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: HT942524PRORPARA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern time (ET), June 18, 2024

- **Invitation to Submit an Application:** July 24, 2024

- **Application Submission Deadline:** 11:59 p.m. ET, September 17, 2024

- **End of Application Verification Period:** 5:00 p.m. ET, September 20, 2024

- **Peer Review:** November 2024

- **Programmatic Review:** January 2025

This program announcement must be read in conjunction with the General Application Instructions, version 901. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Peer Reviewed Orthopaedic Research Program (PRORP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the PRORP in 2009 to provide support for research of high potential impact and exceptional scientific merit focused on optimizing recovery and restoration of function for military personnel with orthopaedic injuries sustained in combat or service-related duties. Appropriations for the PRORP from FY09 through FY23 totaled $518.5 million (M). The FY24 appropriation is $30.0M.

The FY24 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 treatment and rehabilitation from orthopaedic injuries (excluding spinal cord injuries) sustained during combat and service-related activities to maximize return to duty. It is expected that research findings would also benefit the general population. Applications involving interdisciplinary collaborations among academia, industry, the military services, the U.S. Department of Veterans Affairs (VA), and/or other federal agencies are highly encouraged.

II.A.1. FY24 PRORP Applied Research Award Focus Areas

To meet the intent of the funding opportunity, applications submitted to this program announcement must address one of the following FY24 PRORP Applied Research Award (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, interventions, and/or rehabilitation strategies that can facilitate retention on duty or avoid reinjury for common combat-related musculoskeletal injuries. Biomarker studies are excluded. The current standard of care must be noted. The rehabilitation strategy to be used in the proposed study must be specified, as applicable. Capabilities for diagnosis of underlying pathology and efficacy of interventions measurements are encouraged.

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.

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.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 Department of Defense 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.

Although the PRORP is interested in supporting military-focused research, research supported by the PRORP is expected to also apply to all individuals who have sustained a major orthopaedic injury.

With the initiation of the Arthritis Research Program, the FY24 PRORP may not fund arthritis research; however, research that addresses conditions or health abnormalities related to arthritis is permitted provided the proposed research addresses the selected Focus Area.

The FY24 PRORP ARA seeks applied research applications focused on advancing optimal treatment and restoration of function for individuals with orthopaedic injuries sustained during combat and service-related activities. 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 FY24 PRORP ARA Focus Area, listed in Section II.A.1, above.

The FY24 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.

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.

Research Scope: Research proposed under the FY24 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 FY24 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.

Applications to the FY24 PRORP ARA mechanism must support preclinical applied research and may not be used for clinical research studies. Applicants seeking support for clinical research projects should consider the FY24 PRORP Clinical Translational Research Award (Funding Opportunity Number HT942524PRORPCTRA), Clinical Trial Award (Funding Opportunity Number HT942524PRORPCTA), or Women's Health Research Award (Funding Opportunity Number HT942524PRORPWHRA) mechanisms.

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

Rigor of Experimental Design: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Projects that include research on animal models are required to submit [Attachment 8, Animal Research Plan](#), as part of the application package to describe how these standards will be

addressed. Applicants should consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at https://arriveguidelines.org/arrive-guidelines.

Women's Health Research: The CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health. Applications proposing research that solely address women's health may also consider the FY24 PRORP WHRA mechanism, Funding Opportunity Number HT942524PRORPWHRA.

Encouraged Department of Defense (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.

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.

