

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Peer Reviewed Medical Research Program

Focused Program Award

Announcement Type: Modified

Funding Opportunity Number: W81XWH-21-PRMRP-FPA

**Catalog of Federal Domestic Assistance 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), May 13, 2021
- **Invitation to Submit an Application:** June 2021
- **Application Submission Deadline:** 11:59 p.m. ET, August 26, 2021
- **End of Application Verification Period:** 5:00 p.m. ET, August 31, 2021
- **Peer Review:** October 2021
- **Programmatic Review:** December 2021

This program announcement must be read in conjunction with the General Application Instructions, version 601. 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 2021 (FY21) Peer Reviewed Medical Research Program (PRMRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, 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). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP). The PRMRP was initiated in 1999 to provide medical research projects of clear scientific merit and direct relevance to military health. Appropriations for the PRMRP from FY99 through FY20 totaled \$2.71 billion. The FY21 appropriation is \$370 million (M).

The vision of the FY21 PRMRP is to improve the health, care, and well-being 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 and direct relevance to military health. The PRMRP challenges the scientific and clinical communities to address the FY21 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. FY21 PRMRP Topic Areas

All applications for PRMRP funding must specifically address at least one of the Topic Areas as directed by Congress and must be of clear scientific merit and direct relevance to military health. If the proposed research does not specifically address at least one of the FY21 PRMRP Topic Areas, the government will administratively withdraw the application. The government reserves the right to reassign the application's Topic Area if submitted under an inappropriate Topic Area. The FY21 PRMRP Topic Areas are listed below.

- Arthritis
- Burn Pit Exposure
- Cardiomyopathy
- Congenital Heart Disease
- Diabetes
- Dystonia
- Eating Disorders
- Emerging Viral Diseases

- Endometriosis
- Epidermolysis Bullosa
- Familial Hypercholesterolemia
- Fibrous Dysplasia
- Focal Segmental Glomerulosclerosis
- Food Allergies
- Fragile X
- Frontotemporal Degeneration
- Hemorrhage Control
- Hepatitis B
- Hydrocephalus
- Hypertension
- Inflammatory Bowel Diseases
- Malaria
- Metals Toxicology
- Mitochondrial Disease
- Myalgic Encephalomyelitis/Chronic Fatigue Syndrome
- Myotonic Dystrophy
- Non-Opioid Therapy for Pain Management
- Nutrition Optimization
- Pathogen-Inactivated Blood Products
- Peripheral Neuropathy
- Plant-Based Vaccines
- Platelet-Like Cell Production
- Polycystic Kidney Disease
- Pressure Ulcers
- Pulmonary Fibrosis
- Respiratory Health
- Rheumatoid Arthritis
- Sleep Disorders and Restriction
- Suicide Prevention
- Sustained Release Drug Delivery
- Vascular Malformations
- Women's Heart Disease

Applicants should select the FY21 PRMRP program announcement most appropriate to the stage of the proposed research. Areas of Encouragement related to the FY21 PRMRP Topic Areas have been identified by the Department of Defense (DOD), the Department of Veterans Affairs (VA), and other relevant stakeholders ([Appendix 2](#)). Applicants are strongly urged to read and consider these Areas of Encouragement before preparing their applications. ***The information provided is not exhaustive, and applicants are not restricted to submitting applications that address an Area of Encouragement on this list.***

II.B. Award Information

The PRMRP Focused Program Award is intended to optimize research and accelerate solutions to a critical question related to at least one of the Congressionally directed FY21 PRMRP Topic Areas through a synergistic, multidisciplinary research program.

Key aspects of this award include:

Overarching Challenge: Focused Program Award applications must describe a unifying, overarching challenge that will be addressed by a set of research projects. The overarching challenge must be relevant to a critical problem or question in the field of research and/or patient care in at least one of the FY21 PRMRP Topic Areas.

Research Projects: Applications shall include multiple, distinct research projects led by individual project leaders that address complementary aspects of the overarching challenge. Applicants are strongly encouraged to submit a minimum of four research projects; additional studies are allowed. While individual projects must be capable of standing on their own high scientific merits, they must also be interrelated and synergistic with the other proposed projects and advance a solution beyond what would be possible through individual efforts. The exploration of multiple hypotheses or viewpoints of the same line of questioning is encouraged. *This award mechanism is not intended to support a series of research projects that are dependent on the success of one of the other projects.* Each project should propose a unique approach to addressing the overarching challenge and be capable of producing research findings with potential to impact the field and/or patient care. Individual research projects may range from exploratory, hypothesis-developing studies through small-scale clinical trials (i.e., up to and including phase 2 or equivalent). There should be a clear intent to progress toward translational/clinical work over the course of the effort.

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

Research Team: The overall effort will be led by a Principal Investigator (PI) with demonstrated success in leading large, focused projects. The PI is required to devote a minimum of 20% effort to this award. The PI should create an environment that fosters and supports collaboration and innovation in a way that engages all members of the team in all aspects of the research plan. The research team assembled by the PI should be highly qualified and multidisciplinary, with identified project leaders for each of the complementary and synergistic research projects. The resources and expertise brought to the team by each project leader should combine to create a robust, synergistic collaboration. The PRMRP Science Officer assigned to a resulting award should be invited to participate in research team meetings (e.g., annual meetings of the entire research team). The plan for such meetings should be noted in the application.

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

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

The anticipated direct costs budgeted for the entire period of performance for an FY21 PRMRP FPA award will not exceed **\$7.2M**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2022. For additional information refer to [Section II.F.1, Federal Award Notices](#).

The CDMRP expects to allot approximately \$54M to fund approximately five Focused Program Award applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY21 funding opportunity will be funded with FY21 funds, which will expire for use on September 30, 2027.

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, if appropriate to the proposed research

Applicants are strongly 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. 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 FY21 PRMRP Topic Areas can be found in [Appendix 3](#).

Use of DOD or VA Resources: If the proposed research involves access to active-duty military patient populations and/or DOD 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 U.S. Army Medical Research and Development Command (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 a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource 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 is cooperative (i.e., involving 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.

Focused Program Award applications that include a clinical trial have additional application and review requirements. For more information, see [Section II.D.2, Content and Form of the Application Submission](#) and [Section II.E.1, Criteria](#). ***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. Funded trials are required to post a copy of the IRB approved informed consent form used to enroll subjects on a publicly

available federal website in accordance with federal requirements described in the Code of Federal Regulations, Title 32, Part 219 (32 CFR 219).

Clinical research is defined as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) epidemiologic and behavioral studies; and (3) outcomes research and health services research. Note: Studies that meet the requirements for IRB review Exemption 4 are not considered CDMRP-defined clinical research. IRB Exemption 4 refers to research involving the collection or study of existing de-identified specimens or data, if these sources are publicly available.

Research Involving Animals: All DOD-funded research 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 organization 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: 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.***

USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

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

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

The CDMRP 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).

As an exception, applicants may submit a research project described in their FY21 PRMRP Focused Program Award application to the Discovery Award (funding opportunity number W81XWH-21-PRMRP-DA), Investigator-Initiated Research Award (funding opportunity number W81XWH-21-PRMRP-IIRA), Clinical Trial Award (funding opportunity number W81XWH-21-PRMRP-CTA), and/or Expansion Award (funding opportunity number W81XWH-21-PRMRP-EA); however, accepting multiple awards to support the same project will not be allowed.”

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.1. Address to Request Application Package

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

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

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 CDMRP 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 CDMRP 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>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

The applicant organization and associated PI identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP 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 FY21 PRMRP Topic Area addressed by the proposed research. If the proposed research project is aligned with more than one FY21 PRMRP Topic Area, include all, but select the topic area of highest relevance as the required first choice.

- **Tab 2 – Application Contacts**

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

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

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

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

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

[FY21 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 CDMRP 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**

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

- **Preproposal Narrative (six-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should include the following:

- **Topic Area:** Describe how the proposed program relates to at least one of the FY21 PRMRP Topic Areas. If applicable, describe how the proposed research program addresses an FY21 PRMRP Area of Encouragement ([Appendix 2](#)).
- **Overarching Challenge:** Describe the unifying challenge or question to be addressed and how it is relevant to a critical problem or question in the field of research and/or patient care in at least one of the FY21 PRMRP Topic Areas. Clearly articulate the rationale for the overarching challenge; include relevant preliminary data and literature citations.
- **Research Strategy:** The FY21 PRMRP Focused Program Award strongly encourages a minimum of four individual but complementary research projects addressing the overarching challenge. For each proposed project, state the hypothesis to be tested, the specific aims, and the objectives to be reached. Briefly describe the experimental approach. Describe how the projects are interrelated to and synergistic with each other and align with the overarching challenge to advance a solution beyond what would be possible through individual efforts.

