficacious treatment regimens and enable new drug discovery.
- Conduct multi-organ research to better understand the effect of the disease/condition on the whole body.

Prevention

- Develop and test strategies to prevent the disease/condition.

Diagnosis

- Develop and test tools or technologies for early detection, accurate diagnosis, or tracking of disease progression, including analytical tools, noninvasive methods and/or screening tools.
- Develop tools to reduce time between presentation of symptoms and required specialized care for management of disease/condition.
- Conduct biomarker and genetic studies to better understand and differentiate subtypes, heterogeneity, and progression of disease/condition.

Treatment

- Develop and test novel treatments and/or improve upon existing treatments (including repurposing existing drugs), which may include lifestyle interventions (e.g., diet and physical activity) to improve psychosocial functioning and quality of life, especially those that account for sex, gender, ethnic and/or racial differences.
- Develop and test combination therapy and/or intervention treatment approaches to slow the progression of the disease/condition and/or address long-term pain management (includes drugs, lifestyle changes, devices, and surgical interventions).
- Advance the development of artificial organs, including xenobiology research.

Epidemiology

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

NEUROSCIENCE

All applications under this portfolio must be aligned to Neuroscience by addressing one Topic Area and one Strategic Goal listed below:

TOPIC AREAS

- | | |
|--|-------------------------|
| • Computational Biology for Precision Health | • Neuroactive Steroids |
| • Eating Disorders | • Peripheral Neuropathy |
| • Maternal Mental Health | • Proteomics |
| • Myalgic Encephalomyelitis/
Chronic Fatigue Syndrome | • Suicide Prevention |

STRATEGIC GOALS

Foundational Studies

- Identify mechanisms underlying the disease/condition including sex and/or gender, potential relationships to environmental or neurotoxic exposures, injury, stress, or infection.
- Integrate data using computational methods to improve understanding of and/or assess the treatment of the disease/condition.

Prevention

- Develop and test the efficacy of methods (e.g., screening, education programs, counseling) to prevent the disease/condition and/or comorbidities.

Diagnosis

- Improve and validate diagnostics for neurological health, psychological health and/or cognitive assessment, which may include developing and testing personalized clinical decision-making tools or developing objective diagnostic criteria.
- Develop and test strategies, such as predictive analytics, to provide early diagnosis and/or monitoring.
- Develop and test strategies to identify and prioritize at-risk individuals who would benefit from screening and/or diagnostic testing.

Treatment

- Develop and evaluate novel pharmacological or nonpharmacological treatments, strategies, or therapeutic targets, which may include repurposing of existing drugs.
- Develop and test targeted treatment strategies that address sex/gender differences for diseases/conditions that disproportionately affect women.

Epidemiology

- Conduct population-based studies to identify risk factors (e.g., genetic, behavioral, lifestyle, psychosocial, sex and/or gender) that contribute to disease/condition onset and progression.
- Population-based studies to understand how implementing treatment and preventative strategies within a community impacts patient outcomes.
- Identify barriers to treatment access and develop strategies to mitigate these barriers.
- Conduct population-based studies to identify prevalence, medical service usage, and/or quality of life for those affected by the disease/condition.

ORTHOPAEDIC MEDICINE

All applications under this portfolio must be aligned to Orthopaedic Medicine by addressing one Topic Area and one Strategic Goal listed below:

TOPIC AREAS

- Accelerated Aging Processes Associated with Military Service
- Computational Biology for Precision Health
- Musculoskeletal Disorders Related to Acute and Chronic Bone Conditions and Injuries
- Proteomics

STRATEGIC GOALS

Foundational Studies

- Understand mechanisms underlying the pathology of associated musculoskeletal disorders including, but not limited to aging, pain, mechanobiology, gut microbiome, and cell senescence.
- Determine factors that lead to accelerated degeneration following joint injuries, including research focused on the entire joint rather than a specific tissue and studies investigating the role of aberrant mechanobiology or multi-omics studies.
- Elucidate the role of steroid hormones and/or biological sex in orthopaedic health.

