Program Announcement for the Defense Health Agency

Orthopaedic Research Program Clinical Research Award

Funding Opportunity Number: HT942526ORPCRA

Pre-Application Due: August 19, 2026

Application Due: November 18, 2026

This program announcement must be read in conjunction with the General Application Instructions, version CD26_01.

Content

Before You Begin

- **Active SAM.gov, eBRAP.org and Grants.gov registrations are required for application submission.** User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- **Read this funding opportunity announcement in the order it is written before beginning to prepare application materials.** It is the responsibility of the applicant to determine whether the proposed research meets the intent of this funding opportunity and that all parties meet eligibility requirements.
- **To support application preparation, additional resources are available** including an application process FAQ, a Guide for Intragovernmental & Intramural Applicants and a CDMRP Video Series detailing the application process.

Who to Contact for Support

eBRAP Help Desk

301-682-5507
help@eBRAP.org

Questions regarding funding opportunity submission requirements, as well as technical assistance related to pre-application or intramural application submission.

Grants.gov Support Center

800-518-4726
International: 1-606-545-5035
support@grants.gov

Questions regarding Grants.gov registration and Workspace.

This document uses internal links; you can go back to where you were by pressing the Alt + left arrow keys (Windows) or command + left arrow keys (Macintosh) on your keyboard.

Click i to be taken to additional guidance and instructions within the General Application Instructions (GAI).

1. Basic Information About the Funding Opportunity

Summary: The fiscal year 2026 (FY26) Orthopaedic Research Program (ORP) Clinical Research Award (CRA) seeks clinical research that evaluates orthopaedic-specific factors and interventions. The ORP intends for research supported by this mechanism to generate clinically useful evidence with potential to optimize patient outcomes and inform clinical care or policy. Applications must address how the proposed research will impact patient care and reduce the burden of orthopaedic injury and sequela. The ORP expects that research findings benefit Service Members, their families, Veterans and the general public. To meet the intent of the award mechanism, applications **must** specifically address at least one of the FY26 ORP CRA Focus Areas.

Distinctive Features:

- The CRA offers two research levels.

Research Level 1 (RL1) supports **clinical research** in the following FY26 ORP focus areas:

- Ligamentous Trauma
- Osseointegration Outcomes
- Return-to-Duty Strategies
- Military Women's Health

Research Level 2 (RL2) supports **clinical trials** in the following FY26 ORP focus areas:

- Ligamentous Trauma
- Limb Stabilization and Protection
- Return-to-Duty Strategies

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly $4.0M to fund approximately two CRA-RL1 applications with total cost caps of $2.0M per award; and allot roughly $9.6M to fund approximately three CRA-RL2 applications with total cost caps of $3.2M per award. The maximum period of performance is 4 years for both levels. It is anticipated that awards made from this FY26 funding opportunity will be funded with FY26 funds, which will expire for use on September 30, 2032. Awards supported with FY26 funds will be made no later than September 30, 2027.

Submission and Review Dates and Times

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), August 19, 2026
- **Invitation to Submit an Application:** September 25, 2026
- **Application Submission Deadline:** 11:59 p.m. ET, November 18, 2026
- **End of Application Verification Period:** 5:00 p.m. ET, November 23, 2026
- **Peer Review:** January 2027
- **Programmatic Review:** March 2027

Announcement Type: Initial

Funding Opportunity Number: HT942526ORPCRA

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural U.S. Department of War (DOW) organizations are eligible to apply, ***including foreign and domestic organizations, for-profit and nonprofit organizations, and public or private entities***.

2.1.2. Principal Investigator

Independent investigators at all career levels affiliated with an eligible organization are eligible to be named Principal Investigator (PI) on the application, regardless of ethnicity, nationality or citizenship status.

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

2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

2.3. Other

Awards are made to eligible ***organizations***, not to individuals. Refer to the GAI for additional recipient qualification requirements.

3. Program Description

The Defense Health Agency Contracting Activity (DHACA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP is the program office managing this FY26 funding opportunity as part of the Orthopaedic Research Program (ORP). The CDMRP is located within the Defense Health Agency Research and Development (DHA R&D), which is a part of the Department of Defense, DOD, herein referred to using the secondary title Department of War, DOW. Congress initiated the ORP 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 ORP from FY09 through FY24 totaled $548.5 million (M). The FY26 appropriation is $20.0M.

The FY26 ORP 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.

FY26 congressional language for the Arthritis Research Program directed that arthritis research shall not be considered by other CDMRP peer reviewed programs such as ORP. The FY26 ORP will consider research that addresses conditions or health abnormalities related to arthritis.

3.1. Award History

The ORP previously offered a Clinical Translational Research Award and a Clinical Trial Award. The ORP Clinical Research Award mechanism replaces these previous award mechanisms and is being offered for the first time in FY26.

3.2. Intent of the Clinical Research Award

The FY26 ORP CRA seeks clinical research that evaluates orthopaedic-specific factors and interventions. The ORP intends for research supported by this mechanism to generate clinically useful evidence with potential to optimize patient outcomes and inform clinical care or policy. Applications must address how the proposed research will impact patient care and reduce the burden of orthopaedic injury and sequela. The ORP expects that research findings benefit Service Members, their families, Veterans and the general public. To meet the intent of the award mechanism, applications **must** specifically address at least one of the FY26 ORP CRA focus areas.

Applications to the FY26 ORP CRA mechanism must support clinical research and may not be used for preclinical research studies. Applicants seeking support for preclinical research projects should consider the FY26 ORP Applied Research Award (Funding Opportunity Number HT942526ORPARA).