- **Impact:** Describe the potential short-term and long-term impact of the proposed research on a critical problem or question in the field of research and/or patient care in the FY21 PRMRP Topic Area(s) addressed. Explain how the effort is relevant to the healthcare needs of military Service Members, Veterans, and/or beneficiaries.
- **Research Team:** Briefly describe the composition, expertise, and organization of the research team. Identify the project leaders and describe each team member’s role in and commitment to the projects, with additional emphasis on the leadership role and commitment of the PI. Briefly describe how these features will facilitate the success of the key aspects of the projects.
- **Clinical Trial (if applicable):** If one or more of the proposed research projects include a clinical trial, briefly state the clinical intervention(s), subject population(s), and the type and phase of the clinical trial(s). Describe the objectives of the clinical trial(s), how it addresses the overarching challenge, and how it complements the other proposed projects. *Only small-scale (i.e., up to and including phase 2 or equivalent) clinical trials are allowed.*
- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* and are limited to the following:
 - References Cited (two-page limit): List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
 - Key Personnel Biographical Sketches (five-page limit per individual): *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **Tab 6 – Submit Pre-Application**

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

Pre-Application Screening

- **Pre-Application Screening Criteria**

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

- **Overarching Challenge:** How well the unifying challenge or question addresses a critical problem or question in the field of research and/or patient care in at least one of

the FY21 PRMRP Topic Areas. How well the rationale supports the overarching challenge.

- **Research Strategy:** How well a hypothesis and specific aims are defined for each proposed project and to what extent each project's approach will address them. How well the proposed projects complement each other and synergistically address the overarching challenge to advance a solution beyond what would be possible through individual efforts.
 - **Impact:** Whether the potential short-term and long-range outcome(s)/product(s) (intellectual and/or material) of the proposed research, if successful, will impact a critical problem or question in the field of research and/or patient care in the FY21 PRMRP Topic Area(s) addressed. To what degree the project is relevant to the healthcare needs of military Service Members, Veterans, and/or beneficiaries.
 - **Research Team:** To what degree the background, expertise, and commitment of the PI, project leaders, and key personnel are appropriate with respect to their abilities to successfully complete the projects and the extent to which the PI is well prepared and committed to lead the research team and proposed projects.
- **Notification of Pre-Application Screening Results**

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

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

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

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

Each application submission must include the completed full application package for this program announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://www.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-21-PRMRP-FPA from Grants.gov (https://www.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-21-PRMRP-FPA 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.	<p>Tab 1 – Summary: Provide a summary of the application information.</p> <p>Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • 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 	<p>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:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites <p>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.</p>

Extramural Submissions	Intramural DOD Submissions
Application Package Submission	
<p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>Submit a Grants.gov Workspace Package. 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.</p> <p>Note: If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>	<p>Submit package components to eBRAP (https://ebrap.org).</p> <p>Tab 5 – Submit/Request Approval Full Application: After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>
<u>Application Verification Period</u>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i></p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i> Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>

Extramural Submissions	Intramural DOD Submissions
Further Information	
<p>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.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.

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

- **Attachment 1: Project Narrative (40-page limit): Upload as “ProjectNarrative.pdf”.** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

Overall Program: Provide a description of the comprehensive effort using the following outline. Applicants are strongly encouraged to submit a minimum of four research projects; additional studies are allowed. Emphasize areas of synergy throughout the narrative.

- **Overarching Challenge:** Describe the unifying, overarching challenge or question to be addressed and how it is relevant to a critical problem or question in the field of research and/or patient care in at least one of the FY21 PRMRP Topic Areas. If applicable, describe how the proposed research addresses an FY21 PRMRP Area of Encouragement ([Appendix 2](#)). Clearly articulate the rationale for the overarching challenge; include relevant literature citations. Clearly describe how the proposed research projects are not dependent upon each other but are interrelated and synergistic and will advance toward a solution through a multidisciplinary research program. Describe how each project will address the overarching challenge in a unique but complementary way and how the combined efforts of the projects will address the overarching challenge more effectively than if the projects were conducted independently.
- **Leadership:** Describe how the PI's research experience, leadership skills, and commitment to making an impact in their field of research and/or patient care demonstrate substantial qualifications to coordinate this collaborative effort. Describe the PI's demonstrated success in leading large, focused projects and outline the PI's responsibilities during the conduct of the proposed research effort. The PI is required to devote a minimum of 20% effort to this award. Discuss the qualifications of the research team being brought together by the PI and how the assembled expertise will create a robust, synergistic collaboration necessary to address the overarching challenge and enable the success of the proposed research.
- **Implementation Plan and Environment:** Provide an overall strategic implementation plan for completing the proposed projects that identifies critical milestones and explain how these milestones will be achieved. Outline the knowledge, expertise, and technical innovations that the investigative team will utilize to make decisions, allocate resources, and accomplish the milestones. Describe and/or provide evidence that the research can be initiated without delay once the award is made. Present an overall management plan to facilitate a consistent and intensive flow of ideas and information among all team members, including aspects such as adherence to regulatory requirements, administrative support, and oversight to accelerate translation of the projects' outcomes to patients and/or for clinical use. Describe the research environment(s) and how the facilities and resources will support the research requirements and the collaboration. Outline shared resources and/or cores that will be created and/or leveraged through the award. Describe plans for communication, data transfer among the collaborating institutions, and how data, specimens, and/or imaging products obtained during the study will be handled. If applicable, describe how Standard Operating Procedures will be created, reviewed, implemented, and modified during the course of the award. Describe how individual project performance will be assessed during the course of the award, including progression toward defined milestones, realization of study objectives, and addressing

the overarching challenge. If an EAB is to be utilized, describe the role of the board and the expertise to be sought in its members. To avoid potential conflicts of interest in the review of the application, potential candidates for an EAB should not be contacted, recruited, or named during the application process.

Research Plan: Provide the following details for each proposed research project, organizing each project clearly and separately. **Start each project on a separate page.**

- **Title:** Provide a title for each project.
- **Project Leader:** Identify the project leader and any key personnel, as appropriate, describing each person’s qualifications, specific contributions, and evidence of strong commitment to the project.
- **Background:** Briefly describe the ideas and scientific rationale on which the proposed work is based. Provide sufficient preliminary data to support the feasibility of work proposed. If the project is exploratory/hypothesis-developing, preliminary data are not required. For each project, the project leader must demonstrate logical reasoning and provide a sound scientific rationale for the proposed project as established through a critical review and analysis of published literature. If proposing translational or clinical research, it is important to describe the project showing proof of concept and, if applicable, efficacy in an in vivo system(s) to support the translational feasibility and promise of the approach.
- **Hypothesis/Objective:** State the hypothesis to be tested and/or the objective(s) to be reached.
- **Specific Aims:** Concisely explain each project’s specific aims. The specific aims should align with the overall goal of the program and associated tasks described in the Statement of Work (SOW).
- **Research Strategy and Feasibility:** Describe the experimental design, methods, and analyses, in sufficient detail for analysis. Provide a description of how the study will be controlled and how the study variables will be measured. If the project is a clinical trial, define the primary and secondary or interim endpoints/outcome measures, why they were chosen, and how and when they will be assessed. Explain how the research strategy will address the overarching challenge and meet appropriate milestones. Address potential problem areas and present alternative methods and approaches.
 - If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines (<https://journals.plos.org/plosone/article/file?type=supplementary&id=info:doi/10.1371/journal.pone.0146533.s001>).
 - Justify how the model system or human subjects/samples are appropriate to the proposed research project.

- If human subjects or human biological samples will be used, describe the study population and include a detailed plan for the recruitment of human subjects or the acquisition of samples. Describe the availability of the proposed study population and past successes in recruiting similar populations. If active-duty military, military families, and/or Veteran population(s) or datasets will be used in the proposed research project, describe how access to the population(s)/dataset(s) will be obtained.
 - Describe the strategy for the inclusion of women and minorities in the clinical research appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and/or ethnicity, and an accompanying rationale for the selection of subjects. It is not expected that every study will include all genders and racial and ethnic groups. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this requirement. The Policy on Inclusion of Women and Minorities, and Frequently Asked Questions for the policy may be downloaded from eBRAP under “Resources and Reference Material” at <https://ebrap.org/eBRAP/public/Program.htm>.
 - If applicable, describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA).
 - Describe how the research project will be completed within the proposed period of performance.
- **Statistical Plan:** Clearly describe a statistical plan appropriate to the type of study; provide the rationale for the statistical methodology. Define the number of samples and/or subjects (animal and/or human) to be used, and include a power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and provide meaningful outcomes. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.
 - **Impact:** Describe the anticipated outcome(s)/product(s) (knowledge and/or material) that will be directly attributed to the results of the proposed research and their impact(s) on the lives of relevant patient populations. Explain the anticipated short-term and long-term gains from this research and how they address the identified overarching challenge. Compare to the information known/products currently available, if applicable.
 - **Clinical Trial(s) (if applicable):** *Only small-scale (e.g., up to and including phase 2 or equivalent) clinical trials are allowed.* Provide detailed plans for initiating and conducting the clinical trial during the course of this award. As appropriate, outline a plan for applying for and obtaining Investigational New Drug/

Investigational Device Exemption (IND/IDE) status (or other FDA approvals) within 18 months of award. Describe the type of clinical trial to be performed (e.g., treatment, prevention, diagnostic), the phase of trial and/or class of device (as appropriate), and the study model (e.g., single group, parallel, crossover). Provide preclinical and/or clinical evidence to support the safety of the intervention.

