I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Peer Reviewed Orthopaedic Research Program

Applied Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-22-PRORP-ARA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), June 16, 2022

- **Invitation to Submit an Application:** July 20, 2022

- **Application Submission Deadline:** 11:59 p.m. ET, September 13, 2022

- **End of Application Verification Period:** 5:00 p.m. ET, September 16, 2022

- **Peer Review:** November 2022

- **Programmatic Review:** January 2023

This program announcement must be read in conjunction with the General Application Instructions, version 702. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2022 (FY22) Peer Reviewed Orthopaedic Research Program (PRORP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC). The PRORP was initiated in 2009 to provide support for research of exceptional scientific merit focused on optimizing recovery and restoration of function for military personnel with orthopaedic injuries sustained in combat or combat-related duties. Appropriations for the PRORP from FY09 through FY21 totaled $458.5 million (M). The FY22 appropriation is $30M.

The FY22 PRORP challenges the scientific community to address the most significant gaps in care for the leading burden of injury and for facilitating return to duty. The program intends to support high-impact and clinically relevant research to advance the optimal treatment and rehabilitation from musculoskeletal injuries (excluding spinal cord injuries) sustained during combat, combat-related activities, and non-battle injuries that impact unit readiness and the ability to return to duty/work. It is expected that research findings would also benefit the general population. Applications involving multidisciplinary collaborations among academia, industry, the military Services, the U.S. Department of Veterans Affairs (VA), and/or other federal agencies are highly encouraged.

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

II.A.1. FY22 PRORP Applied Research Award (ARA) Focus Areas

In September 2021, the PRORP hosted a stakeholders meeting to identify critical knowledge and capability gaps in orthopaedic research and care. Representatives from non-profit organizations, academia, industry, government institutions, and the public shared broad perspectives on potential barriers in research and patient outcomes, key knowledge and scientific gaps, and potential approaches for addressing orthopaedic needs. Resources shared during the meeting and outcomes of the effort can be found on the CDMRP website (https://cdmrp.army.mil/prorp/default). The FY22 PRORP Focus Areas incorporate several of the stakeholder-identified gaps.

Applications submitted to this program announcement must address one of the following FY22 PRORP ARA Focus Areas. Selection of the appropriate Focus Area is the responsibility of the applicant.

1. Limb Stabilization and Protection: Development of rapid limb stabilization and novel wound protectants for severely or critically wounded limbs to enable prolonged care and eventual transport to the point of definitive treatment.

2. Retention Strategies: Development and/or optimization of battlefield-feasible diagnostic capabilities, decision support tools, and/or interventions that can facilitate retention on duty or avoid reinjury for common combat-related musculoskeletal injuries. Biomarker studies are excluded.

> 2a. *Battlefield Care:* Strategies that can be utilized at or near the point of injury to allow an injured Service Member to remain on the battlefield or on mission without the need for evacuation. Treatment strategies that allow return to mission effectiveness within 30 days will be considered.

> 2b. *Return to Duty:* Treatment strategies that can be utilized along the continuum of care and enable return to duty of the Service Member within 1 year of injury.

3. Osseointegration: Identification of best practices to address infection, rejection, and/or failure of percutaneous osseointegrated prosthetic limbs.

4. Composite Tissue Regeneration: Advanced tissue regeneration therapeutics in composite tissue for the restoration of traumatically injured extremities. Isolated bone, cartilage, muscle, or nerve tissue engineering studies are excluded. Techniques aimed at improving outcomes following high-energy extremity trauma, with a focus on improving wound healing, neuromuscular recovery following composite tissue loss and segmental bone loss are encouraged.

II.A.2. Award History

The PRORP Applied Research Award mechanism was first offered in FY15. Since then, 357 Applied Research Award applications have been received, and 58 have been recommended for funding.

II.B. Award Information

Orthopaedic injuries have a profound impact on military readiness and return to work/activity/duty. In the military, extremity battle wounds comprise approximately 50% of injuries reported in the Joint Theatre Trauma Registry. Additionally, orthopaedic injuries and conditions that occur outside of combat (e.g., during training, leisure activities, resultant from old injuries, etc.) present one of the greatest threats to the readiness of our Service Members and military. Early stabilization, treatment, and rehabilitation of orthopaedic injuries in both civilian and military populations have led to better outcomes, particularly in the prevention of secondary complications and in minimizing morbidity. Availability of orthopaedic care and treatment as early as possible, or as close to the point of injury as possible, also minimizes limb loss and affects military readiness. The PRORP is interested in supporting research that will have an impact on the lives of all individuals that have sustained a major musculoskeletal injury.