The anticipated total costs budgeted for the entire period of performance for an FY24 PRORP Applied Research Award should not exceed **$750,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

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

The CDMRP expects to allot approximately $3.75M to fund approximately five ARA applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

Extramural Organization: An eligible non-DOD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal

government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

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

Awards are made to eligible *organizations*, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

II.C.1.b. Principal Investigator

Independent investigators at all academic levels (or equivalent) may be named by the organization 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.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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

II.D. Application and Submission Information

II.D.1. Location of Application Package

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

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

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural

applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

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

Application Submission Workflow
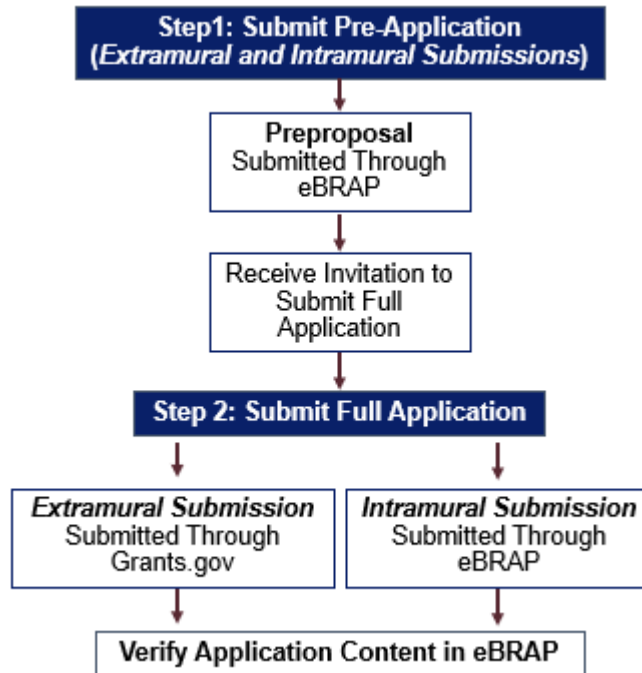
Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524PRORPARA from Grants.gov (https://grants.gov). Full applications from extramural organizations **must** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524PRORPARA from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods

for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

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

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

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

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

FY24 PRORP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.org/).

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, 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.i. Pre-Application Components

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

Note: Upload documents as individual PDF files unless otherwise noted.

- **Preproposal Narrative (one-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 be written using the outline below. Clarity and completeness within the space limits are highly important.

○ **Background:** State the FY24 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:** State explicitly how the proposed work may have an impact on patient care for those who have sustained traumatic orthopaedic injuries, service-related or otherwise.

• **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.

II.D.2.a.ii. 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 FY24 PRORP ARA Focus Area and the intent of the award mechanism.

• **Research Idea and Strategy:** How well the reasoning, objectives, and specific aims support the research idea. Whether the proposed study design is appropriate to the specific aims.

• **Impact:** To what extent the potential outcome(s) of the proposed study, if successful, will produce results that are likely to translate into improved patient care for those who have sustained traumatic orthopaedic injuries, service-related or otherwise.

II.D.2.a.iii. Notification of Pre-Application Screening Results

Following the pre-application screening, PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section I, Overview of the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full 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.

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

Applicants must receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

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

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

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

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

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

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

(b) Attachments:

   Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 2.

- ○ **Attachment 1: Project Narrative (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 that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

  Describe the proposed project in detail using the outline below.

  - – **Background:** Establish the relevance of the study to an <u>FY24 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. Provide evidence to support availability of and access to the animal model or human samples required for the study, as applicable.

  - – **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. The Supporting Documentation attachment should not include additional information such as figures,

tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.

- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.

- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.

- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- **Letters of Organizational Support (one-page limit per letter *is recommended*):** 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 and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

- **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.

- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to the CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about the CDMRP's expectations for making data and research resources publicly available.

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

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

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

Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

- **Background:** State the FY24 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, and addresses issues of particular interest to the affected community. *Abstracts of all funded research projects will be posted publicly.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. **Graphics are not allowed.** *Do not duplicate the technical abstract.*

Lay abstracts should address the points outlined below *in a manner that will be readily understood by readers without a background in science or medicine*. Avoid overuse use of scientific jargon, acronyms, and abbreviations.

- Summarize the objectives and rationale for the proposed research.

- Describe the ultimate applicability of the research.

    ▪ Which [FY24 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, combat-related or otherwise.

○ **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested Statement of Work (SOW) format and recommended strategies for assembling the SOW.