3.2.1. Focus Areas for the CRA

Applications submitted to the FY26 ORP must address one or more of the following focus areas:

Focus Areas for Research Level 1

- **Ligamentous Trauma:** Musculoskeletal extremity soft tissue trauma treatments for shoulder, knee or chronic ankle instability and sequelae only to optimize return to duty, work or reintegration.
- **Osseointegration Outcomes:** Identification of best practices to optimize outcomes of patients who have percutaneous osseointegrated prosthetic limbs (e.g., infection, rejection, adapters and fail-safe devices, clinical outcomes).
- **Return to Duty Strategies:** Optimization and/or validation of decision-support tools, interventions and/or rehabilitation strategies that can retain a Service Member on duty, enable them to return to duty within one year of injury, or avoid reinjury for common combat-related musculoskeletal injuries. Treatment strategies that can be utilized along the continuum of care are encouraged. 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.
- **Military Women's Health:** Studies that assess the impact of novel or established orthopaedic injury care interventions on military women's health. Application must describe how outcomes of the proposed research will address areas and conditions that affect women uniquely, disproportionately or differently from men. Areas of interest include preservation of function and physical ability, quality of life, symptom management and resilience in military women, as well as sex-specific considerations following orthopaedic injury and treatment.

Focus Areas for Research Level 2

- **Ligamentous Trauma:** Musculoskeletal extremity soft tissue trauma treatments for shoulder, knee or chronic ankle instability and sequelae only to optimize return to duty, work or reintegration.
- **Limb Stabilization and Protection:** Development and/or clinical evaluation 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. Interventions that solely address infection will not be considered.
- **Return to Duty Strategies:** Optimization and/or validation of decision-support tools, interventions and/or rehabilitation strategies that can retain a Service Member on duty, enable them to return to duty within one year of injury or avoid reinjury for common combat-related musculoskeletal injuries. Treatment strategies that can be utilized along the continuum of care are encouraged. 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.

3.2.2. Key Elements for the CRA

The FY26 ORP CRA requires inclusion of preliminary and/or published data relevant to the proposed research. Applications 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.

The FY26 ORP CRA offers two research levels based on the scope of research proposed. The applicant must select the research level that is most appropriate for the research proposed.

- **RL1** supports clinical ***research***.
    - Projects with potential to impact the standard of care, both immediate and long-term, as well as contribute to evidence-based guidelines for the evaluation and care of military, Veterans and all patients with orthopaedic injuries.
- **RL2** supports clinical ***trials***.
    - Clinical trials with potential to have a significant impact on the treatment or management of military combat or service-related orthopaedic injuries that significantly impact unit readiness and return-to-duty/work rates.

For RL2 Applications Only:

- **Study Population:** Evidence of availability and access to a suitable patient population that will support a meaningful outcome for the study is required. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.
- **Intervention Availability:** Evidence of documented availability and access to the drug/compound, device and/or other materials needed, as appropriate, for the proposed duration of the study is required.
- **Study Team:** Evidence of the study team's expertise and experience in all aspects of conducting clinical trials, including appropriate statistical analysis, knowledge of U.S. Food and Drug Administration (FDA) processes (if applicable) and data management is required.

3.2.3. Other Important Considerations for the CRA

Funding from this award mechanism must support clinical research (CRA-RL1) or a clinical trial (CRA-RL2).

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. An ***intervention*** includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

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

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

- Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness and/or efficacy outcomes of an intervention.

Research meeting this definition may include but is not limited to: (a) mechanisms of human disease; (b) diagnostic or detection studies (e.g., biomarker or imaging); (c) health disparity studies; and (d) development of new technologies.

- Epidemiologic and behavioral studies that do ***not*** seek to assess the safety, effectiveness and/or efficacy outcomes of an intervention.
- Outcomes research and health services research that do not fit under the definition of clinical trial.

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

Proposed clinical trials submitted to CRA-RL2 are expected to begin no later than six months after the award date. Unless otherwise noted, for the purposes of this funding opportunity, Regulatory Agency refers to the FDA or any equivalent international regulatory agency.

If an Investigational New Drug (IND) application, Investigational Device Exemption (IDE) or equivalent, is required, a regulatory application ***must be submitted to the relevant regulatory agency prior to the CRA submission deadline***. The regulatory application should be specific for the product and indication to be tested in the proposed clinical trial.

Animal research is not allowed under the CRA mechanism.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research, such as those described in the STROBE, CONSORT, SPIRIT and ARRIVE 2.0 guidelines.

Applications from investigators within the DOW and applications involving multidisciplinary collaborations among academia, industry, the DOW, the VA and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, their Families and the American Public. If the proposed research relies on access to unique 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.

3.3. Funding Instrument

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

3.4. Funding Details

Period of Performance: The maximum period of performance is **4** years.

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **$2.0M for Research Level 1 or $3.2M for Research Level 2**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

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

The appropriateness of the budget for the proposed research will be assessed during peer review.

Direct Cost Restrictions: For this award mechanism, direct costs:

Must be requested for:

- Travel costs for up to two investigators to present project information or disseminate project results at one DOW-sponsored meeting (e.g., the Military Health System Research Symposium) during Year 3 or 4 of the project's period of performance. 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.

May be requested for (not all-inclusive):

- Research subject compensation and reimbursement for study-related out-of-pocket costs (e.g., travel, lodging, parking, costs associated with caregiving and resources/equipment to enable participation).
- Travel in support of multi-institutional collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY26 ORP CRA.

Must not be requested for:

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

4. Application Contents and Format

4.1. Application Overview

Application submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP) and a ***full application*** submitted through eBRAP or Grants.gov. Depending on the submission portal, certain aspects of the application will differ.

Intramural DOW organizations submitting a full application should follow instructions for submission through eBRAP.

Extramural organizations submitting a full application must follow instructions for submission through Grants.gov.

4.2. Pre-Application Components

Pre-application submissions must include the following components.

Upload documents as individual PDF files unless otherwise noted. Files must comply with the formatting guidelines listed in the GAI.

- **Preproposal Narrative (two-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:

  - **Background/Research Problem/Rationale:** Describe the research problem to be addressed by the proposed study and the rationale on which it is based. State how the proposed research addresses the intent of the award mechanism. Clearly identify whether the proposed study is clinical research or a clinical trial.
  - **Objective/Hypothesis:** State the objective(s) to be reached and/or hypothesis to be tested.
  - **Specific Aims and Study Design:** Concisely state the specific aims of the study and describe the scientific approach and how it will accomplish the study aims. Include a description of controls, as appropriate.
  - **Clinical Impact:** State the FY26 ORP CRA Focus Area(s) addressed by the proposed research. Briefly describe how the proposed project will 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.
- **Key Personnel Biographical Sketches:** ***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.