The FY22 PRORP ARA seeks applied research applications focused on advancing optimal treatment and restoration of function for individuals with musculoskeletal injuries sustained during combat, combat-related activities, and non-battle injuries that impact unit readiness and the ability to return to duty/work. Applicants are encouraged to address how the proposed research will support patient care and allow patients to more quickly return to duty/work. It is expected that any research findings would also provide benefit to the general population. To meet the intent of the award mechanism, applications **must** specifically address an FY22 PRORP ARA Focus Area, listed in Section II.A.1, above.

The FY22 PRORP ARA is focused on **applied research**, defined as work that refines concepts and ideas into potential solutions with a view toward evaluating technical feasibility of promising new knowledge products, pharmacologic agents, behavioral and rehabilitation interventions, diagnostic and therapeutic techniques, clinical guidance, and/or emerging approaches and technologies.

Research Scope: Research proposed under the FY22 PRORP ARA may include small- to large-scale projects. Upon successful completion, the proposed research is expected to yield knowledge products, approaches, or technologies that have the potential to advance toward clinical translation. Strong transition plans are expected.

Inclusion of preliminary and/or published data relevant to the proposed research is required.
Applicants must demonstrate logical reasoning for the proposed work. To be competitive, the application must include a sound scientific rationale and a well-formulated, testable hypothesis established through a critical review and analysis of the literature.

Studies allowed under the FY22 PRORP ARA may include, but are not limited to:

- Refinement of concepts and ideas into potential solutions, or research tools, with a view toward evaluating technical feasibility of emerging approaches, technologies, and promising new knowledge products.

- Evaluation, maturation, and/or down-selection of potential product candidates (drugs, biologic constructs, or devices/systems) in vitro and/or in vivo.

- Preparation activities needed to support a future clinical trial or regulatory submission.

Awards may not be used to support fundamental basic research. Basic research is defined as research directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward process or products in mind.

Applications to the FY22 PRORP ARA mechanism must support preclinical applied research and may not be used for clinical research studies. 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. (3) Outcomes research and health services research. ***Note:*** Studies that meet the requirements for IRB 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.

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

The anticipated total] costs budgeted for the entire period of performance for an FY22 PRORP Applied Research Award will not exceed **$725,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

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

The CDMRP expects to allot approximately $3.62M to fund approximately five Applied Research Award applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY22 funding opportunity will be funded with FY22 funds, which will expire for use on September 30, 2028.

Research Involving Human Anatomical Substances or Human Cadavers: All DOD-funded research involving new and ongoing research with human anatomical substances or human cadavers must be reviewed and approved by the USAMRDC Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is ***not*** required. Allow up to 3 months to complete the HRPO regulatory review and approval process following submission of ***all required and complete*** documents to the HRPO. Refer to the General Application Instructions, Appendix 1, and the Human Research Protections Office Resources and Overview document available on the electronic Biomedical Research Application

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

If the proposed research involves more than one institution a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Research Involving Animals: All research funded by the FY22 PRORP Applied Research Award 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.

Rigor of Experimental Design: All projects should adhere to accepted standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. Core standards are described in Landis, S.C., et al., A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 (https://www.nature.com/articles/nature11556). While these standards were written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in research and should be applied consistently across basic and translational studies. Applicants should consult the ARRIVE 2.0 (Animal Research: Reporting In Vivo Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE 2.0 guidelines can be found at https://arriveguidelines.org/arrive-guidelines.

Encouraged DOD and/or VA Collaboration: Military relevance is a key feature of this award. Principal Investigators (PIs) are encouraged, but not required, to collaborate with DOD or VA researchers and clinicians (Appendix 2).

Use of DOD or VA Resources: If the proposed research involves access to DOD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to Section II.D.2.b.ii, Full Application Submission Components, for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

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

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

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

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

II.C.1.b. Principal Investigator

Independent investigators at all academic levels (or equivalent) may be named by organizations as the PI on the application

There is no limitation on the number of applications for which an investigator may be named as a PI.