- Identify the intervention to be tested and describe the projected outcomes. Describe how the proposed intervention compares with currently available interventions and/or standards of care. Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications (as appropriate).
- Describe the study population, and how the sample population represents the targeted patient population that might benefit from the proposed intervention. Explain the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random). Provide information on and justification for the inclusion and exclusion criteria. Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment.
- Describe the strategy for the inclusion of women and minorities in the clinical research appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and/or ethnicity, and an accompanying rationale for the selection of subjects. It is not expected that every study will include all genders and racial and ethnic groups. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this requirement. The Policy on Inclusion of Women and Minorities, and Frequently Asked Questions for the policy may be downloaded from eBRAP under “Resources and Reference Material” at <https://ebrap.org/eBRAP/public/Program.htm>.
- Describe the process for obtaining informed consent and any screening procedures required to determine eligibility for study participation. Describe the degree to which the informed consent, screening, and retention processes for human subjects will meet the needs of the proposed clinical trial.
- Define each arm/study group of the proposed trial, if applicable. Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures). Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers). If multiple site studies are involved, state the approximate number of subjects to be enrolled at each site.
- Outline the timing and procedures planned during the follow-up period. Estimate the potential for subject loss to follow-up, and how such loss will be handled/mitigated.

- Provide evidence to document the availability of and access to all critical reagents, including the intervention itself, if applicable, for the duration of the proposed trial.
 - Describe how quality control will be addressed. Describe how compliance with current Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), and Good Clinical Practice (GCP) guidelines will be established, monitored, and maintained, as applicable.
 - Describe the composition of the clinical trial team. Provide details on how the team (including investigator(s), study coordinator, and statistician) possesses the appropriate expertise in conducting clinical trials.
 - If applicable, describe measures taken to ensure the consistency of dosing of active ingredients for nutritional supplements.
- **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 will demonstrate 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 2 CFR 200.315, “Intangible Property.”
 - Intellectual and Material Property Plan: Provide a plan for resolving intellectual and material property issues among participating organizations.
- Use of DOD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.
- Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **Attachment 3: Technical Abstract (no page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

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

- **Overarching Challenge:** Identify the unifying, overarching challenge or question that will be addressed by the research plan and describe how it relates to a critical

problem or question in at least one of the FY21 PRMRP Topic Areas. If applicable, also state which FY21 PRMRP Area(s) of Encouragement the proposed research addresses.

- **Background:** Briefly articulate the rationale for the overarching challenge and the proposed research.
- **Research Plan:** Provide a brief description of the studies proposed, including hypotheses, objectives, and scientific approach.
- **Impact:** Briefly describe the potential short-term and long-term impact of the results of the proposed research on at least one of the FY21 PRMRP Topic Areas and its related research field(s) and patient population(s).
- **Relevance to Military Health:** Explain how the effort is relevant to the healthcare needs of military Service Members, Veterans, and/or beneficiaries.
- **Attachment 4: Lay Abstract (no page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.
- ***Lay abstracts must be provided for the overall program, as well as each individual project, with the abstract for each project starting on a separate page.*** Describe how the proposed research program addresses at least one of the FY21 PRMRP Topic Areas. Include a comprehensive overview of the effort that can be ***readily understood by readers without a background in science or medicine.*** Clearly describe the critical problem or question to be addressed and the ultimate applicability and impact of the research. ***Do not duplicate the technical abstract.***
- **Attachment 5: Statement of Work (no-page limit): Upload as “SOW.pdf”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>.

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

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

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

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

- Explain how the proposed overall program or project will make important scientific advances, will promote greater understanding of the causes and progression of the relevant disease(s) or condition(s), and/or will promote the development of improvements in prevention, detection, diagnosis, treatment, or quality of life in the FY21 PRMRP Topic Area(s) addressed. Describe how the overarching challenge addresses a critical problem or question in the relevant Topic Area(s). If applicable, describe how the program or project addresses an FY21 PRMRP Area of Encouragement ([Appendix 2](#)). For projects with clinical trials, explain how the sample population represents the targeted patient population that might benefit from the proposed intervention and how the outcome(s) will ultimately be translated to patients.
 - **Describe the short-term impact:** Detail the anticipated outcome(s)/product(s) (knowledge and/or materiel) that will be directly attributed to the results of the proposed research and their impact(s) on the lives of relevant patient populations.
 - **Describe the long-term impact:** Explain the anticipated long-term gains from this research. Compare to the information known/products currently available, if applicable. Explain the long-range vision for how the research will impact the field of study and/or patient care.
- **Attachment 7: Relevance to Military Health Statement (one-page limit): Upload as "MilRel.pdf".**
- Describe how the proposed effort 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 to be studied in the general population as well as in military Service Members, Veterans, and/or beneficiaries.
 - If active-duty military, military families, and/or Veteran population(s) or dataset(s) will be used in the proposed research project, describe the population(s)/dataset(s)

and the appropriateness of the population(s)/dataset(s) for the proposed study. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., military Service Members, Veterans, and/or beneficiaries).

- If applicable, show how the proposed research project aligns with DOD and/or VA areas of research interest and/or patient care. Provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to benefit the civilian population and address a military need, as appropriate.

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

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

- A description of the outcomes expected upon completion of the proposed research efforts. Outcomes should be specific and measurable, and should include the intended end user.
- Details of the funding strategy that will be used to bring the outcomes to the next phase of development and/or delivery to market or incorporation into patient care (e.g., specific potential industry partners, specific funding opportunities to be applied for).
- For knowledge outcomes, a description of how the knowledge will be further developed, disseminated, and incorporated into clinical/patient care.
- Details of the development plan and FDA regulatory strategy that will support the planned product indication, to include considerations for compliance with current GMP, GLP, and GCP guidelines (if applicable). Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy.
- A description of collaborations and other resources that will be used to provide continuity of development.
- A brief schedule and milestones for bringing the outcomes to the next phase of development (e.g., further research, clinical trials, transition to industry, delivery to the market, incorporation into clinical practice, approval by the FDA).

- If applicable, ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government’s ability to access such products or technologies in the future.
- **Attachment 9: Data and Research Resource Sharing Plan (one-page limit): Upload as “Sharing.pdf”.**
 - Describe how data and resources generated during the performance of the proposed research projects will be shared with the research community. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the proposed projects. Specifically describe a plan to make animal models, tissue samples, and other resources developed as part of the proposed research projects available to the scientific community. If there are limitations associated with a pre-existing agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data and/or research resource sharing plan. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
 - In preparing requested budgets, applicants may include anticipated costs associated with data and research resource sharing (i.e., making a large dataset available to the public or developing an important resource for the scientific community).
- **Attachment 10: IND/IDE Documentation: *Only applicable for applications that include a clinical trial(s).* If submitting multiple documents, start each document on a new page. Combine and upload as a single file named “IND-IDE.pdf”.** If more than one clinical trial is proposed, provide the below information for each trial/intervention. The IND/IDE Documentation Form located on the eBRAP website may not be used in place of this information.
 - State the product/intervention name.

For products/interventions that do not require regulation by the FDA:

- Explain why the product/intervention is exempt from FDA oversight. Provide confirmation that the trial does not require regulation by the FDA in writing from the IRB of record or the FDA. No further information for this attachment is required.

For products that require regulation by the FDA:

- State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the U.S.
- If the product is marketed in the U.S., state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using

- the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).
- If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification. Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor’s understanding of all sponsor responsibilities and commitment to oversee execution of the study.
 - If an IND or IDE is required, it should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed clinical trial. If an IND or IDE application has already been submitted to the FDA, provide the date of submission, the application number, and a copy of the FDA letter acknowledging the submission. If there are any existing cross-references in place, provide the application number(s) and associated sponsor(s). Provide an explanation of the status of the application (e.g., past the critical 30-day period, pending response to questions raised by the FDA, on clinical hold, on partial clinical hold). If the IND or IDE application has been placed on clinical hold or partial hold, explain the conditions that must be met for release of the hold. Provide a summary of previous meetings with the FDA on development of this product, if appropriate. A copy of the Agency meeting minutes should be included if available. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application. If the IND or IDE has not been submitted to the FDA yet, indicate when the application will be submitted to the FDA.
 - If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.
 - If an active IND or IDE for the investigational product is in effect, but an amendment is needed to include the proposed trial, describe the type and nature of the amendment(s) and the timeline for submission. Indicate whether the amendment increases the risk of the intervention.
 - Provide the current status for manufacturing development (e.g., manufacturer’s name, GMP-compliant lots available, status of stability testing), non-clinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support phase 1 testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).
 - **Attachment 11: Inclusion of Women and Minorities Inclusion Enrollment Report format: Upload as “IWAM.pdf”.** As applicable, for each proposed research project, provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and/or ethnicity. ***All project enrollment reports should be uploaded as a single combined file.*** Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this requirement. The suggested Inclusion Enrollment Report format, Policy on Inclusion

of Women and Minorities, and Frequently Asked Questions for the policy may be downloaded from eBRAP under “Resources and Reference Material” at <https://ebrap.org/eBRAP/public/Program.htm>.