4.3. Full Application Components

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

Each application submission must include the completed full application package for this program announcement. See Appendix 1 for a checklist of the full application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov submissions only)*:

IMPORTANT: *When completing the SF424 R&R, enter the* ***eBRAP log number*** *assigned during pre-application submission into* ***Block 4a – Federal Identifier****.*

(b) Attachments:

Each attachment of the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines in the GAI.

- **Attachment 1: Project Narrative (30-page limit): Upload as "ProjectNarrative.pdf".**

  Describe the proposed project in detail using the outline below.

  – **Background:** Establish the relevance of the study to an FY26 ORP CRA Focus Area. Describe in detail the rationale for the study questions and/or study hypotheses. Detail the scientific rationale for the study, establish the study's relevance and clearly explain the basis for the study questions and/or study hypotheses.

  Provide a literature review and analysis. Describe the preliminary studies and/or preclinical data that led to the development of the proposed clinical study. Provide a summary of other relevant ongoing, planned or completed clinical studies and describe how the proposed study differs. Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications, if applicable.

  If the proposed clinical study was initiated using other funding prior to this application, explain the history and background of the clinical study and declare the source of prior funding. Specifically identify the portions of the study that will be supported with funds from this award.

  – **Intervention *(if applicable)*:**

    - Identify the intervention to be tested. Include the following components, as applicable: intervention type (drug, device, behavioral, surgical, etc.), complete name and composition, source, general concept of design, administration route.
    - Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights, along with access to the

intervention itself, for conduct of the clinical trial. As applicable, appropriate letters of commitment should be provided in Attachment 2: Supporting Documentation, demonstrating the study team's access to the intervention(s) for the duration of the clinical trial.

- Describe how the intervention addresses current clinical needs and how it compares with currently available interventions and/or standards of care.
- Clearly delineate research procedures from routine clinical procedures.
- Discuss any preclinical and/or clinical evidence that supports the safety and stability (as appropriate) of the intervention.
- Discuss the clinical monitoring plan and explain how it addresses the level of risk of the clinical trial.
- Describe measures to ensure consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).
- Explain how the proposed intervention and its endpoints are feasible and rational for use in its intended environment. If proposing that an intervention has utility or is deployable on the battlefield or military setting, describe how the clinical setting of the study accurately represents that environment. Describe any limitation in the evaluative setting and any anticipated hurdles for translation to the final treatment environment.

– **Objectives/Specific Aims/Hypotheses:** Clearly identify the proposed study as clinical research or a clinical trial. Describe the purpose of the study with detailed objectives, specific aims and/or study questions/hypotheses.

– **Study Design:** Describe the proposed research in sufficient detail to evaluate its appropriateness and feasibility.

- Describe the type of study to be performed (e.g., treatment, prevention, diagnostic), the study phase or class (if applicable) and the study model (e.g., single group, parallel, crossover). Outline the proposed clinical research methodology and study variables in sufficient detail to demonstrate a clear course of action and justification.
- Provide a schedule (e.g., flowchart or diagram) of study intervention(s), evaluation(s) and follow-up procedures, if applicable, including any biospecimens to be acquired, the collection schedule and amount.
- Describe the interaction with the human subject and what they will experience. Provide sufficient detail in chronological order for a person not involved in the study to understand what the study participant will experience.
- Briefly describe and justify the study population and the inclusion and exclusion criteria that will be used to meet the objectives of the proposed clinical research. Summarize the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random). Additional details should be provided in Attachment 6: Study Population Recruitment and Safety Plan.
- Define each arm/study group of the proposed clinical study, if applicable, and describe how group assignment will occur. Include a description of controls, as appropriate. Specify the approximate number of study participants to be enrolled. If multiple study sites are involved, state the approximate number to be enrolled

at each site. Indicate whether subjects, clinicians, data analysts and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias.

- Describe all evaluations and define all endpoints and outcome measures relevant to the objectives of the study; explain why they were chosen, and describe how, when and where they will be measured. Include a description of controls, as appropriate. If questionnaires or other research data collection instruments will be used, include a copy of them in Attachment 2: Supporting Documentation. Describe the reliability and validity of the selected evaluations, endpoints and outcome measures, along with the applicable quality standards. Explain how the results of evaluations and/or data collection instruments will be used to meet the objectives of the study and/or to monitor safety of human subjects.
- Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA or any equivalent international regulatory agency, if applicable.
- Provide detailed plans for initiating the clinical study within six months of the award.
- Describe potential challenges and discuss alternative methods/approaches that may be employed to overcome them. Estimate the potential for human subject loss to follow-up and how such loss will be handled/mitigated.

– **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Ensure sufficient information is provided to allow for a thorough evaluation of statistical calculations during review of the application.

- Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. Describe all clinical and statistical justifications and assumptions that support the sample size calculations. Explain any anticipated subgroup analyses and demonstrate that such analyses will be appropriately powered.
- Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.

Consult appropriate guidelines to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.

If the proposed research involves access to military and/or VA patient populations and/or DOW or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Also include a plan for obtaining any required data sharing, memorandum of understanding or other agreements required to access and publish data. Refer to the General Application Instructions, Appendix 4, for additional considerations.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".**

  There are no page limits for these components unless otherwise noted. Include only 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 in the Project Narrative using a standard reference format (include URLs, if available).
  - **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; include 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 the original or present government award under which the facilities or equipment items are now accountable. There is not a standardized 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 Support (1-page limit per letter recommended):** Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOW collaborator(s) and/or access to military populations, databases or DOW resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or an individual designated by the VA Facility Director(s), confirming access to VA patients, resources and/or VA research space.
  - **Letters of Commitment (*if applicable*; one-page limit per letter 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.
  - **Sex as a Biological Variable Strategy (two-page limit recommended):** Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. If needed, provide a strong rationale for proposing a single-sex study, based on justification from scientific literature, preliminary data or other relevant considerations. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.