For the ARA mechanism, refer to the "Example: Assembling a Generic Statement of Work" document, for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

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 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 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, service-associated trauma care, and/or allow patients to more quickly return to duty/work.

○ **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 plan for resolving intellectual and material property issues among participating organizations.

- – 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 (five-page limit): Upload as "AnimalResPlan.pdf".** *(Attachment 8 is only applicable and required for applications proposing animal studies.)*

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

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

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

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

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

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

- ○ **Attachment 9: 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:**

      - ❖ 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 U.S. Food and Drug Administration, 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** *(Extramural Submissions Only)***: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.

- ○ **Attachment 11: Suggested Intragovernmental/Intramural Budget Form** *(if applicable)***: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The *total* costs per year for each subaward (direct and indirect costs) should

be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- ○ **PI Biographical Sketch (six-page limit):** Upload as "Biosketch_LastName.pdf".

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

- ○ **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".

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.

- ○ **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.

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

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

- ○ **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.

- ○ **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 11.

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

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

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

The applicant organization must be registered as an entity in SAM (https://www.sam.gov/content/home) and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

II.D.4. Submission Dates and Times

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity.

II.D.5. Funding Restrictions

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

The application's total costs budgeted for the entire period of performance should not exceed **$750,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

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

- Travel costs for the PI to present project information or disseminate project results at one DOD-sponsored meetings (e.g., the Military Health System Research Symposium) during the period of performance in Year 3 of the project. For planning purposes, it should be assumed that the meeting will be held in the National Capital or Central Florida areas. These travel costs are in addition to those allowed for annual scientific/technical meetings.

Must not be requested for:

- Clinical trial costs

- Clinical research costs

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **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 or human samples required for the study, as appropriate.

  ○ How well the animal study (or studies) is designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used, if applicable.

  ○ How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.

- Whether the 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.

- 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 [FY24 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 short- and long-term outcomes for patients.

    - To what extent and how quickly the proposed study, if successful, will impact unit readiness, point of injury care, service-associated trauma care, 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 COIs or biases have been addressed.

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

- **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 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 priorities of the DHP and FY24 PRORP, as evidenced by the following:

  ○ Adherence to the intent of the funding opportunity

  ○ 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.health.mil/about/2tierRevProcess.

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

II.E.3. Integrity and Performance Information

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

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

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

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

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

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

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

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

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

II.F.2. PI Changes and Award Transfers

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

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

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

II.F.3. Administrative and National Policy Requirements

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

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

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

Refer to full text of the latest DoD R&D Terms and Conditions and the USAMRAA Research Terms and Conditions: Addendum to the DoD R&D Terms and Conditions for further information.

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

II.F.4. Reporting

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

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

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

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 $10.0M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

> Phone: 301-682-5507

> Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace:

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

> Email: support@grants.gov

II.H. Other Information

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

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- Preproposal Narrative exceeds page limit.

- Preproposal Narrative is missing.

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

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

- Project Narrative exceeds page limit.

- Project Narrative is missing.

- Budget is missing.

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

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

II.H.2.b. Modification

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

- Documents not requested will be removed.

II.H.2.c. Withdrawal

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

- An FY24 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, including letters of support/recommendation. *A list of the FY24 PRORP Programmatic Panel members can be found at https://cdmrp.health.mil/prorp/panels/panels24*.

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

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

- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).

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

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

- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.

- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.

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

- The PI does not meet the eligibility criteria.

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

- Clinical research is proposed.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐
Transition Plan – Attachment 7, upload as "Transition.pdf"	☐
Animal Research Plan – Attachment 8, upload as "AnimalPlan.pdf"	☐
Data Management – Attachment 9, upload as "DataManage.pdf"	☐
Representations *(Extramural submissions only)* – Attachment 10, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 11, upload as "IGBudget.pdf"	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐
Budget *(Intramural submissions only)* Include budget justification	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ARA	Applied Research Award
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
M	Million
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PI	Principal Investigator
PRORP	Peer Reviewed Orthopaedic Research Program
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
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