Prevention

- Develop strategies for improved point-of-injury care to mitigate risk of secondary complications and to address joint preservation.

- Develop and test strategies to prevent bacterial and/or fungal infections that occur with severe fractures or trauma.
- Develop and test strategies to prevent orthopaedic-related conditions in women.

Diagnosis

- Develop and test novel strategies for early and precise diagnosis, including but not limited to research involving patient profiling, omics, and machine learning/artificial intelligence approaches.

Treatment

- Advance intra-articular treatments for joint injuries to address whole joint preservation, regeneration, or resurfacing, and to improve joint microenvironment.
- Develop and test strategies to increase quality of life or halt/slow disease progression (may include regenerative medicine approaches and/or biologics).
- Develop and test strategies for rehabilitation regimens for the musculoskeletal system and associated disorders to facilitate Service Members returning to duty.
- Develop and test treatment strategies for orthopaedic-related conditions in women.

Epidemiology

- Conduct patient-reported outcomes research to inform treatment guidelines and/or improve exercise recommendations to optimize joint longevity; research with a focus on large data sets is encouraged.

RARE DISEASES AND CONDITIONS

All applications under this portfolio must be aligned to Rare Diseases and Conditions by addressing one Topic Area and one Strategic Goal listed below:

TOPIC AREAS

- | | |
|--|------------------------------|
| • Computational Biology for Precision Health | • Hereditary Ataxia |
| • Dystonia | • Hydrocephalus |
| • Ehlers-Danlos Syndrome | • Mitochondrial Disease |
| • Epidermolysis Bullosa | • Myotonic Dystrophy |
| • Fibrous Dysplasia/McCune-Albright Syndrome | • Proteomics |
| • Fragile X | • Rett Syndrome |
| • Frontotemporal Degeneration | • Sickle-Cell Disease |
| | • Von Hippel-Lindau Syndrome |

STRATEGIC GOALS

Foundational Studies

- Identify biological mechanisms underlying disease onset, disease progression, or phenotype/symptomatic heterogeneity, including studies to address sex, gender, ethnic and/or racial differences.
- Elucidate how biomarkers (including genotype) are linked to disease phenotype or subtype.
- Develop novel preclinical models that recapitulate the phenotype of human disease.

Diagnosis

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

Treatment

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

Epidemiology

- Conduct population-based studies to identify risk (i.e., carrier status), lifestyle determinates of health or protective factors that influence onset, progression and/or outcomes.
- Conduct natural history/longitudinal studies to understand incidence, prevalence, and progression of the disease/condition and carrier and modifier gene status.
- Develop and validate research tools to collect, mine, and integrate real-world data (patient-reported data, longitudinal data, etc.) with electronic medical records to guide precision medicine approaches.
- Develop clinically relevant endpoints for clinical trials.

RESPIRATORY HEALTH

All applications under this portfolio must be aligned to Respiratory Health by addressing one Topic Area and one Strategic Goal listed below:

TOPIC AREAS

- Computational Biology for Precision Health
- Proteomics
- Pulmonary Fibrosis
- Respiratory Health

STRATEGIC GOALS

Foundational Studies

- Determine how airborne hazards cause respiratory injury/disease (i.e., climate change-related, toxin/toxicant or nanomaterial exposure).
- Improve understanding of how genetics and/or immune system activation lead to respiratory distress.

Prevention

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

Diagnosis

- Develop and validate physiological 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 respiratory illnesses, including developing and validating wearable sensors for early detection of chronic pulmonary diseases.
- Identify biomarkers to diagnose and/or monitor progression of chronic respiratory diseases.

Treatment

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

Epidemiology

- Improve understanding of difference in incidence, risk factors, outcomes, and disease progression in populations based on race, genetics, and/or age.