- **Research Sharing Plan:** Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe the mechanism (e.g., direct sharing, repository, mixed mode) by which data and resources generated during the period of performance will be shared with the research community and other affected communities, including clinical research participants. Include the name of the repository(ies) where scientific data and resources arising from the proposed study will be archived, if applicable. Identify and provide the rationale for any data or resources that will not be shared (e.g. for intellectual property, feasibility, cost or other considerations). The plan should also protect participant privacy, confidential and proprietary data and performer/third-party intellectual property. Provide a milestone plan for disseminating data/results including when data and resources will be made available to other users. In cases where the study participant could potentially derive medical or other benefit from the information, explain whether the results of screening and/or study participation will be shared with the participant or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.

  Do not submit a copy of the National Institutes of Health (NIH) Data Management and Sharing Plan or duplicate the Data Management Plan which will be requested only after a recommendation for funding is made.

  Refer to the CDMRP Directive on Sharing Data and Research Resources for more information about the CDMRP's expectations for making data and research resources publicly available.

- **Questionnaires and Other Research Data Collection Instruments *(if applicable)*:** Include a copy of the most recent version of questionnaires, data collection forms, rating scales, interview guides or other instruments. This should include any drafts that are currently in use or underdevelopment.
- **Informed Consent Documents *(if applicable)***: Include a copy of the most recent version of the consent forms for the proposed clinical study. The following must appear in the consent form for human subject participation in a DOW-funded research study:
  - A statement that the DOW is providing funding for the study.
  - A statement that representatives of the DOW are authorized to review research records.
  - In the event that Health Insurance Portability and Accountability Act authorization is required, the DOW must be listed as one of the parties to whom protected health information may be disclosed.

- **Attachment 3: Technical Abstract (1-page limit): Upload as "TechAbs.pdf".**

  Write the technical abstract using the outline below. Clarity and completeness within the space limits are highly important.

  - **Background:** Present the scientific rationale behind the proposed research project.
  - **Hypothesis/Objective(s):** Identify the proposed study as clinical research or a clinical trial. State the hypothesis to be tested and/or objective(s) to be reached.
  - **Specific Aims:** State the specific aims of the study.

- **Study Design:** Describe the study design, including appropriate controls.
- **Clinical Impact:** Briefly describe how the proposed project will have an impact on patient care and restoration of function for those who have sustained traumatic orthopaedic injuries, service-related or otherwise. Include the impact on at least one of the FY26 ORP CRA Focus Areas.
- **Military Relevance:** Describe how the study is relevant to military health.

- **Attachment 4: Lay Abstract (1-page limit): Upload as "LayAbs.pdf".**

  The lay abstract should address the points outlined below ***in a manner that is readily understood by readers without a background in science or medicine.*** Avoid overuse of scientific jargon, acronyms and abbreviations. ***Do not duplicate the technical abstract.***

  - Summarize the objectives and rationale for the proposed research.
  - Identify the FY26 ORP CRA Focus Area(s) to be addressed.
  - Identify the population the research will help and explain how it will help them.
  - Identify the potential applications, benefits and risks of the anticipated outcomes.
  - Describe the likely contributions of the proposed research project to advancing research, patient care and/or quality of life for individuals who have sustained traumatic orthopaedic injuries, service-related or otherwise?
  - Explain the potential benefit of the proposed study and the anticipated outcomes to Service Members, Veterans and/or their Families.

- **Attachment 5: Statement of Work (5-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the Suggested SOW Format.

  For guidance on preparing the SOW, refer to the Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work. Include milestones for data or research resource(s) sharing.

- **Attachment 6: Study Population Recruitment and Safety Plan (no page limit): Upload as "StudyPopPlan.pdf".** Include the components listed below.
  - **Enrollment Distribution:** Provide anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race and ethnicity using the Public Health Service (PHS) Inclusion Enrollment Report. The enrollment table(s) should be appropriate to the objectives of the study.
  - **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. If limiting inclusion by age, race, ethnicity or sex, provide strong rationale based on justification from scientific literature, preliminary data or other relevant considerations. List and describe any evaluations (e.g., laboratory procedures, history or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Describe how the study population represents the population anticipated to benefit from the intervention.
  - **Study Population Availability:** Demonstrate that the research team has access to the proposed study population at each site. Describe the approximate number, pertinent demographic information and other relevant characteristics of the study population at each enrollment site. Indicate whether the actual size of available study

population may be affected by ongoing clinical trials that compete for the same population. If the proposed research involves access to military and/or VA patient populations and/or DOW or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Also include a plan for obtaining any required data sharing, memorandum of understanding or other agreements required to access and publish data. Refer to the General Application Instructions, Appendix 4, for additional considerations.

- **Recruitment and Retention Process:** Explain methods for identification of potential study participants (e.g., medical record review, obtaining sampling lists, health care provider identification). Describe the recruitment process in detail; address who will identify potential study participants, who will recruit them and what methods will be used to recruit them. Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study. If study participants will be compensated, include a detailed description of and justification for the compensation plan. Describe the methods that will be employed to retain participants within the study. Discuss past efforts in recruiting and retaining study participants for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention. Estimate the potential for participant loss to follow up and how such loss will be handled/mitigated. Indicate whether the study team has considered barriers to clinical trial participation and, if applicable, how the team aims to mitigate or overcome these barriers.
- **Women and Minorities Recruitment/Retention Strategy:** Describe the strategy for recruitment, enrollment and retention specific to women and minorities in the clinical trial appropriate to the objectives of the study.
- **Informed Consent Process:** Specifically describe the plan for obtaining informed consent from study participants; include information regarding the timing and location of the consent process. If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, describe the plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent. Appendix 6 of the General Application Instructions contains additional considerations unique to DOW-sponsored research. A copy of the latest version of the Informed Consent documents should be uploaded under Attachment 2: Supporting Documentation.
- **Privacy and Confidentiality:** Describe plans for ensuring appropriate privacy and confidentiality of enrolled human subjects. Explain situations where this might not be possible and how study participants will be made aware of these circumstances in advance.
- **Risks/Benefits Assessment:**
  - **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Address special precautions to be taken by the human subjects before, during and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention). If applicable, identify any potential risk to the study personnel.