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

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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

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

II.D. Application and Submission Information

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

II.D.1. eBRAP and Grants.gov

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

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

Contact information for the eBRAP Help Desk and the Grants.gov Contact Center can be found in <u>Section II.G, Federal Awarding Agency Contacts</u>.

Extramural Submission:

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

- Full application packages must be accessed and submitted at Grants.gov.

Intramural DOD Submission:

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

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

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

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

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

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

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

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

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

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

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

The applicant organization and associated PI identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the eBRAP Help Desk at help@eBRAP.org 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.

- **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.

  FY22 PRORP Programmatic Panel members should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

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

- **Tab 5 – Pre-Application Files**

  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 (three-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:

– **Alignment with a Focus Area:** Explain how the proposed work addresses an <u>FY22 PRORP ARA Focus Area</u>. State how this project addresses an important problem relevant to combat-related orthopaedic injuries or restoration of function, as appropriate.

– **Research Idea:** State the ideas and reasoning on which the proposed work is based. State the hypothesis to be tested or the objective to be reached.

– **Research Strategy:** Clearly describe the research strategy for the proposed project. Concisely state the specific aims and ultimate goals of the project. Describe the proposed methods and how they will accomplish the project's aims.

– **Impact:** State explicitly how the proposed work may have a short- and/or long-term impact on patient care and/or restoration of function for those who have sustained traumatic orthopaedic injuries.

– **Military Benefit:** Describe how the proposed work may have an impact on unit readiness and the healthcare needs of Service Members and/or Veterans who have sustained combat-related orthopaedic injuries, as well as the treatment of non-battle injuries that significantly impact return to duty/work rates.

– **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the described research (detailed key personnel biographical sketches [six pages per individual] are allowed as part of pre-application supporting documentation, as described below).

○ **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* and are limited to the following:

– **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).

– **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.

– **Key Personnel Biographical Sketches (six-page limit per individual):** *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **Tab 6 – Submit Pre-Application**

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

Pre-Application Screening

- **Pre-Application Screening Criteria**

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

  ○ **Alignment with a Focus Area:** How well the project addresses an [FY22 PRORP ARA Focus Area](#) and the intent of the award mechanism.

  ○ **Research Idea and Strategy:** How well the rationale, objectives, and specific aims support the research idea. Whether the proposed methodology is appropriate to the specific aims.

  ○ **Impact:** To what extent the potential short- and/or long-range outcome(s) of the proposed study, if successful, will produce results that are likely to translate into improved patient care and/or restoration of function for those who have sustained traumatic orthopaedic injuries.

  ○ **Military Benefit:** How well the proposed study will directly or indirectly impact unit readiness and the healthcare needs of Service Members and/or Veterans who have sustained combat-related orthopaedic injuries, as well as non-battle injuries that significantly impact return to duty/work

  ○ **Personnel:** Whether the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed research.

- **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://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.

<p align="center">**Table 1. Full Application Submission Guidelines**</p>

Extramural Submissions	Intramural DOD Submissions
Application Package Location	
Download application package components for W81XWH-22-PRORP-ARA from Grants.gov (https://grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-22-PRORP-ARA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.

Extramural Submissions	Intramural DOD Submissions
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel • Budget • Performance Sites **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission. *Note:* If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID *prior to* the application submission deadline. ***Do not password protect any files of the application package, including the Project Narrative.***	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email. ***Do not password protect any files of the application package, including the Project Narrative.***

Extramural Submissions	Intramural DOD Submissions
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified *with the exception of the Project Narrative and Research & Related Budget Form*.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified *with the exception of the Project Narrative and Research & Related Budget Form*. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.
Further Information	
Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

  Attachments:

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

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

  ○ **Attachment 1: Project Narrative (12-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

    Describe the proposed project in detail using the outline below.

    – **Background:** Establish the relevance of the study to an <u>FY22 PRORP ARA Focus Area</u>. Describe in detail the rationale for the study questions and/or study hypotheses. Cite relevant literature. Include pilot or preliminary data that led to the development of the proposed project. State how the proposed work is a refinement or maturation of any existing work or research.