II.B. Award Information

The PRMRP Investigator-Initiated Research Award (IIRA) supports fundamental research studies that will make an important contribution toward research, patient care, and/or quality of life for a disease or condition related to one of the FY24 PRMRP Topic Areas and one of the FY24 PRMRP Strategic Goals. This award mechanism is intended to support basic research that is exploratory in nature and seeks to further or validate preliminary findings for short- or long-term impact. Research projects may focus on any stage of basic laboratory research, ranging from fundamental research for the generation of knowledge, hypothesis, or models, to expansion of mature data.

The rationale for a research idea may be derived from a laboratory discovery, population-based studies, a clinician's first-hand knowledge of patients, or anecdotal data. The project should include a well-formulated testable hypothesis based on existing evidence. Applications **must include** relevant preliminary data that support the rationale and feasibility for the proposed study. These data may be unpublished or from the published literature.

This award mechanism is not intended to support translational research. Applicants seeking funding for projects that have progressed beyond the realm of basic research should consider one of the other FY24 PRMRP program announcements being offered. For information about these award mechanisms, see [Section II.A.1, FY24 PRMRP Research Development Pipeline](#).

Key aspects of the FY24 PRMRP Investigator-Initiated Research Award:

- **Impact:** The Investigator-Initiated Research Award is designed to support research with the potential to yield highly impactful data that could lead to critical discoveries or major advancements. The application must clearly demonstrate the project's potential short-term and long-term outcome(s)/product(s) (knowledge and/or materiel) and how they will impact a critical problem or question in the field of research and/or patient care in the FY24 PRMRP Topic Area and FY24 PRMRP Strategic Goal addressed.
- **Preliminary Data:** The Investigator-Initiated Research Award is intended to support fundamental research investigations that address key issues or questions by utilizing previous research findings. Applications must include preliminary data to support the rationale and

feasibility of the study. Any unpublished preliminary data provided should originate from the laboratory of the Principal Investigator (PI) or a member of the research team.

- **Relevance to Military Health:** Relevance to the health care needs of military Service Members, Veterans, and their Families is a key feature of this award. Investigators are encouraged to consider the following characteristics as examples of how a project may demonstrate relevance to military health:
 - Explanation of how the project addresses an aspect of the target disease/condition/technology that has direct relevance to the health of military Service Members, Veterans, and/or other Military Health System Beneficiaries.
 - Description of how the knowledge, information, products, or technologies gained from the proposed research could be implemented in a dual-use capacity to benefit the civilian population and also address a military need.
 - Use of military or Veteran populations, samples, or datasets in the proposed research, if appropriate.
 - Collaboration with Department of Defense (DOD) or Department of Veterans Affairs (VA) investigators or consultants. A list of websites that may be useful in identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration within the FY24 PRMRP Topic Areas can be found in [Appendix 2](#).

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

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 (<http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html>). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies.

CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

This award mechanism may not be used to conduct clinical trials; however, noninterventional clinical research studies are allowed. Applicants seeking funding for a clinical trial should consider one of the other FY24 PRMRP program announcements being offered. For information

about these award mechanisms, see [Section II.A.1, FY24 PRMRP Research Development Pipeline](#).

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

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

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

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

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

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

The anticipated direct costs budgeted for the entire period of performance for an FY24 PRMRP Investigator-Initiated Research Award should not exceed **\$1.0M**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately \$30.0M to fund approximately 20 FY24 PRMRP Investigator-Initiated Research Award applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period

based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

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

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

Awards are made to eligible *organizations*, not to individuals.

Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

II.C.1.b. Principal Investigator

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

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

An investigator may be named on only one FY24 PRMRP IIRA application as a PI.