- **Risk management and emergency response:** Appropriate to the study's level of risk, describe how safety monitoring and reporting to the IRB and Regulatory Agency (if applicable) will be managed and conducted. Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the costs of such care.
- **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.

- **Attachment 7: Regulatory Strategy (if applicable, no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".** Answer the following questions and provide supporting documentation as applicable.

  – State the product/intervention name.

  For products/interventions that do not require regulation by a Regulatory Agency:

  – Provide evidence that the clinical study does not require regulation by a Regulatory Agency. Submissions providing "not applicable," "none" or similar responses do not satisfy this request. No further information for this attachment is required.

  For products that require regulation by a Regulatory Agency:

  – Describe the overall regulatory strategy and product development plan that will be performed during the project's period of performance to support the planned product indication/label. Include, as appropriate, a description of the regulatory application submission strategy.

    - State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the United States. If the product is marketed in the United States, state the product label indication. State whether the proposed research involves a change to the approved label indication.
    - If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use and whether an IND or IDE application was submitted. ***If an IND or IDE is required, the application must be submitted to the FDA prior to the FY26 ORP Clinical Research Award submission deadline.*** The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed clinical trial. Provide the date of submission, the application number and a copy of the FDA letter acknowledging the submission.
    - Provide a summary of any meetings the research team had with regulatory agencies or consultants regarding the proposed research. Include key outcomes, action items and recommendations. If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.
    - If the clinical trial will be conducted at international sites, provide equivalent information and supporting documentation relevant to the product indication/label and regulatory approval and/or filings in the host country(ies).

- **Attachment 8: Study Personnel and Organization (no page limit): Start each document on a new page. Combine into one document and upload as "Personnel.pdf".** The Study Personnel and Organization attachment should include the components listed below.
  - **Organizational Chart:** Provide an organizational chart that identifies key members of the study team and provides an outline of the governing structure for multi-institutional studies. Provide justification for the inclusion of any international sites. Identify collaborating organizations, centers and/or departments and name each person's position on the project. Include any separate laboratory or testing centers. Identify the data and clinical coordinating center(s) and note any involvement from Contract Research Organizations, as appropriate, including the location of the organization. If applicable, identify the Regulatory Agency sponsor and any external consultants or other experts who will assist with Regulatory Agency sponsor applications. While there is no specified format for this information, a table(s) or diagram is recommended.
  - **Study Personnel Description:** Describe the composition of the study team in enough detail to determine whether the team includes relevant subject matter expertise to accomplish the proposed work. Include the roles of individuals named in the organizational chart along with any external consultants or advisors who will provide critical guidance and input to the study team (e.g., statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate). Study coordinator(s) should be included. Describe how the levels of effort for each individual are appropriate to successfully support the proposed clinical trial.
  - **Study Management Plan:** Describe the day-to-day management of the proposed clinical trial. Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial involves more than one institution, clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. If applicable, describe how communication and data transfer between/among the collaborating institutions will occur, as well as how data, specimens and/or imaging products obtained during the study will be handled and shared. Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Attachment 9: Impact Statement (two-page limit): Upload as "Impact.pdf".** The impact statement summarizes the potential short- and long-term impact of the proposed clinical trial. The statement should address the points outlined below written ***in a manner that will be readily understood by readers without a background in science or medicine***.
  - Summarize the potential benefit(s) of the intervention and/or research outcome of the proposed clinical study as it relates to the FY26 ORP CRA Focus Area(s).
  - Detail the anticipated research outcome(s) that will be directly attributed to the results of the proposed clinical study and describe the anticipated benefits of these outcomes for individuals who have sustained traumatic orthopaedic injuries and/or for the orthopaedic research field.
  - Describe how the proposed clinical research may result in an improvement over currently available interventions, standards of care, point of injury care, service-associated trauma care and/or quality of life for individuals with orthopaedic injuries.

- If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- Discuss potential military impact of the proposed clinical research. The following are examples of ways in which proposed studies may demonstrate military impact. ***Although not all-inclusive*****,** these examples are intended to help applicants frame the potential military impact of the proposed research:
  - Has the potential to change the standard of care for military orthopaedic injuries.
  - Proposes new paradigms or challenges existing paradigms in patient care of service-related orthopaedic injuries.
  - Contributes to development or validation of evidence-based policy or guidelines for patient evaluation and care of service-related orthopaedic injuries.
  - Improves unit readiness and/or return to duty.
- Describe any potential challenges that might limit the impact of the proposed clinical research, including barriers to implementation or acceptance by users. Describe any relevant controversies, treatment issues or health disparities that will be addressed by the proposed study.

- **Attachment 10: Post-Award Transition Plan (three-page limit): Upload as "Transition.pdf".** Discuss the anticipated methods and strategies necessary to move the anticipated research outcome (e.g., intervention, product, methodology, finding) to the next phase of development (e.g., clinical trials, commercialization and/or delivery to the civilian or military market), assuming a positive outcome from the proposed clinical trial. Investigators are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. Applicants are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development when preparing the transition plan. ***The post-award transition plan should:***
  - Name the project's anticipated research outcomes including knowledge products and/or clinical products for development. A "knowledge product" is a non-materiel product that aims to transition into medical practice, training, tools or to support materiel solutions; and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.
  - Include a timeline with defined milestones describing the logical next steps to advance the research outcome to the next stage of clinical development/implementation/dissemination. Include steps regarding Regulatory Agency approval as appropriate.
  - Describe collaborations and other resources (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources) that are in place or will be established to execute the steps described above. Include a discussion of the funding strategy necessary to transition the research outcome to the next level of investigation, development and/or commercialization. This discussion should include potential opportunities for securing funding through commercial sponsorship, venture capital, federal or nonfederal funding opportunities, or other relevant resources.
  - As appropriate, discuss ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award. Include a plan for resolving intellectual and material

property issues among participating organizations. If the intellectual property rights are not owned by the applicant, PI or a member of the study team, describe the planned next steps necessary to make the product available to the target population.