    – **Hypotheses/Objectives/Specific Aims:** State the hypotheses to be tested or the objectives to be reached. Concisely explain the specific aims of the proposed project.

    – **Research Strategy:** Describe the study design, methods, and models, including appropriate controls, in sufficient detail for assessment of the application. Explain how this research strategy will meet the research goals and milestones. Provide a well-developed, well-integrated, and detailed research plan that supports the translational feasibility and promise of the approach. If active-duty military and/or Veteran dataset(s) will be used in the proposed research, describe the dataset(s), the appropriateness of the dataset(s) for the proposed study, and the feasibility of using the dataset(s).

    – **Technical Risks:** Identify and describe potential problem areas in the proposed approach and alternative methods and approaches that will be employed to mitigate any risks that are identified.

- **Statistical and Data Analysis Plan:** Describe the statistical model and data analysis plan with respect to the study objectives as appropriate to the type of study. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.

  ○ If any biological material will be used in the proposed studies, the name, definition, pathological classification, and source of the material must be provided.

  ○ If human anatomical samples will be used, include a detailed plan for the acquisition of samples.

○ **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** *(one-page limit per letter is recommend):* 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; one-page limit per letter is recommended):* Provide a signed letter from each collaborating individual or organization that demonstrates that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

– **Letters of Commitment** *(if applicable; one-page limit per letter is recommended):* If the proposed study involves use of an investigational drug, device, or biologic, provide a letter of commitment from the entity that holds the intellectual property rights indicating availability of the product for the duration of the study, support for the proposed phase of research, and support for the indication to be tested.

– **Intellectual Property:** Information can be found in the Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), "Intangible Property."

   ▪ **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.

– **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

– **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.

– **Use of VA Resources (if applicable):** Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

– **Quad Chart:** The Quad Chart template is a one-page PowerPoint file that must be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm in the "Generic Forms for Application Submission" section, then completed and saved as a PDF file.

- ○ **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  Technical abstracts should be written using the outline below. Clarity and completeness within the space limits of the technical abstract are highly important for the review of the application.

  - – **Background:** State the FY22 PRORP ARA Focus Area addressed by the proposed research. State how the proposed research addresses the intent of the award mechanism. Present the ideas and reasoning behind the proposed work.

  - – **Objective/Hypothesis:** State the objective to be reached/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

  - – **Specific Aims:** State the specific aims of the study.

  - – **Study Design:** Briefly describe the study design, including appropriate controls.

  - – **Impact and Military Benefit:** State explicitly how the proposed work may have a short- and/or long-term impact on patient care and/or restoration of function for those who have sustained traumatic orthopaedic injuries, combat-related or otherwise.

- ○ **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information***. ***Do not duplicate the technical abstract.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  - – Describe the objectives and rationale for the application in a manner that will be readily understood by readers without a background in science or medicine. ***Do not duplicate the technical abstract.***

  - – Describe the ultimate applicability of the research.

    - ▪ Which FY22 PRORP ARA Focus Area will be addressed?

    - ▪ What are the potential research and clinical applications, benefits, and risks?

    - ▪ What is the projected time it may take to achieve a clinically relevant outcome? If the research is far from clinical applicability, describe the interim outcomes.

    - ▪ Describe how the proposed work may have a short- and/or long-term impact on patient care and/or restoration of function for those who have sustained traumatic orthopaedic injuries.

○ **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf".** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). Recommended strategies for assembling the SOW can be found at https://ebrap.org/eBRAP/public/Program.htm.

For the Applied Research Award mechanism, refer to the "***Suggested SOW Strategy Generic Research***" document for guidance on preparing the SOW and use the blank SOW format titled "Suggested SOW Format". The SOW must be in PDF format prior to attaching.

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

○ **Attachment 6: Impact and Military Benefit Statement (three-page limit): Upload as "Impact.pdf".**

   – Describe the short- and long-term impact of this study *in a manner that will be readily understood by readers with and without a background in science or medicine.* Discuss how the expected results of the proposed work will contribute to the goals of decreasing the clinical impact of traumatic orthopaedic injuries and provide better long-term outcomes for these patients. Provide information about the incidence and/or prevalence of the project-relevant orthopaedic injuries in military Service Members and/or Veterans, as well as the incidence in the general population, if appropriate and available.