- **Attachment 12: 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 13: 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. Include information that describes the PI’s background and expertise. All biographical sketches should be submitted in uneditable PDF format.

- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.

For extramural submissions, refer to the General Application Instructions, Section III.A.4 for detailed information.

For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch_LastName.pdf”.
 - Include a biographical sketch for each Project Leader.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.
 - Include previous/current/pending support for each Project Leader.

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 13](#). (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. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)

Applicant organizations and all sub-recipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Verify the status of the applicant organization’s Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the federal awarding agency is ready to make a federal award, the federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that determination as a basis for making a federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI): Through April 2022, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

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 anticipated direct costs budgeted for the entire period of performance will not exceed **\$7.2M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the government exceeding **\$7.2M** 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 must be requested for:

- Travel costs for the PI and up to three additional members of the research team to attend a 1-day DOD PRMRP Milestone Meeting to be held in the National Capital Area during the award period of performance. This meeting will be held to provide a presentation on progress. Costs associated with travel to this meeting should be included in year 3 of the budget. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all inclusive):

- Support for multidisciplinary collaborations, including travel.
- Costs for up to four investigators to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the PRMRP Focused Program Award.
- Travel costs for the PI to disseminate project results at one DOD-supported meeting (e.g., the Military Health Research Symposium).

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

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

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Overall Impact**
 - To what extent the overarching challenge impacts a critical problem or question in the field of research and/or patient care in the designated FY21 PRMRP Topic Area(s).
 - To what degree the proposed program could, if successful, make a significant impact on the lives of relevant patient populations in the short term or long term.
 - How well the research projects are not dependent upon each other but are interrelated and synergistic, and will advance toward a solution through a multidisciplinary approach.

- How well the research program will, if successful:
 - Make important scientific advances in the relevant field of research
 - Promote greater understanding of the causes and progression of the relevant disease(s)/condition(s), or
 - Promote the development of improvements in prevention, detection, diagnosis, treatment, or quality of life.
- **Implementation Plan**
 - How well the proposed projects are supported by a detailed implementation plan that identifies critical milestones and explains how these milestones will be achieved.
 - How well research resources and/or cores that will be created or leveraged will be utilized and shared.
 - To what extent the plans to assess individual project performance during the course of the award are appropriate.
 - How well the overall management plan will facilitate consistent and intensive interactions and communication by all team members.
 - How the proposed plans for communication, data and specimen collection, data transfer, and periodic meetings are appropriate.
 - To what extent the plans for creating, reviewing, implementing, and modifying Standard Operating Procedures are appropriate, if applicable.
- **Leadership and Environment**
 - To what degree the PI is experienced in successfully leading large, focused projects and is therefore well-positioned to lead the research team in achieving the overarching goal of the proposed effort.
 - How well the PI demonstrates experience, leadership skills, and commitment to making an impact in the relevant field of research and/or patient care.
 - Whether the PI will devote a minimum of 20% effort to this award.
 - To what degree the scientific environment(s) is appropriate for the proposed research.
 - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including patient populations, samples, and collaborative arrangements).
 - To what degree the quality and extent of organizational support are appropriate for the proposed research.

- **Transition Plan and Regulatory Strategy**

- The degree to which the strategy proposed to bring the anticipated outcomes to the next phase of development and/or clinical use, including funding, milestones, and schedule, is realistic and achievable.
- Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.
- Whether the regulatory strategy and development plan are appropriate and well described.
- How well the application identifies intellectual property ownership, and whether there is sufficient evidence of a plan to resolve intellectual and material property issues, if applicable.
- Whether the applicant has demonstrated they have access to all intellectual property rights necessary for development and commercialization, and evidence that the government has the ability to access such products or technologies, if applicable.
- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.

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

- **Impact**

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

- **Research Strategy and Feasibility**

- How well the scientific rationale supports the research and its feasibility, as demonstrated by a critical review and analysis of the literature, the presentation of preliminary data (where applicable), and logical reasoning.
- How well the hypothesis, objectives, and aims are developed.
- To what degree the experimental design, methods, endpoints, and analyses support completion of the aims and are designed to achieve rigorous and reproducible results.
- How well the choice of model (animal, human subjects or samples, or other) is justified and whether it is appropriate.

- If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
- To what degree the statistical plan and power analysis, including sample size projections, are appropriate for the proposed project, and will allow for a meaningful outcome.
- Whether there is sufficient evidence to support availability and accessibility of the populations, samples, or other resources required for the study, if applicable.
- How well potential problems are acknowledged and alternative approaches are addressed.
- **Personnel**
 - To what degree the project team’s background and expertise are appropriate with respect to its ability to perform the proposed work, including whether there is evidence of sufficient expertise for all aspects of the work and whether there is evidence of strong commitment to the projects.
 - To what degree the levels of effort are appropriate for successful conduct of the proposed work.

Scored Review Criteria for Individual Research Projects with clinical trials:

- **Impact**
 - To what extent the individual project impacts the overarching challenge.
 - How well the individual project will, if successful, make important scientific advances in the relevant field of research.
 - How well the sample population represents the targeted patient population that might benefit from the proposed intervention.
 - How the potential outcomes of the proposed clinical trial will provide/improve short-term benefits for individuals.
 - To what degree the long-term benefits for implementation of the intervention may impact patient care and/or quality of life.
- **Research Strategy and Feasibility**
 - How well the scientific rationale supports the research and its feasibility, as demonstrated by a critical review and analysis of the literature, the presentation of preliminary data, and logical reasoning.
 - How well the hypothesis and/or objectives and specific aims are developed.
 - To what degree the experimental approach, methods, endpoints, and analyses support completion of the aims and are designed to achieve rigorous and reproducible results.

- To what degree the statistical plan and power analysis, including sample size projections, are appropriate for the proposed trial and any proposed correlative studies, and will allow for a meaningful outcome.
 - How well the application demonstrates the availability of and access to the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects.
 - 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 and delays (e.g., slow accrual, attrition) are acknowledged and alternative approaches are addressed.
- **Clinical Strategy**
 - How the intervention compares with currently available interventions and/or standards of care.
 - Whether there is evidence of support, indicating availability of the intervention from its source, for the duration of the proposed clinical trial (if applicable).
 - To what degree the PI has provided preclinical and/or clinical evidence to support the safety of the intervention.
 - How well the inclusion and exclusion criteria meet the needs of the proposed clinical trial.
 - The degree to which the informed consent, screening, and retention processes for human subjects will meet the needs of the proposed clinical trial.
 - Whether a member of the study team holds the IND/IDE for the indication proposed or how well the documentation provided supports the feasibility of acquiring an active IND or IDE covering the proposed trial, if applicable.
 - For investigator-sponsored INDs, whether there is evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the FDA.
 - Whether plans to comply with current GMP, GLP, and GCP guidelines are appropriate.
 - Whether measures are described to ensure the consistency of dosing of active ingredients for nutritional supplements (if applicable).
 - **Personnel**
 - To what degree the project team's background and expertise are appropriate with respect to its ability to perform the proposed work, including whether there is evidence of sufficient expertise for all aspects of the work and whether there is evidence of strong commitment to the project.

- How well the project leader has assembled an appropriate and robust clinical team with the combined backgrounds and expertise needed to enable successful conduct of the clinical trial.
- To what degree the levels of effort are appropriate for successful conduct of the proposed work.

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

- **Data and Resource Sharing**

- To what degree the plan for sharing of project data and research resources is appropriate and reasonable to facilitate use by the wider research community.

- **Budget**

- Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.
- Whether the budget is appropriate for the proposed research.

- **Environment**

- If applicable, to what degree the intellectual and material property plan is appropriate

- **Application Presentation**

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

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY21 PRMRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Relevance to military health
 - Relative impact

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 **programmatically 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, on behalf of the DHA and the OASD(HA). ***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 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 200.88, 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 FY21 funds are anticipated to be made no later than September 30, 2022. 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 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 other non-profit organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Application Instructions, Section III.A.5.

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

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

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

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

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

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

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

II.F.2. Administrative and National Policy Requirements

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

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

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

Refer to full text of the latest [DoD R&D General Terms and Conditions](#); 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.

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.