– Describe plans to mitigate any real or perceived financial conflicts of interest or biases.

- **Attachment 11: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations document available on eBRAP.
- **Attachment 12 Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOW organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the Suggested Intragovernmental/Intramural Budget form available on eBRAP.

(c) Additional Application Materials:

The following are additional forms for application submission. Follow the instructions specific to the submission portal, as found within the GAI.

Grants.gov	eBRAP.org
i. Research & Related Senior/Key Person Profile (Expanded) ○ **Biographical Sketch** ○ **Current/Pending Support** *Intragovernmental applicants must include their internally supported research and development programs.*	
ii. Research & Related Budget	
iii. Project/Performance Site Location(s)	
iv. Research & Related Subaward Budget Attachment(s) *(if applicable, Grants.gov submissions only)*	

4.4. Other Application Elements

If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DoD Instructions 3200.12 will be requested.

The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT94252626ORPCRA from Grants.gov or eBRAP, depending on which submission portal will be used.

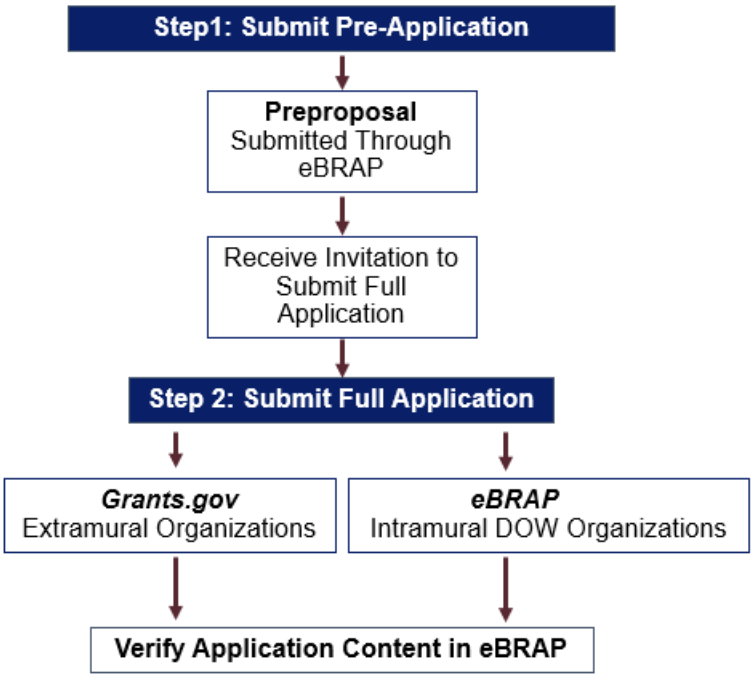
5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), SAM.gov, and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the unique entity identifier (UEI) generated by the SAM in applications to this funding opportunity and maintain an active registration in the SAM at all times during which it has an active Federal award or an application under consideration.

5.3. Submission Instructions

The CDMRP uses two portal systems to accept pre- and full application submissions. The workflow below shows which portal system to use for pre- and full application submissions, respectively.

Application Submission Workflow



5.3.1. Pre-Application Submission

All pre-application components must be submitted by the PI through eBRAP.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title and all information for the PI, 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. Contact the eBRAP Help Desk if any changes need to be made.

When starting the pre-application, PIs should select a Mechanism Option appropriate to their pre-application:

Application Includes:	Select Mechanism Option:
Clinical Research	Research Level 1
Clinical Trial	Research Level 2

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace.

eBRAP Submissions: Only intramural DOW organizations may submit full applications through eBRAP.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of the submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log in to eBRAP to review, modify and verify the full application submission. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the application verification period ends. The full application cannot be modified once the application verification period ends.

5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The DHACA cannot make allowances/exceptions for submission problems encountered by the applicant.***

Submission dates and times are specified in Section 1, Basic Information.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

6. Application Review Information

6.1. Application Compliance Review

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).

While it is allowable to propose similar research projects to different programs within the CDMRP or to other organizations, duplication of funding or accepting funding from more than one source for the same research is prohibited. See the CDMRP's Directive on Research Duplication.

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.

Members of the FY26 ORP Programmatic Panel must not be involved in any pre-application or full application including, but not limited to, concept design, application development, budget preparation and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic panel members ***may*** provide letters to confirm PI eligibility and access to laboratory space, equipment and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). ***A list of the FY26 ORP Programmatic Panel members can be found on the CDMRP website.***

Additional restrictions and associated administrative responses are outlined in Section 9.2, Administrative Actions.

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

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

- **Background/Research Problem/Rationale**
  - How well the background and scientific rationale demonstrate sufficient evidence to support the proposed clinical research.
  - How well the proposed work meets the intent of the award mechanism.
- **Research Strategy**
  - How well the objective(s), hypothesis, specific aims and study design support the research idea.
- **Impact and Alignment with Focus Area**
  - How well the proposed clinical research addresses at least one of the FY26 ORP CRA Focus Areas.
  - How well the proposed clinical study will impact the treatment or management of military combat- or service-related orthopaedic injuries.