   – Identify where along the military (and civilian) pathway of care the proposed product or intervention will be applied. Describe how the proposed study may impact unit readiness, point of injury care, prolonged field care (PFC), and/or allow patients to more quickly return to duty/work. (The North Atlantic Treaty Organization defines PFC as field trauma care extended beyond doctrinal timelines until the patient can be transported from the point of injury to an appropriate level of care.)

○ **Attachment 7: Transition Plan (two-page limit): Upload as "Transition.pdf".** Describe/discuss the methods and strategies proposed to move the anticipated research outcomes to the next phase of development (e.g., clinical research trials, commercialization, transition to industry, and/or delivery to the civilian or military market) after successful completion of the award. Outline the regulatory strategy, as applicable. Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan and description of the collaborations and resources that will be used to provide continuity of development. **PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development.** The plan for post-award transition of the anticipated research outcome

should include the components listed below, as appropriate and applicable to the research proposed.

- A brief schedule and milestones for transitioning the anticipated research outcomes to the next phase of development.

- Details of the funding strategy to transition to the next level of development and/or commercialization (e.g., partners, internal/external funding opportunities to be applied for). A description of collaborations and other resources that will be used to provide continuity of development.

- For knowledge products, the description of collaborations and other resources that will provide continuity of development may include proposed development or modification of Clinical Practice Guidelines and recommendations; provider training materials, patient brochures, and other clinical support tools; scientific journal publications; models; simulations; and applications. (A "knowledge product" is a non-materiel product that addresses an identified need, Topic Area, or capability gap; is based on current evidence and research; aims to transition into medical practice, training, tools, or support for materiel solutions [systems to develop, acquire, provide, and sustain medical solutions and capabilities]; and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.)

- The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication.

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

- If applicable, address any real or perceived financial conflict of interests (COIs) or biases and briefly state how the COI or bias will be mitigated.

○ **Attachment 8: Animal Research Plan (if applicable; *required for all studies proposing animal research*) (five-page limit): Upload as "AnimalPlan.pdf".**

When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:

- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.

- Summarize the procedures to be conducted. Describe how the study will be controlled.

- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.

- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.

- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).

- Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the Food and Drug Administration (FDA), if applicable.

○ **Attachment 9: Data Management (if applicable;** *required for all studies using human anatomical substances***) (no page limit): Upload as "Data_Manage.pdf".** The Data Management attachment should include the components listed below.

- **Data Management:** Describe all methods used for data collection to include the following:

  ▪ **Confidentiality:**

    ❖ Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.

    ❖ Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRDC are eligible to review study records.

    ❖ Address requirements for reporting sensitive information to state or local authorities.

  ▪ **Data capture, verification and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored.

  ▪ **Data reporting:** Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

- **Storage:** Describe specimen storage, to include location of storage, how long specimens have been or will be stored, any special conditions required, labeling, and disposition. Outline the plan to store specimens for future use, if applicable.

- **Laboratories performing evaluations and special precautions:** Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. If transport of samples is required, describe provisions for ensuring proper storage during transport.

○ **Attachment 10: Representations, if applicable (extramural submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

○ **Attachment 11: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as "MFBudget.pdf".** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using "Suggested Collaborating DOD Military Facility Budget Format", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

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

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

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

  ○ PI Biographical Sketch (six-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The

National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

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

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

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

- Key Personnel Biographical Sketches (six-page limit each): Upload as "Biosketch_LastName.pdf".

- Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

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

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

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

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

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

- **Extramural Applications Only**

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

  - **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

- ○ **Intramural DOD Collaborator(s):** Complete the "Suggested Collaborating DOD Military Facility Budget Format" and upload to Grants.gov attachment form as Attachment 11. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