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

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 to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

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

II.D. Application and Submission Information

II.D.1. Location of Application Package

Submission is a two-step process requiring both a **pre-application** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a **full application** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

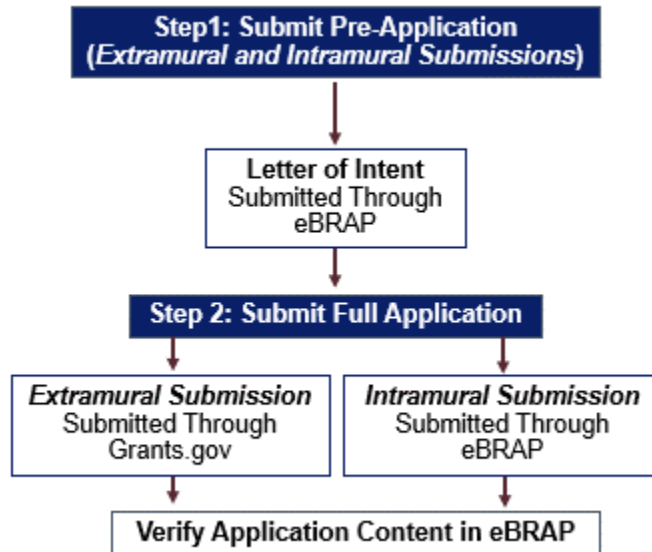
The CDMRP uses two portal systems to accept pre- and full application submissions.

eBRAP (<https://ebrap.org>) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

Grants.gov (<https://grants.gov>) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

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).

Application Submission Workflow



Extramural Submission: An application submitted by an [extramural organization](#) for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions.) Download application package components for HT942524PRMRPIIRA from Grants.gov (<https://grants.gov>). Full applications from extramural organizations *must* be submitted through Grants.gov.

Intramural Submission: An application submitted by an [intramural DOD organization](#) for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524PRMRPIIRA from the anticipated submission portal eBRAP (<https://ebrap.org>) or Grants.gov.

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

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

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

Unnecessary duplication of funding, or accepting funding from more than one source for the same research, is prohibited. See CDMRP's full position on research duplication at <https://cdmrp.health.mil/funding/researchDup>.

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

FY24 PRMRP Programmatic Panel members should not be involved in any pre-application or full 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.

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

Regardless of submission type (i.e., extramural or intramural), all pre-application (LOI) components must be submitted by the PI through eBRAP.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, the Business Official(s), performing organization(s), and contracting organization(s) 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.

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

Select the FY24 PRMRP Portfolio addressed by the proposed research.

Select the FY24 PRMRP Topic Area addressed by the proposed research.

Select the FY24 PRMRP Continuum of Care category addressed by the proposed research.

Select the FY24 PRMRP Strategic Goal addressed by the proposed research.

II.D.2.a.i Pre-Application Components

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for detailed instructions regarding pre-application submission):

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the PRMRP Portfolio, FY24 PRMRP Topic Area, and FY24 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. An invitation to submit a full application is NOT provided after LOI submission. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.

II.D.2.b. Step 2: Full Application Submission

II.D.2.b.i. Full Application Submission Type

Extramural Submissions: Full applications from extramural organizations *must* be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CMDRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

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

Each application submission must include the completed full application package for this program announcement. See [Section II.H.3](#) of this program announcement for a checklist of the required application components.

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

(b) 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 2.

- **Attachment 1: Project Narrative (10-page limit): Upload as “ProjectNarrative.pdf”.** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer

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

Describe the proposed project in detail using the outline below.

- **Background:** Present the scientific rationale behind the proposed work. Cite relevant literature. Describe previous experience most pertinent to the project. Include relevant preliminary data; these data may be unpublished from the PI’s laboratory or from the published literature.
- **Hypothesis:** State the hypothesis to be tested. State which FY24 PRMRP Topic Area the proposed research addresses. Additionally, describe how the proposed research project addresses one of the FY24 PRMRP Strategic Goals.
- **Specific Aims:** Concisely explain the project’s specific aims and the objective(s) to be reached. 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, data collection procedures, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches.
 - Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis. If cell lines or animals are to be used, ***justify why the proposed cell line(s) or animal model(s) were chosen.*** If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE guidelines 2.0 ([The ARRIVE guidelines 2.0 | ARRIVE Guidelines](#)).
 - If human subjects, human biological samples, or datasets will be used, describe the study population and include a detailed plan for the recruitment of human subjects or the acquisition of samples/datasets. 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. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- **Letters of 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 and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.
- **Intellectual Property:** Information can be found in the 2 CFR 200.315, "Intangible Property."
 - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
 - **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and