6.2.2. Peer Review Criteria

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

- **Research Strategy and Feasibility**
    - How well the scientific rationale for the proposed clinical study is supported by preliminary data and/or critical review and analysis of the literature.
    - To what degree the application includes preclinical and/or clinical evidence to support the safety and stability (as appropriate) of the intervention, if applicable.
    - How well the specific aims, hypotheses, experimental design, data collection procedures and analyses are designed to clearly address the clinical objective(s) and purpose of the study.
    - How well the clinical research methodology and study variables are described and demonstrate a clear course of action and justification.
    - How well a schedule (e.g., flowchart or diagram) outlines the study intervention(s), evaluation(s) and follow-up procedures, if applicable, including collection schedule and amount of any biospecimens to be acquired.
    - How well the proposed study population and the inclusion/exclusion criteria are appropriate to meet the objectives of the study, as applicable.
    - How well each arm or study group is defined, and the group assignment method is described, including controls, as appropriate. Whether the number of human subjects to be enrolled is stated and delineated for each arm/study group and study site, as appropriate. How well any blinding procedures or other measures to reduce bias are described and are sufficient and appropriate for the study.
    - To what degree the data collection instruments, as well as plans to collect biospecimens and conduct laboratory evaluations, are sufficient and appropriate to the proposed clinical research, if applicable.
    - How well all endpoints, evaluations and outcome measures are described, are reliable and valid, are sufficient and appropriate, and will help meet the objectives of the study and/or monitor safety of human subjects. How well controls and quality standards are sufficient and appropriate for the selected endpoints, evaluations and outcome measures.
    - To what degree plans for data reporting and documentation are sufficient and appropriate to support a regulatory filing with the FDA or equivalent international regulatory agency, as applicable.
    - How well plans for initiating the clinical study within six months of the award are sufficient and appropriate.
    - How well the application acknowledges potential challenges, including an estimation of the potential for human subject loss to follow-up, and addresses alternative methods and/or approaches that may be employed to mitigate and/or overcome them.
- **Intervention *(Research Level 2 only)***
    - How well the intervention is identified and described, including intervention type (e.g., drug, device, behavioral, surgical), intervention name and composition, source, general concept of design and administration route.

- Whether there is evidence of support, indicating availability of and access to the intervention from its source, for the duration of the proposed clinical study (if applicable).
- To what degree the intervention addresses current clinical need(s) described in the application.
- How the intervention compares with currently available interventions and/or standards of care.
- To what degree the application includes preclinical and/or clinical evidence to support the safety and stability (as appropriate) of the intervention.
- Whether the proposed intervention and its endpoints are feasible and rational for use in its intended environment. If intended for a battlefield or military setting, whether the clinical setting of the study accurately represents the intended environment, and whether any limitations in the evaluative setting and any anticipated hurdles for translation to the final treatment environment are sufficiently discussed.
- How well the research procedures are clearly delineated from routine clinical procedures.
- Whether measures are described to ensure the consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).
- To what degree the clinical monitoring plan addresses the level of risk of the clinical trial.

- **Recruitment, Accrual and Retention**
  - Whether an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race and ethnicity is included.
  - To what degree the number of human subjects to be enrolled is reasonable based upon the proposed timeline, study procedures, available study population, inclusion/exclusion criteria and planned efforts to achieve accrual goals.
  - Whether the strategy for the inclusion of women and minorities and the distribution of proposed enrollment are appropriate for the proposed research, including a description of the composition of the proposed study population in terms of sex, racial and ethnic group and an accompanying rationale for the selection of subjects.
  - How well the application addresses the availability of human subjects for the clinical research, access to the proposed human subject population, the prospect of their participation and the ability to achieve recruitment goals.
  - The degree to which the recruitment, informed consent, screening and retention processes for human subjects will meet the objectives of the proposed clinical study.
  - How well the application identifies possible delays (e.g., slow/low enrollment, poor retention) and presents adequate mitigation plans to resolve them.
- **Impact and Military Benefit**
  - How well the proposed clinical research addresses the selected FY26 ORP CRA Focus Area(s).
  - To what degree the anticipated research outcomes of the proposed project will benefit individuals who sustain or who have sustained traumatic orthopaedic injuries and/or impact the orthopaedic research field.

- To what degree the proposed clinical research may result in an improvement over currently available interventions, standards of care, point of injury care, service-associated trauma care and/or quality of life for individuals with orthopaedic injuries.
- If applicable, to what extent the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- To what degree and in what capacity the proposed clinical research has the potential for military impact (e.g., change standard of care, propose new paradigms, develop/validate evidence-based policy, improve unit readiness and/or return to duty).
- How well any potential impact-limiting challenges (e.g., barriers to implementation, acceptance by the users), relevant controversies, treatment issues or health disparities are sufficiently addressed in the proposed clinical research.

- **Statistical Plan and Data Analysis**
  - How well studies are designed to achieve rigorous and reproducible results, including the choice of model and the endpoints/outcomes to be measured.
  - To what degree the statistical model and data analysis plan are suitable for the planned study objectives.
  - To what degree the sample size projections and power analysis are adequate to ensure proper power for the study, and as applicable, any subgroup analysis.
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study or whether the justification for a single-sex study is sufficiently strong.
- **Ethical Considerations**
  - How well the application describes what the human subject will experience in chronological order throughout the study, and to what degree the planned route and schedule are reasonable for study participants to experience.
  - How well the evidence shows that the study procedures are consistent with sound research design and, when appropriate, that these procedures are already in use for diagnostic or treatment purposes.
  - To what degree the population selected to participate in the clinical study stands to benefit from the knowledge gained.
  - To what extent the proposed clinical research might affect the daily lives of the individual human subjects participating in the study (e.g., will human subjects still be able to take their regular medications while participating in the clinical study? Are human subjects required to stay overnight in a hospital?) To what degree any barriers to clinical research participation have been considered and/or addressed.
  - How the level of risk to human subjects is minimized and how the safety monitoring and reporting plan is appropriate for the level of risk.
  - To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
  - To what degree privacy and confidentiality issues are appropriately considered.
  - If applicable, how well the inclusion of international sites is justified.