Awards resulting from this program announcement will incorporate 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 \$10,000,000 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. 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. CDMRP 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 CDMRP 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 CDMRP 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 601a. The program announcement numeric version code will match the General Application Instructions version code 601.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

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

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

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

- An FY21 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 FY21 PRMRP Programmatic Panel members can be found at <https://cdmrp.army.mil/prmrp/panels/panels21>.*
- 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 FY21, 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. Refer to [Section II.D, Application and Submission Information](#), for exceptions.
- The proposed research project does not address at least one of the Congressionally directed FY21 PRMRP Topic Areas.
- The PI and/or project leaders do 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. 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"	
	Data and Research Resources Sharing Plan: Upload as Attachment 9 with file name "Sharing.pdf"	
	IND/IDE Documentation: Upload as Attachment 10 with file name "IND-IDE.pdf" if applicable	
	Inclusion of Women and Minorities Inclusion Enrollment Report: Upload as Attachment 11 with file name "IWAM.pdf" if applicable	
	Representations (extramural submissions only): Upload as Attachment 12 with file name "RequiredReps.pdf" if applicable	
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 13 with file name "MFBudget.pdf" if applicable	

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

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
ALS	Amyotrophic Lateral Sclerosis
ARDS	Acute Respiratory Distress Syndrome
ARRIVE	Animal Research: Reporting <i>In Vivo</i> Experiments
B	Billion
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CFS	Chronic Fatigue Syndrome
DHA	Defense Health Agency
DHP	Defense Health Program
DOD	Department of Defense
DODGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
EAB	External Advisory Board
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FH	Familial Hypercholesterolemia
FTD	Frontotemporal Degeneration
FXPOI	Fragile X-Associated Primary Ovarian Insufficiency
FXTAS	Fragile X-Associated Tremor/Ataxia Syndrome
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HIV	Human Immunodeficiency Virus
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board

M	Million
ME	Myalgic Encephalomyelitis
MIPR	Military Interdepartmental Purchase Request
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
PRMRP	Peer Reviewed Medical Research Program
RDT&E	Research, Development, Test, and Evaluation
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	Department of Veterans Affairs

APPENDIX 2: AREAS OF ENCOURAGEMENT

Applications addressing any of the FY21 PRMRP Topic Areas are of interest to the program. ***Any aspect of research relevant to an FY21 PRMRP Topic Area may be considered for funding.*** Areas of Encouragement related to each FY21 PRMRP Topic Area have been identified by the DOD, VA, and other relevant stakeholders and are listed below under each Topic Area. Applicants are strongly urged to read and consider these Areas of Encouragement before preparing their applications. ***The information provided is not exhaustive, and applicants are not restricted to submitting applications that address an Area of Encouragement on this list.***

Arthritis (other than [Rheumatoid Arthritis](#), which is a separate Topic Area listed below)

- Research quantifying the impacts of obesity, weight loss, physical fitness (all components, e.g., cardiovascular, strength, flexibility, balance), and dietary factors on the development of or prevention/risk reduction of arthritis.
- Determine factors that lead to accelerated degeneration (post-traumatic osteoarthritis within 3 years) following military-relevant joint injuries.
- Basic and translational research to identify treatments to mitigate and/or reverse osteoarthritis.
- Research to establish activity recommendations for maximal joint life following joint repair, particularly in young patient populations.
- Intra-articular treatments that offer sustained relief of symptoms and/or disease-modifying effects compared to current treatments.
- Research on therapies that target multiple phases of the cellular response pathways that are implicated in the development of arthritis, including cell death, oxidative stress, inflammation, mechanotransduction, matrix changes, and changes in metabolic responses.
- Identification and/or validation of diagnostic biomarkers that can serve as surrogate endpoints.

Burn Pit Exposure

- Research on the etiology and pathophysiology of adverse health events associated with exposure to airborne hazards and/or open burn pits.
- Development of improved methods for assessing and treating lung injury due to chemical, metal, or smoke inhalation/exposure.
- Toxicological studies to characterize emissions from open air burns, burn boxes, incinerators, and simulated burn pits to ascertain the toxicity and mechanisms of action of such chemicals and airborne environmental dust and mixtures, as well as interactions among pollutants and particulate materials.

- Validation of biomarkers and development of fieldable assays, particularly from the lung microbiome, of exposure to burn pit combustion products, burning biomass and refuse, and geogenic dusts.
- Development and validation of sensors/instruments for assessing (including in real time) area and/or individual levels of exposure to airborne hazards for use in research and for occupational and environmental exposure monitoring.
- Studies exploring the effect of combination traumatic lung injury and burn pit exposure.

Cardiomyopathy

- Development of novel therapeutic approaches for primary and secondary cardiomyopathies.
- Strategies to identify risk factors associated with the development of cardiomyopathy (i.e., genetic, lifestyle, exposure) in the civilian and/or military populations.
- Research to improve the understanding of the pathophysiology of cardiomyopathies.
- Improvement of noninvasive diagnostic techniques for primary and secondary cardiomyopathies.
- Research on the multiple etiologies of cardiomyopathy (e.g., hypertension, ischemia, hemochromatosis, sleep apnea, radiation therapy, medications, smallpox vaccine, infections).

Congenital Heart Disease

- Development of approaches, including regenerative medicine, that provide structural support, restore native activity, allow for tissue growth, and prevent the need for reoperation.
- Population-based or outcomes-based research to assess the health outcomes of individuals with congenital heart disease across their life spans.
- Research to improve understanding of the causes of congenital heart defects, including genomic, proteomic, and metabolomic profiling.
- Research to design and implement improved or novel models (in vitro or in vivo) with an established phenotype to increase the efficacy of discovering drug targets, screening existing drugs, performing cardiotoxicity testing, or uncovering pathogenesis.
- Research both on the risk of neurologic injury and on enhanced neuroprotection before, during, and after surgery for congenital heart disease.

Diabetes

- Identification and/or evaluation of interventions to reduce metabolic dysregulation and the development of diabetes among individuals meeting the clinical criteria for prediabetes.

- Research on interventions to prevent or treat diabetes complications, including diabetic retinopathy, nephropathy, neuropathy, cardiomyopathy, and impaired wound healing.
- Understanding factors/mechanisms responsible for adverse metabolic effects (insulin resistance, beta cell dysfunction, dyslipidemia, nonalcoholic fatty liver disease) of obesity and why some people with obesity are protected from the adverse metabolic effects of excess adiposity.
- Research to understand immunologic contributions to pathophysiology and treatment of adult onset type 1 diabetes, which comprises 25% of all type 1 diabetes cases.
- Research to better understand the heterogeneity of diabetes including the identification of novel biomarkers (especially the metabolomics biomarkers that are common between diabetes and post-traumatic stress disorder).
- Research on the transplantation of allogenic or autologous pancreatic islet cells for long-term natural insulin production, including current good laboratory/clinical/manufacturing practices (as needed) for cell line development.
- Research to design and implement improved or novel models (in vitro or in vivo) to model pancreatic islets to uncover pathogenesis and improve the efficiency of drug discovery.
- Research to improve sensitivity and functionality of biosensor systems to improve quality of life for users.

Dystonia

- Research to improve identification of delayed onset dystonia following traumatic brain injury.
- Research on interventions to prevent, slow the progression of, or treat dystonia.
- Studies into the natural history, genetics, and/or neurobiology of dystonia.
- Research to identify the relationship between specific molecular/genetic changes and circuitry/network alterations in dystonia.
- Identification and development of novel research tools (cellular models, phenotypic models, etc.) to aid dystonia research.

Eating Disorders

- Studies to identify the most effective treatment or preventive strategies for patients with an eating disorder, including those with a comorbid disorder.
- Studies on the pathophysiological consequences of eating disorders, including effects on organ functions and metabolic processes.

- Assessment of patterns of comorbidity between eating disorders and other mental health conditions, including an examination of whether eating disorders are more likely to precede or follow the development of other mental health conditions.
- Research to advance the understanding of the biological, genetic, lifestyle, and/or environmental factors or the effects of social media on eating disorders.
- Investigations into the prevalence, diagnosis, risk factors, and treatment patterns of eating disorders.

Emerging Viral Diseases

- Predictive modeling tools that leverage advanced analytics (machine learning, artificial intelligence, etc.) approaches to predict outbreaks and epidemics and support strategies for mitigating the threat of emerging viral diseases as defined by the National Institute of Allergy and Infectious Diseases.¹
- Rapid prediction of protective antigens/epitopes and testable correlates of protection on emerging or novel pathogens with an emphasis on emerging respiratory viruses with epidemic potential.
- Development of a highly sensitive diagnostic system for use at the point of injury that provides early diagnosis of viral infection prior to the onset of classical symptoms.
- Research, development, and validation of animal models for the study of emerging viral diseases, including novel infections such as the WHO's Disease X,² that demonstrate the pathophysiological mechanism of the disease and provide translational data to advance drug products to human clinical trials.
- Development of meaningful and relevant immunological and virological readouts that translate and/or predict human responses to vaccination or infection.
- Development of risk assessment strategies for vector-borne diseases and novel interventions for vector control, including but not limited to novel insecticides, larvicide applications, and barrier methods.