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

The applicant organization must be registered as an entity in SAM (https://www.sam.gov/SAM/) and receive confirmation of an "Active" status before submitting an application through Grants.gov. As published in the Federal Register, July 10, 2019, (https://www.federalregister.gov/documents/2019/07/10/2019-14665/unique-entity-id-standard-for-awards-management), the UEI for awards management generated through SAM will be used instead of the Data Universal Numbering System (DUNS) number as of April 2022. ***All federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI.*** USAMRDC will transition to use of the UEI beginning with FY22 announcements and utilize the latest SF424, which includes the UEI. The DUNS will no longer be accepted. Applicant organizations will not go to a third-party website to obtain an identifier. During the transition, your SAM registration will automatically be assigned a new UEI displayed in SAM. (For more information, visit the General Services Administration: https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/iae-information-kit/unique-entity-identifier-update). Current SAM.gov registrants are assigned their UEI and can view it within SAM.gov. ***Authorized Organizational Representatives with existing eBRAP accounts should update their organizational profile to include the UEI prior to submission of the full application to Grant.gov (see Section II.D.4, Submission Dates and Times below).*** Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.4. Submission Dates and Times

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

Applicant Verification of Full Application Submission in eBRAP

For Both Extramural and Intramural Applicants: eBRAP allows an organization's representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***If either the***

Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Extramural Submission: The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified.

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

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

II.D.5. Funding Restrictions

The maximum period of performance is **3** years.

The anticipated total costs budgeted for the entire period of performance will not exceed **$725,000**. 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 **$725,000** total 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.

For this award mechanism, direct costs must be requested for:

- Costs for the PI to present project information or disseminate project results at two DOD-sponsored meetings (e.g., the Military Health System Research Symposium) should be requested. The meetings may occur in years 2 and/or 3 of the period of performance. These costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Travel in support of multidisciplinary collaborations.

- Travel costs for <u>one</u> investigator to travel to <u>one</u> scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meeting(s) is to disseminate project results from PRORP ARA.

Must not be requested for:

- Clinical trial costs

- Clinical research costs

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

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

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Research Strategy and Feasibility**

  - How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, logical reasoning, and the presentation of preliminary data or published data.

  - How well the hypotheses or objectives, aims, experimental design, data management plan (if applicable), methods, and analyses are developed and support successful completion of the project aims.

- How well potential problems are acknowledged and alternative approaches are addressed.

- Whether the application includes sufficient evidence to support availability of and access to the animal model/samples required for the study, as appropriate.

- If applicable, whether the animal research plan is rigorous and reproducible, and will provide data that can be used in a future regulatory filing, if needed.

- Whether the plan for acquiring the necessary research resources is sufficient for the proposed research project, if applicable.

- How consistent the methods and procedures are with sound research design.

- If applicable, to what degree the statistical plan and power analysis are appropriate for the proposed project and future transition to the next level of development.

- **Impact and Military Benefit**

  - How well the proposed study addresses the selected [FY22 PRORP ARA Focus Area](#).

  - To what degree the proposed research, if successful, will contribute to the goal of decreasing the clinical impact of traumatic orthopaedic injuries and provide better long-term outcomes for patients.

  - To what extent and how quickly the proposed study, if successful, will impact unit readiness, point of injury care, PFC, and/or return to duty/work.

- **Transition Plan**

  - Whether the identified next level of development and/or commercialization is well-described and realistic.

  - If applicable, whether the development plan required to support a new indication for the product label is appropriate.

  - Whether the funding strategy described (e.g., partners, internal/external funding opportunities to be applied for) to bring the anticipated research outcomes to the next level of development is reasonable and realistic.

  - Whether the planned collaborations, schedule, and milestones for bringing the study results to the next level of development (e.g., clinical research or trial, transition to industry, delivery to the market) are achievable.

  - How well the application identifies intellectual property ownership, describes an appropriate intellectual and material property plan among all participating organizations (if applicable), and addresses impact of any intellectual property issues on product or technology development and subsequent government access to products or technologies supported by this program announcement.

- If applicable, whether the mitigation of any real or perceived financial conflict of interests (COIs) or biases have been addressed.

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

- **Personnel**

  - How well the background and expertise of the PI and other key personnel demonstrate their ability to successfully complete the proposed research.

  - How appropriate the composition of the research or study team is to accomplishing the proposed work.

  - How appropriate the levels of effort by the PI and other key personnel are for successful conduct of the proposed work.

- **Environment**

  - How well the research requirements are supported by the availability of and the accessibility to facilities and resources (including collaborative arrangements).

  - Whether the quality and extent of institutional support are appropriate for the proposed project.