management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, [DoD Instructions 3200.12](#). *Do not duplicate the Data and Research Resources Sharing Plan.* Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.
- **Inclusion Enrollment Plan (only required if clinical research is proposed):** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form that can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.
- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP’s Policy on Data & Resource Sharing located on the eBRAP “Funding Opportunities & Forms” web page <https://ebrap.org/eBRAP/public/Program.htm> for more information about CDMRP’s 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 signed by 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. If the VA-affiliated non-profit corporation is not identified as the applicant organization 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.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important as programmatic reviewers typically do not have access to the full application and rely on the technical abstract for appropriate description of the project.

- **Background:** Present the scientific rationale behind the proposed research project.
 - **Relevance to Topic Area:** State the relevance of the project to one of the FY24 PRMRP Topic Areas. Additionally, describe how the proposed research project addresses one of the FY24 PRMRP Strategic Goals.
 - **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached.
 - **Specific Aims:** State the specific aims of the study.
 - **Study Design:** Describe the study design, including appropriate controls.
 - **Impact:** Briefly describe how the proposed project will have an impact on research and patient care in the specified disease(s)/condition(s).
 - **Relevance to Military Health:** Describe the study’s relevance to the health care needs of military Service Members, Veterans, and/or their Families.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers, and addresses issues of particular interest to the affected community. *Abstracts of all funded research projects will be posted publicly.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. *Do not duplicate the technical abstract.*

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

- State the FY24 PRMRP Topic Area addressed by the proposed research project. Additionally, describe how the proposed research project addresses one of the FY24 PRMRP Strategic Goals.

- Summarize the objectives and rationale for the proposed research.
 - What population will the research help, and how will it help them?
 - What are the potential applications, benefits, and risks of the anticipated outcomes?
 - What are the likely contributions of the proposed research project to advancing research, patient care, and/or quality of life?
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** Refer to the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for the suggested SOW format and recommended strategies for assembling the SOW.

For the FY24 PRMRP Investigator-Initiated Research Award, refer to either the “Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work” or “Example: Assembling a Generic Statement of Work”, whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW. Use the “Suggested SOW Format” to develop the SOW for the proposed research. Submit as a PDF.

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf”.**
 - Explain how the proposed research project will address a critical problem or question in one of the [FY24 PRMRP Topic Areas](#). Additionally, describe how the project addresses one of the [FY24 PRMRP Strategic Goals](#).
 - Describe how the proposed research project, if successful, will make important scientific advances in the relevant field of research.
 - Describe the short-term impact: Detail the anticipated outcome(s)/product(s) (knowledge and/or materiel) that will be directly attributed to the results of the proposed research. Describe how the results of the research will impact the field of study and/or improve patient care in the near term as compared to current practice or currently used treatments.
 - Describe the long-term impact: Explain the anticipated long-term gains from this research. Compare to information known/products currently available, if applicable. Describe the anticipated long-range impact of the anticipated research findings on the field of study and/or patient care.
- **Attachment 7: Relevance to Military Health Statement (one-page limit): Upload as “MilRel.pdf”.**
 - Describe how the proposed study is responsive to the health care needs of military Service Members, Veterans, and their Families. Provide information about the incidence and/or prevalence of the disease or condition in the general population as well as in military Service Members, Veterans, and/or their Families.

- If active-duty military, military Families, and/or Veteran population(s) or datasets will be used in the proposed research project, describe the population(s)/dataset(s) and the appropriateness of the population(s)/dataset(s) for the proposed study. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., military Service Members, Veterans, and their Families).
- If applicable, show how the proposed research project aligns with 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: Animal Research Plan (three-page limit): Upload as “AnimalResPlan.pdf”.** (Attachment 8 is only applicable and required for applications proposing animal studies.)