Endometriosis

- Research to elucidate the underlying pathogenesis, evolution, pathophysiology, and progression of endometriosis. (How does it start, why does it start, and why does it get so bad in some women?)
- Improve detection and diagnosis of endometriosis through non-invasive techniques.

¹ <https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens>

² <https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts>

- Development of novel treatments, including non-opioid pain therapies, or alternative therapies to alleviate symptoms and reduce progression and secondary effects of endometriosis such as pain, scarring, and infertility.
- Research to identify risk factors for subsequent cancer development, such as endometrioid and clear cell ovarian cancer.
- Research to optimize surgical techniques that improve fertility in endometriosis patients and reduce progression and symptoms of disease.

Epidermolysis Bullosa

- Research, including clinical trials, focused on therapeutics (topical or systemic) or dressings that enhance wound healing in inherited epidermolysis bullosa.
- Development of novel therapeutics to reduce epidermolysis bullosa symptoms, improve quality of life, or lead to a cure.
- Research to provide further insight into those cellular pathways that promote the development of squamous cell carcinomas in recessive dystrophic and junctional epidermolysis bullosa.
- Research, including randomized controlled clinical trials, focused on systemic drugs that prevent, delay the onset, or modify the aggressiveness of squamous cell carcinoma in patients with recessive dystrophic and junctional epidermolysis bullosa.

Familial Hypercholesterolemia

- Research to understand the approaches to clinical management to treat familial hypercholesterolemia (FH) patients at higher risk for progressing to clinical atherosclerotic cardiovascular disease.
- Gene editing or gene therapy studies addressing monogenic causes of FH.
- Research to improve early diagnosis of FH and the implementation of diagnostic tools, including in the pediatric population.
- Development of evidence-based approaches for risk stratification to understand FH disease progression and comorbidities (e.g., early onset cardiovascular disease and coronary artery disease), including panomic (genomics, proteomics, metabolomics, transcriptomics, and clinical data) studies to identify and evaluate polygenic risk factors.
- Studies to identify social and/or biological disparities in diagnosis and treatment and how they affect risk.
- Studies to systematically identify individuals at risk for FH using machine learning tools.

Fibrous Dysplasia

- Research to better understand the underlying pathophysiology of fibrous dysplasia, including elucidating any genetic and cellular signaling factors that contribute to pathogenesis.
- Research that explores the prevention of lesion development or expansion in adolescents, or the development of implants that accommodate adolescent growth.
- Research to develop or better characterize animal models of fibrous dysplasia to assist in understanding disease pathogenesis, discover relevant biomarkers, or evaluate therapeutic efficacy.
- Research to discover and explore novel effective therapies for fibrous dysplasia outside of surgical interventions.
- Development of novel diagnostic tools for early and accurate detection of fibrous dysplasia.

Focal Segmental Glomerulosclerosis

- Development of a curative therapy or treatments to delay or halt the progression of focal segmental glomerulosclerosis and/or prevent post-transplantation recurrence.
- Research to improve understanding of the causes of primary and/or secondary focal segmental glomerulosclerosis, including genetic mutations, lifestyle factors, or comorbidities.
- Development of non-invasive methods to diagnose focal segmental glomerulosclerosis and its variants, especially in newborn or pediatric diagnostics for early detection and intervention.
- Research to determine the efficacy of medications used off-label (outside the U.S. Food and Drug Administration [FDA]-approved indication) to treat focal segmental glomerulosclerosis.
- Development of surrogate endpoints to accelerate approval of new treatments.

Food Allergies

- Studies to investigate the role of immunoglobulin E in the development or treatment of food allergies.
- Studies to understand cellular immunologic contributions to development or treatment of food allergies.
- Studies to determine the role of maternal diet on the incidence of food allergies in children.
- Research to understand the impact of environment (urban versus rural) on the incidence and type of food allergy.

- Studies aimed at determining the relationship between gut permeability and food allergies and manipulation of the biome to prevent, mitigate, and treat food allergies.
- Studies to understand the link between the food-processing techniques and food allergies.

Fragile X

- Development and evaluation of gene modification (e.g., gene editing or gene reactivation) therapeutics for the treatment of fragile X syndrome (including fragile X-associated tremor/ataxia syndrome [FXTAS] and fragile X-associated primary ovarian insufficiency [FXPOI]).
- Identification and validation of functional measures of the manifestations of fragile X syndrome (including FXTAS and FXPOI) across the life span.
- Research to advance the understanding of the pathophysiology/natural history or life course of fragile X syndrome (including FXTAS and FXPOI).
- Identification of novel targets and/or testing novel or existing therapeutics (e.g., repurposing drugs) for fragile X syndrome (including FXTAS and FXPOI).
- Research to establish the benefits of early diagnosis/early treatment of fragile X syndrome in patients and progeny.
- Development of a preclinical model that is representative of human fragile X syndrome.
- Development and testing of behavioral interventions to improve symptoms of fragile X syndrome.

Frontotemporal Degeneration

- Basic research to establish in vivo and in vitro models or research tools for disease pathology, behavioral/cognitive symptoms, or the frontotemporal degeneration/amyotrophic lateral sclerosis (FTD/ALS) spectrum.
- Research to understand the neurological basis of deficits in social cognition and emotional regulation.
- Research to improve diagnostics of and/or prognostics for frontotemporal degeneration and related proteinopathies.
- Research to identify risk factors (e.g., gene or epigenetic networks, environmental factors, and family history of neurodegeneration or linked to FTD/ALS gene mutations).
- Development/advancement of evidence-based treatments (including pharmacological and non-pharmacological) for FTD and associated disorders.

Hemorrhage Control

- Development of new and innovative capabilities to stop non-compressible intracavitary hemorrhage as well as improved technologies to stop junctional and pelvic bleeding in pre-hospital environments.
- Development of battlefield hemostatic wound solutions or dressings with integrated antimicrobial and/or analgesic effects. Hemostatic effects should arrest major hemorrhage within 3 minutes of placement.
- Development of innovative damage control resuscitation and damage control surgical and non-surgical capabilities, especially interventions to be used in an austere environment by physician or non-physician providers.
- Research on strategies (e.g., innovative technologies, wearable devices, analyte indicators) for early (e.g., pre-hospital) detection (especially internal bleeding) and treatment for hemorrhage, coagulopathy of trauma, and hemodynamic decompensation/hypovolemic shock.
- Research on novel or engineered blood products that offer physiological, logistical, or cost advantages over current products. Hemoglobin-based oxygen carrier research should address nitric oxide scavenging.
- Research on adjunctive pharmacological solutions for hemorrhage, shock, coagulopathy, transfusion, and/or the stabilization of polytrauma, with attention to the impact on potential traumatic brain injury.
- Research to evaluate the effects of current combat blood product transfusion guidelines on immunological status and clinical outcomes.
- Research on treatment of mitochondrial dysfunction during hemorrhagic shock.

Hepatitis B

- Impact of co-infection with hepatitis C or human immunodeficiency virus (HIV) on hepatitis B pathogenesis.
- Research on strategies to reduce vertical (mother-to-child) transmission of hepatitis B.
- Development of strategies for reliable, non-invasive, early detection of hepatitis-related liver disease and hepatocellular carcinoma.
- Research on strategies to promote reversal of liver fibrosis and/or assess the associated clinical and pathological outcomes.
- Clinical studies to evaluate combination or curative therapies for treatment of hepatitis B infection.

- Basic/translational research leading to new therapies for viral hepatitis and hepatocellular carcinoma.

Hydrocephalus

- Research on the etiology, prevention, diagnosis, and treatment of post-traumatic hydrocephalus.
- Discovery or validation of novel and/or innovative therapies and therapeutic targets for the treatment of hydrocephalus and its sequelae, including therapies directed at myelin regeneration and repair.
- Development or validation of biomarkers and imaging techniques, particularly multimodal approaches, to aid in diagnosis, prognosis, and monitoring of therapeutic efficacy.
- Research on the prevention of shunt failure or the development of novel shunt technologies.
- Development or validation of improved hydrocephalus model systems.

Hypertension

- Studies that leverage digital phenotyping, genomic, metabolomic, microbiomic, immunological, and/or other systems approaches to identify objective markers of increased risk of hypertension, including hypertension associated with post-traumatic stress, acute stress disorder, and/or other stress-related psychological conditions and diagnoses.
- Research on the etiology, prevalence, and trends of hypertension in children and adolescents.
- Research on the vascular structure changes in pre-hypertensive individuals, especially in children and adolescents.
- Research to develop inexpensive and effective tools to detect secondary hypertension and its causes at an early stage (e.g., diagnostic algorithms).
- Research to understand ethnic/racial differences in the pathophysiology of hypertension and the response to treatments.
- Research to elucidate the impact of hypertension on the heart, brain, arteries, and other target organs across a patient's life span.