- **Budget**

  - Whether the **total** costs exceed the allowable total costs as published in the program announcement.

  - Whether the budget is appropriate for the proposed research.

- **Application Presentation**

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

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers

- Relevance to the mission of the DHP and FY22 PRORP, as evidenced by the following:

  - Adherence to the intent of the award mechanism

- Program portfolio composition

- Relative impact and military benefit

II.E.2. Application Review and Selection Process

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

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

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

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

The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when

determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

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

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

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY22 funds are anticipated to be made no later than September 30, 2023. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

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

Pre-Award Costs: An institution of higher education, hospital, or non-profit organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Application Instructions, Section III.A.5.

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

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

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

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

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

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

II.F.2. Administrative and National Policy Requirements

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

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

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

Refer to full text of the latest DoD R&D General Terms and Conditions; the USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions; and the USAMRAA General Research Terms and Conditions with For-Profit Organizations, for further information.

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

- Certify that the current and pending support provided on the application is current, accurate, and complete;

- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and

- Have been made aware of the requirements under Section 223(a)(1) of this Act.

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

II.F.3. Reporting

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

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

The Award Terms and Conditions will specify if more frequent or additional 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 may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10M are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

>   Phone: 301-682-5507

>   Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

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

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

>   Email: support@grants.gov

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

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 702a. The program announcement numeric version code will match the General Application Instructions version code 702.

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 exceeds page limit.

- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.

- Project Narrative exceeds page limit.

- Project Narrative is missing.

- Budget is missing.

- Animal Research Plan (Attachment 8) is missing, *for studies proposing animal research.*

- Data Management (Attachment 9) is missing, *for studies using human anatomical substance.*

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.

- Documents not requested will be removed.

II.H.2.c. Withdrawal

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

- An FY22 PRORP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the

development of any supporting documentation. ***A list of the FY22 PRORP Programmatic Panel members can be found at https://cdmrp.army.mil/prorp/panels/panels22.***

- The application fails to conform to this program announcement description.

- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY22, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.

- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.

- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.

- The pre-application or application does not address at least one of the FY22 PRORP ARA Focus Areas in Section II.A.1.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.

- The research proposed in the application is outside the scope of the research described in the pre-application.

- Clinical research is proposed.

- The PI does not meet the eligibility criteria.

II.H.2.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

II.H.3. 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 and Military Benefit Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Transition Plan: Upload as Attachment 7 with file name "Transisition.pdf"	
	Animal Research Plan: Upload as Attachment 8 with file name "AnimalPlan.pdf" if applicable	
	Data Management: Upload as Attachment 9 with file name "Data Manage.pdf" if applicable	
	Representations (extramural submissions only): Upload as Attachment 10 with file name "RequiredReps.pdf"	
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 11 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

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

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	Food and Drug Administration
FY	Fiscal Year
HRPO	Human Research Protection Office
IRB	Institutional Review Board
M	Million
MB	Megabyte
MIPR	Military Interdepartmental Purchase Request
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PFC	Prolonged Field Care
PI	Principal Investigator
PRORP	Peer Reviewed Orthopaedic Research Program
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs

APPENDIX 2: DOD AND VA WEBSITES

PIs are encouraged, but not required, to collaborate with DOD and/or VA investigators. 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.

Air Force Office of Scientific Research
https://www.wpafb.af.mil/afrl/afosr/

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

Armed Forces Radiobiology Research Institute
https://afrri.usuhs.edu/home

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 Health Agency
https://health.mil/dha

Defense Technical Information Center
https://discover.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/Naval-Medical-Research-Center/Naval-Health-Research-Center/

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

Naval Medical Research and Development
https://www.med.navy.mil/Naval-Medical-Research-Center/

Navy and Marine Corps Public Health Center
https://www.med.navy.mil/sites/nmcphc

Office of Naval Research
https://www.onr.navy.mil

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

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

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

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

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

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

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

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

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

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

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

U.S. Army Sharp, Ready & Resilient Directorate
https://www.armyresilience.army.mil/sharp/

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

U.S. Army Research, Development and Engineering Command
https://www.arl.army.mil/

U.S. Army Resiliency Directorate
https://www.armyresilience.army.mil/