If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. Consult the ARRIVE guidelines 2.0 (Animal Research: Reporting In Vivo Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at <https://arriveguidelines.org/arrive-guidelines>. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the Institutional Animal Care and Use Committee (IACUC). The Animal Research Plan should address the following points to achieve reproducible and rigorous results for each proposed animal study:

- Briefly describe the research objective(s) of the animal study. 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.
- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
- **Attachment 9: Prior Outcomes Statement (if applicable; one-page limit): Upload as “Outcomes.pdf”.** If applicable, list all of the PI’s prior or in-progress CDMRP/PRMRP

research projects/awards including resulting publications, abstracts, patents, or other tangible outcomes. Only research and outcomes directly relevant to this application should be listed. **Attachment 9 will be available for programmatic review only.**

- **Attachment 10: Representations (*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 8, Section B, Representations.
 - **Attachment 11: Suggested Intragovernmental/Intramural Budget Form (*if applicable*): Upload as “IGBudget.pdf”.** If an [intramural DOD organization](#) will be a collaborator in performance of the project, complete a separate budget using the “Suggested Intragovernmental/Intramural Budget Form”, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The *total* costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.
- (c) Research & Related Personal Data:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.
- (d) Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.
- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch_LastName.pdf”.
 - **PI Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf”.
 - **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”.
- (e) Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.
- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural

submissions, refer to General Application Instructions, Section V.A.(e) Budget Justification Instructions.

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

(g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Extramural Submissions Only): Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate “[Suggested Intragovernmental/Intramural Budget Form](#)” for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 11.

II.D.2.c. Applicant Verification of Full Application Submission in eBRAP

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

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. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

II.D.4. Submission Dates and Times

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.

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

II.D.5. Funding Restrictions

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

The application's direct costs budgeted for the entire period of performance should not exceed **\$1.0M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

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

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

- Travel in support of multi-institutional collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to disseminate project results from the FY24 PRMRP IIRA.

Must not be requested for:

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

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, 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 individually evaluated according to the following **scored criteria**, which are listed in decreasing order of importance:

- **Impact**

- To what extent the project impacts a critical problem or question in the PI-selected FY24 PRMRP Topic Area.
- To what extent the proposed research project addresses the PI-selected FY24 PRMRP Strategic Goal.
- How the proposed research project, if successful, will make important scientific advances in the relevant field of research or advance patient outcomes.
- To what extent the proposed research has potential for impact, both short-term and long-term, on the field of study and/or patient care.

- **Research Strategy and Feasibility**

- How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, supporting data, and logical reasoning.
- How well the hypothesis, specific aims, and objective(s) are developed.
- How well the experimental design, methods, data collection procedures, and analyses are developed and support completion of the aims.
- To what degree the statistical plan and power analysis are appropriate for the proposed project.
- If animal studies are included, how well they are designed to achieve reproducible and rigorous results, including the choice of model and the endpoints/outcomes to be measured.
- If human subjects, human biological samples, or datasets will be used, how well the application provides evidence of availability of, and access to, the necessary study populations and/or resources.
- If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
- How well potential problems are identified, and alternative methods or approaches are addressed.

- **Personnel**

- How appropriate the levels of effort are for successful conduct of the proposed work.
- How well the PI's record of accomplishment demonstrates their ability to perform the proposed work.

- How appropriate the PI and research team's background and expertise are with regard to their ability to accomplish the proposed work.

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

- **Budget**

- Whether the budget is appropriate for the proposed research.

- **Environment**

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

- **Application Presentation**

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

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 priorities of the Defense Health Program and FY24 PRMRP, as evidenced by the following:
 - Adherence to the intent of the funding opportunity
 - Relative impact
 - Relevance to the FY24 PRMRP Topic Areas
 - Relevance to the FY24 PRMRP Strategic Goals
 - Relevance to military health

- Program portfolio composition
- Relative outcomes from the PI's previous CDMRP-/PRMRP-funded research (if applicable)

II.E.2. Application Review and Selection Process

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

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 review panel. Violations of confidentiality can result in the dissolution 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 a 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 SAM.