Inflammatory Bowel Diseases

- Studies directed toward understanding how acute enteric infections may trigger chronic inflammatory bowel diseases, including studies aimed at elucidating the interactions between chronic/post-traumatic stress and infection that may provoke inflammatory bowel disease.

- Studies that leverage genomic, metabolomic, microbiomic, immunological, and systems biology approaches to prevent or treat inflammatory bowel disease (especially inflammatory bowel diseases associated with acute enteric infection).
- Studies to elucidate pathological processes involved in inflammatory bowel disease-related complications, such as strictures or primary sclerosing cholangitis, or progression to cancer with the goal of prevention or treatment.
- Research on the role of diet in the development and progression of inflammatory bowel diseases.
- Research on treatment strategies for patients with inflammatory bowel diseases to include, but not limited to, microbiome-related and those that target epithelial health and function strategies, including those who are refractory to standard care.

Malaria

- Investigation of mechanisms of drug resistance in malaria, to include host, pathogen, and region-specific resistance against drugs used for treatment and prophylaxis.
- Studies to determine the levels of naturally occurring resistance to currently used prophylactic drugs in endemic regions of the world.
- Development of long-lasting (6 months) passive immunization approaches for the management of malaria.
- Identification of novel and/or innovative malaria drug targets for blood and liver stage malaria parasites.
- Studies evaluating co-infections with malaria, including host susceptibility and changes in risk.

Metals Toxicology

- Validation of biomarkers and development of fieldable assays to evaluate acute exposure to toxic metals by inhalation and/or ingestion (e.g., drinking water).
- Development of microsurgical techniques to remove embedded toxic metals.
- Understanding the effects of embedded metals as a confounder on medical treatment of trauma injury and patient outcomes.
- Evaluating the long-term effects of exposure to nano/micro/airborne/aerosolized or non-removable embedded toxic metals.
- Studies exploring the effect of combination traumatic injury and exposure to toxic metals.
- Retrospective studies to evaluate risks and exposure to toxic metals among workers at industrial facilities.

Mitochondrial Disease

- Research on novel and/or innovative treatments to alleviate symptoms or slow down the progression of mitochondrial diseases.
- Development of tools and methodologies to assess mitochondrial heteroplasmy on a cellular, tissue, and organ level.
- Identification and testing of non-invasive techniques and biomarkers to monitor mitochondrial function, aid in clinical diagnosis, and/or evaluate therapeutic efficacy.
- Development of improved tools and animal models to study primary mitochondrial diseases and evaluate therapeutics.
- Development of tools to distinguish whether mitochondrial dysfunction is inherited or acquired.
- Research to better understand the progression of mitochondrial diseases.

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome

- Development and testing of treatments or preventive measures for myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS).
- Research to understand the mechanisms underlying ME/CFS.
- Epidemiological research to understand the link between medical history and ME/CFS.
- Research to identify biomarkers to diagnose and test potential therapeutics for ME/CFS.

Myotonic Dystrophy

- Research on the role of epigenetic factors in the onset, progression, and/or severity of myotonic dystrophy in relevant animal models or patients.
- Research into the mechanisms of expanded CTG or CCTG repeat instability in somatic or germ line cells in myotonic dystrophy.
- Identification of biomarkers that can be detected through minimally invasive means to signal early changes in the progression of myotonic dystrophy, especially in myotonic dystrophy type 2.
- Development and/or testing of novel and/or innovative treatments, including those utilizing gene editing or silencing.
- Clinical research into the natural history of myotonic dystrophy in order to understand disease progression and develop/validate clinical trial endpoint measures across the multiple organ systems involved in the disease.

Non-Opioid Therapy for Pain Management

- Development of non-opioid, non-addictive pain management therapies, including non-pharmacological interventions and those that do not affect the cardiorespiratory system.
- Research to identify and address biopsychosocial aspects of pain to reduce or eliminate the use of opioid pain medication(s).
- Research to identify and reduce disparities in opioid prescribing practices for pain management.
- Research on non-opioid, non-addictive pain management strategies for patients with limited access to skilled providers and resources, including battlefield and resource-limited environments.

Nutrition Optimization

- Research into nutrition-based strategies to prevent or reduce the impact of disease.
- Determining therapeutic effects and mechanisms of selected diets (Mediterranean, plant-based low-fat, low-carb, etc.) in people with obesity and other metabolic diseases.
- Development or validation of nutrition-based strategies that mitigate the consequences of environmental and/or physiological stressors.
- Development of prolonged nutrition care using oral and/or intravenous approaches including precision nutrition care following injury or illness.
- Research on the impact of the use of nutrition strategies or dietary supplements on physical or cognitive performance.
- Development or validation of improved nutrition strategies to enhance and sustain performance in operational environments, extreme climates/weather, or resource-limited settings.
- Research to develop strategies to apply metabolomics to optimize individual nutrition and the development of tools or devices to monitor nutritional intake at an individual level.
- Research to study how diet or changes to the gut microbiome impact brain health.
- Investigation into treatment strategies for obesity and weight management therapies, especially in the VA Health Care System.

Pathogen-Inactivated Blood Products

- Development and validation of next-generation technologies and/or devices to reduce the production time, increase portability, decrease weight, or develop unpowered technologies for pathogen reduction/inactivation in whole blood.

- Research on lyophilization of pathogen-reduced/-inactivated blood products and derivatives (platelets, plasma, red cells, cryoprecipitate, coagulation factors, etc.).
- Development and advancement of technologies to improve the safety of blood products to include pathogen reduction/inactivation in whole blood for military/civilian blood donor centers and blood banks that meet the requirements for FDA licensure in support of domestic and global contingency/combat operations.
- Expansion and validation of the library of blood-borne pathogens that are reduced/inactivated to include emerging pathogens, genetically modified pathogens, and pathogens designed for biological warfare.
- Advancement in pathogen reduction technology to further improve the log-kill reduction for known blood-borne pathogens (e.g., hepatitis B, hepatitis C, cytomegalovirus, Korean hemorrhagic fever virus, Bunyaviruses, HIV, Rift Valley fever virus, malaria, *Trypanosoma cruzi* and *T. brucei*, Ebola virus, West Nile virus, dengue virus, chikungunya virus, Zika virus).
- Research studies, including clinical trials, to further characterize the effects of pathogen reduction technologies in blood products (e.g., whole blood, platelets, plasma, cryoprecipitate).

Peripheral Neuropathy

- Research on the role of intense physical training, especially in a military setting, in the rapid onset and progression of hereditary neuropathy with liability to pressure palsies.
- Research on treatment strategies for patients with hereditary peripheral neuropathy.
- Research on the etiology and/or progression of idiopathic neuropathy with a focus on clinical description and clinical studies.
- Mechanistic studies to inform the treatment development for diabetic neuropathy or chemo-induced neuropathy.
- Research to discover and develop novel effective non-pharmacological therapies for idiopathic neuropathy or other peripheral neuropathy such as those induced by diabetes or chemotherapy.
- Regenerative medicine based solutions for peripheral nerve injury, such as gene therapy.
- Research on the etiology and progression of peripheral neuropathies associated with autoimmune diseases.
- Refinement of existing or development of new model systems (in vivo and in vitro) that better represent a neuropathy disease state and progression of the particular neuropathy.

- Addition of new sites to the consortium supporting the Peripheral Neuropathy Research Registry biobank housing DNA sample, plasma and serum, and associated data such as demographics, medical history of patient and family, lab and clinical tests from peripheral neuropathy patients (<https://www.foundationforpn.org/research/research-registry>).

Plant-Based Vaccines

- Optimize expression and purification systems for plant-based vaccine production.
- Research to demonstrate safety and efficacy of plant-based vaccines, including oral administration of non-purified forms, such as food or feed product.

Platelet-Like Cell Production

- Development of a lyophilized or manufactured platelet-like cell product that reduces hemorrhage or dilutional coagulopathy with a safety and efficacy profile that demonstrates compatibility with licensed blood products or derivatives (red blood cells, plasma – liquid or dried, platelets, cryoprecipitate, fibrinogen, albumin, etc.).
- Development of a lyophilized platelet-like product that provides universal compatibility, a shelf life of 2-3 years, and immediate reconstitution with sterile water/buffered solution and that is pathogen-reduced and a pooled product (e.g., 10 donors).
- Research toward early-stage animal model studies (safety) and first-in-human efficacy in clinical trials.

Polycystic Kidney Disease

- Development of improved treatment strategies for polycystic kidney disease, including approaches to identify and monitor patients at higher risk for progressing to end-stage renal disease.
- Research on the underlying pathobiology and molecular mechanisms of polycystic kidney disease, including studies of genetic factors, cyst formation and growth, the role of cilia, and factors that modify disease progression and/or severity.
- Research on the lifestyle factors or comorbidities that may modify the progression of polycystic kidney disease.
- Development of surrogate endpoints to accelerate approval of new treatments.

Pressure Ulcers

- Strategies to prevent or reduce the formation of pressure ulcers during prolonged immobilization of casualties in a pre-hospital environment (e.g., spinal cord injuries) or long-range transport/aeromedical evacuation.

- Development of (novel) point-of-care diagnostics or tools, such as artificial intelligence or algorithms using structured or unstructured data, for detecting early formation of pressure ulcers.
- Novel strategies for the treatment of pressure ulcers, including the mitigation of progression to advanced stages.
- Research on novel synthetic production, delivery, and adhesion methodologies leading to permanent closing of pressure ulcers. Methodologies might encompass synthetic fibers, novel tissue culture methodologies, growth factors, dermal printing, artificial skin, skin graft substitutes, regenerative medicine, etc.
- Development of novel wound healing and infection prevention strategies that are easy to administer and will prevent bacterial colonization, biofilm formation, and sepsis with extended activity (e.g., up to 72 hours) once placed.

Pulmonary Fibrosis

- Development and/or testing of novel and/or innovative treatments, including precision medicine approaches, to delay or modify the progression of pulmonary fibrosis.
- Development and/or validation of improved in vitro and in vivo models (excluding mice) to study pulmonary fibrosis and evaluate therapeutics.
- Identification of biomarkers of pulmonary injury or early predictors of interstitial lung disease.
- Research into the pathobiology and molecular mechanisms underlying the development and progression of pulmonary fibrosis.
- Retrospective studies to determine the risk and incidence of pulmonary fibrosis among military Service Members and/or Veterans.

Respiratory Health (excluding lung cancer and mesothelioma)

- Development and/or testing of novel and/or innovative treatments including precision medicine approaches, to prevent, or delay the progression of, acute lung injury (ALI)/acute respiratory distress syndrome (ARDS).
- Research on the etiology and prevention of ARDS caused by host responses to trauma, transfusion, mechanical ventilation, burns, infection, hemorrhagic shock, inhalation, and/or oxygen exposure.
- Development of improved methods for assessing and treating lung injury due to inhalation burn or high-dose radiation exposure.

- Strategies to stabilize and support the safe transport of patients with ARDS in order to optimize therapeutic interventions, particularly in operational scenarios requiring prolonged or extended care and/or longer transport times prior to definitive care.
- Studies to identify the prevalence and associated morbidity and mortality of blast overpressure, including combined overpressure and burn/lung injury.
- Research on the causes, treatment, and prevention of obstructive pulmonary diseases (e.g., chronic obstructive pulmonary disease and bronchiectasis), including identification and validation of biomarkers and disease phenotypes, as well as employing personalized medicine in clinical research and disease management.
- Development of biomarker metrics to associate the long-term health outcomes of ARDS with degradation of physiological and physical performance.
- Research on airborne chemical and pollution hazards that affect lung function associated with specific acute health outcomes for first responders or deployed Service Members.
- Research focused on acute and chronic lung injury/disorders due to viral infections, such as SARS-CoV-2.

Rheumatoid Arthritis

- Research to better understand the relationship between genetic risk, environmental exposures, and triggers in developing rheumatoid arthritis.
- Studies that identify or validate biomarkers or personalized medicine strategies that allow for individualized medication choice based on the patient's underlying biology or disease state.
- Research on the long-term use of immunosuppressive and other therapies in patients with rheumatoid arthritis.
- Research to better characterize and understand the preclinical disease stage of rheumatoid arthritis for early diagnosis and treatment.
- Research on management of comorbidities, including biopsychosocial outcomes, for patients with rheumatoid arthritis.
- Research to establish activity recommendations following joint replacement for maximal joint life.

Sleep Disorders and Restriction

- Research on the effects of disrupted normal sleep and circadian rhythms on the physical and psychological health, safety, performance, and productivity, including sex differences.

- Research on the physiology or treatment of sleep alterations in critically ill and injured patients.
- Research on the prevention and/or mitigation of sleep disorders and sleep restriction.
- Development and/or testing of non-pharmacological treatments for sleep disorders associated with long-term exposure to limited daylight or enclosed environments (e.g., aircraft, submarines, and/or tanks).
- Research on the objective screening and triage, precision diagnosis, management, and/or treatment (including non-pharmacological treatments such as cognitive behavioral interventions) of sleep disorders, especially following traumatic brain injury and/or related to post-traumatic stress disorder.
- Research to examine the impact of cognitive behavioral interventions, or other non-pharmacological interventions among Service Members post-deployment for preventing chronic sleep disruption.

Suicide Prevention

- Research on treatment strategies to prevent suicidality.
- Research to examine effectiveness of public health interventions, including which interventions or combinations of interventions are most helpful, and under what specific circumstances are interventions most helpful.
- Determining strategies for an efficacy of lethal means safety and restriction methods, especially in military populations.
- Determination of risk factors and prevention strategies for suicide in those that have recovered from critical illness, polytrauma, and/or traumatic brain injury.
- Research on effective public messaging, tools, policies and practices for communications and public awareness to reduce suicide risk and rates in the population (e.g., reducing barriers to help-seeking while avoiding risks of normalizing suicidal behavior, safe messaging, encouraging help-seeking, normalizing lethal means safety practices).

Sustained Release Drug Delivery

- Development of technology platforms or formulations for long-term sustained-release delivery of drugs, especially for radiation pre-exposure prophylaxis, post-traumatic stress disorder, substance use or abuse, suicidality, pain control, allergies, attention deficit/hyperactivity disorder, and chemoprophylaxis for any condition.
- Development of a sustained drug delivery system for pre-hospital trauma and pain medications for up to 24 hours prior to definitive care, including passive slow release or closed loop feedback delivery solutions, particularly in far-forward military operational environments.

- Development of a delivery system (including novel Good Manufacturing Practice-grade biomaterials) that could accurately deliver prescription and non-prescription medications.
- Development of novel and/or innovative approaches for bioavailable and sustained-release oral formulations of existing broad-spectrum fungicidal, antimicrobial, antiparasitic, and antiviral medications.
- Research into techniques to provide sustained release of drugs in tissue repair applications, such as bone or nerve regeneration or vision restoration.

Vascular Malformations

- Studies into the natural history, genetics, and pathogenesis of vascular malformations, including, but not limited to, lymphatic, capillary, venous, and arteriovenous and hemangiomas.
- Research to develop or improve methods to diagnose and manage vascular malformations, including, but not limited to, lymphatic, capillary, venous, and arteriovenous and hemangiomas.
- Research to discover or develop novel and/or innovative therapeutic targets and treatments to regress or prevent vascular malformations (both hereditary and acquired) including, but not limited to, lymphatic, capillary, venous, and arteriovenous and hemangiomas.
- Development of non-invasive or minimally invasive technologies or approaches for the control of internal bleeding, including cerebral arteriovenous malformations, associated with vascular malformations.
- Development of in vivo or in vitro models of vascular malformations for the purpose of identifying novel and/or innovative drug targets, screening existing drugs, and/or elucidating the pathogenesis of the disease.
- Research to understand and diagnose high-risk vascular malformations to prevent severe adverse events.

Women's Heart Disease

- Identification of sex- and/or gender-specific approaches, as appropriate, to develop novel diagnostics, treatments, or artificial intelligence/machine learning using structured and/or unstructured data, or to increase the effectiveness of current practice to improve clinical care using these tools.
- Research on factors to predict and prevent the long-term impacts of the endocrine system, gestational diabetes, gestational hypertension, menopause, or preeclampsia on the cardiovascular health of women.

- Research on trauma-induced cardiac arrest secondary to hemorrhage and polytrauma.
- Research focused on elucidating the potential relationship between post-traumatic stress disorder and women's heart disease.
- Studies to determine the risk and incidence of heart disease among female Service Members operating extreme environments (e.g., hot, cold, altitude, subterranean).
- Research investigating drug-induced arrhythmias.

APPENDIX 3: 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 FY21 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://www.usuhs.edu/afri/>

Combat Casualty Care Research Program

<https://ccc.amedd.army.mil>

Congressionally Directed Medical Research Programs

<https://cdmrp.army.mil>

Defense Advanced Research Projects Agency

<https://www.darpa.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/>

Military Infectious Diseases Research Program

<https://midrp.amedd.army.mil>

Military Operational Medicine Research Program

<https://momrp.amedd.army.mil>

Naval Health Research Center

<https://www.med.navy.mil/sites/nmrc/nhrc/>

Navy and Marine Corps Public Health Center

<https://www.med.navy.mil/sites/nmcphc/>

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. Army Institute of Surgical Research

<https://usaisr.amedd.army.mil>

U.S. Army Medical Materiel Development Activity

<https://www.usamma.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. 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>