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the FY24 PRMRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

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

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

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

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

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Application Instructions, Section IV.B.(e), for additional information about pre-award costs.

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

II.F.2. PI Changes and Award Transfers

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

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

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

II.F.3. Administrative and National Policy Requirements

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

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

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

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

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

II.F.4. Reporting

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

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

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

PHS Inclusion Enrollment Reporting Requirement (*only required for clinical research studies*): 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 SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

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

Email: support@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 900. The program announcement numeric version code will match the General Application Instructions version code 900.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- Pre-application (LOI) 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 full application:

- An FY24 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, including letters of support/recommendation. *A list of the FY24 PRMRP Programmatic Panel members can be found at <https://cdmrp.health.mil/prmrp/panels/panels24>.*
- 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.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.health.mil/about/2tierRevProcess>).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety

of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.

- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application fails to address one of the congressionally directed FY24 PRMRP Topic Areas
- The application fails to address one of the FY24 PRMRP Strategic Goals.
- The investigator is named as PI on more than one application submitted to the FY24 PRMRP IIRA mechanism.
- A clinical trial is proposed.
- The PI does not meet the eligibility criteria.

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. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance <i>(Extramural submissions only)</i>	<input type="checkbox"/>
Summary (Tab 1) and Application Contacts (Tab 2) <i>(Intramural submissions only)</i>	<input type="checkbox"/>
Attachments	
Project Narrative – Attachment 1; upload as “ProjectNarrative.pdf”	<input type="checkbox"/>
Supporting Documentation – Attachment 2; upload as “Support.pdf”	<input type="checkbox"/>
Technical Abstract – Attachment 3; upload as “TechAbs.pdf”	<input type="checkbox"/>
Lay Abstract – Attachment 4; upload as “LayAbs.pdf”	<input type="checkbox"/>
Statement of Work – Attachment 5; upload as “SOW.pdf”	<input type="checkbox"/>
Impact Statement – Attachment 6; upload as “Impact.pdf”	<input type="checkbox"/>
Relevance to Military Health Statement – Attachment 7; upload as "MilRel.pdf"	<input type="checkbox"/>
Animal Research Plan – Attachment 8; upload as "AnimalResPlan.pdf"	<input type="checkbox"/>
Prior Outcomes Statement – Attachment 9; upload as "Outcomes.pdf" if applicable	<input type="checkbox"/>
Representations <i>(Extramural submissions only)</i> – Attachment 10; upload as “RequiredReps.pdf”	<input type="checkbox"/>
Suggested Intragovernmental/Intramural Budget Form <i>(if applicable)</i> – Attachment 11; upload as “IGBudget.pdf”	<input type="checkbox"/>
Research & Related Personal Data	<input type="checkbox"/>
Research & Related Senior/Key Person Profile (Expanded)	<input type="checkbox"/>
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	<input type="checkbox"/>
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	<input type="checkbox"/>
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	<input type="checkbox"/>
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	<input type="checkbox"/>
Research & Related Budget <i>(Extramural submissions only)</i> Include budget justification	<input type="checkbox"/>
Budget <i>(Intramural submissions only)</i> Include budget justification	<input type="checkbox"/>
Project/Performance Site Location(s) Form	<input type="checkbox"/>
Research & Related Subaward Budget Attachment(s) Form <i>(if applicable)</i>	<input type="checkbox"/>

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
IACUC	Institutional Animal Care and Use
IIRA	Investigator-Initiated Research Award
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
PRMRP	Peer Reviewed Medical Research Program
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
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	U.S. 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 [FY24 PRMRP Topic Areas](#).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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>

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

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

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

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

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

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

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

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

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

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

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

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

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