- **Regulatory Strategy and Transition Plan**
  - Whether the application includes documentation that the study is exempt from regulatory agency oversight, or that the IND or IDE application (and/or international equivalent) has been submitted to the Regulatory Agency, as appropriate.
  - How well the documentation provided supports the feasibility of acquiring an active IND or IDE (and/or international equivalent) covering the proposed trial, if applicable.
  - To what extent the regulatory strategy and product development plan are well described and appropriate to support the product indication or product label change, if applicable.
  - To what degree the next logical steps to be taken upon successful completion of the proposed clinical research are realistic and appropriate to bring the research outcome(s) (e.g., intervention, product, methodology, guideline) to the next stage of clinical development/implementation/dissemination.
  - To what degree the collaborations and other resources (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources) intended to help advance the research outcome(s) are established and/or achievable.
  - Whether the funding strategy described to bring the intervention or research outcome(s) to the next level of development (e.g., specific industry partners, specific funding opportunities to be applied for) is reasonable and achievable.
  - Whether the schedule and milestones for bringing the product/intervention to the next level of development (clinical trials, transition to industry, delivery to the market, incorporation into standard practice and/or approval by the FDA) are achievable.
  - To what degree ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award are considered and planned for, including plans for resolving any issues among participating organizations.
  - If applicable, whether the mitigation of any real or perceived financial COIs or biases have been addressed.
- **Personnel and Communication**
  - To what degree the composition of the study team, including any external consultants or advisors (e.g., study coordinator, statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate), is appropriate to accomplish the proposed work.
  - To what degree the study team's background and expertise are appropriate to accomplish the proposed work (e.g., statistical expertise, expertise in the treatment of orthopaedic injuries, and clinical studies).
  - To what degree the levels of effort of the study team members are appropriate for successful conduct of the proposed clinical study.
  - How well the study management plan of the clinical study (e.g., communication plan, data transfer and management, standardization of procedures, multi-institutional structure governing the research protocol[s]) are appropriate and meet the needs of the proposed clinical trial. For multi-site clinical research projects, how well the lead site responsibilities and human research protections regulatory coordination are defined and planned for.

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**:

- **Research Sharing Plan**
  - To what extent the plan for sharing of project data and research resources is appropriate and reasonable and includes dissemination to affected communities, study participants and/or the scientific community. If applicable, whether specific repository(ies) are named where data and research resources arising from the project will be stored.
- **Budget**
  - Whether the budget is appropriate for the proposed research.
- **Environment**
  - To what degree the scientific environment, clinical setting and the accessibility of institutional facilities and resources support the proposed clinical research at each participating center or institution (including collaborative arrangements).
  - Whether there is evidence for appropriate institutional commitment from each participating institution.
- **Application Presentation**
  - To what extent the writing, clarity and presentation of the application components influence the review.

6.2.3. 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 peer reviewers
- Relevance to the priorities of the FY26 ORP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Program portfolio composition
  - Programmatic relevance to FY26 ORP CRA Focus Areas
  - Relative clinical impact and military benefit

6.3. Application Review and Selection Process

6.3.1. Pre-Application

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 1, Basic Information about 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.

6.3.2. Full Application

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 subject to review and approval by a designated official. ***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 6.2.3, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found on the CDMRP website.

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.

6.4. Risk, 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 SAM.

An applicant organization may review the 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.

In accordance with National Security Presidential Memorandum-33 and all associated laws, all fundamental research funded by the DOW must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the DOD Component Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

7. Federal Award Notices

For each compliant full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. 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 application receipt and review process for the ORP 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. After all awards are made, the CDMRP includes individual award information in a searchable database.

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 DHACA 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).***

Intragovernmental 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 DOW 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 DOW 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.

8. Post-Award Requirements

8.1. 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.

The GAI contain information regarding administrative requirements and national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the DHACA Terms and Conditions for further information.

If there are delinquencies in technical reporting requirements for any existing Defense Health Agency (DHA) or U.S. Army Medical Research and Development Command awards at the applicant organization, DHACA will not issue any new awards to the applicant organization until all delinquent reports have been submitted.

Applications recommended for funding that involve animals, human data, human specimens, human subjects or human cadavers must be reviewed for compliance with federal animal and/or human subjects protection requirements and must be approved by the DHA R&D Office of Research and Regulatory Compliance (ORRC), prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee (IACUC), IRB or Ethics Committee (EC) review.

8.2. Reporting

RL1: Annual technical progress reports and quad charts as well as a final technical progress report and final quad chart will be required.

RL2: Quarterly and annual technical progress reports and quad charts as well as a final technical progress report and final quad chart will be required.

Quarterly, annual and final technical progress 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.

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 the SAM about certain civil, criminal and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with their 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.

8.3. Additional Requirements

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

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

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

9. Other Information

9.1. Program Announcement Version

Questions related to this program announcement should refer to the program name, the program announcement name and the program announcement version code CD26_01d.

9.2. Administrative Actions

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

9.2.1. Rejection

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

- Preproposal Narrative is missing.

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

- The Project Narrative is missing.
- The Budget is missing.
- Submission of an application for which a letter of invitation was not issued.

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to reviewing all documents.
- Documents not requested will be removed.

9.2.3. Withdrawal

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

- A member of the FY26 ORP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the pre-application or application processes.
- The application includes the name(s) of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY26, the identities of the peer review contractor and the programmatic review contractor may be found on the CDMRP website.
- 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.
- The application from an extramural organization, including non-DOW federal agencies, is received through eBRAP.
- The federal government recipient organization (including an intramural DOW organization): (a) cannot accept and execute the entirety of the requested budget in FY26 funds; and/or (b)

cannot coordinate the use of contractual, assistance or other appropriate agreements to provide funds to collaborators.

- The application fails to conform to this program announcement description.
- The application includes URLs, with the exception of links in the References Cited and Publication and/or Patent sections.
- The application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- The same research project is submitted to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.
- The invited application proposes a different research project than that described in the pre-application.

9.2.4. 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 DHACA Grants Officer for a determination of the final disposition of the application.

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance ***(Grants.gov submissions only)***	☐
Summary (Tab 1) and Application Contacts (Tab 2) ***(eBRAP 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"	☐
Study Population Recruitment and Safety Plan – Attachment 6, upload as "StudyPopPlan.pdf"	☐
Regulatory Strategy – Attachment 7, upload as "Regulatory.pdf"	☐
Study Personnel and Organization – Attachment 8, upload as "PersonnelOrg.pdf"	☐
Impact Statement – Attachment 9, upload as "Impact.pdf"	☐
Post-Award Transition Plan – Attachment 10, upload as "Transition.pdf"	☐
Representations ***(Grants.gov submissions only)*** **– Attachment 11, upload as "RequiredReps.pdf"**	☐
Suggested Intragovernmental/Intramural Budget Form ***(if applicable)*** **– Attachment 12, upload as "IGBudget.pdf"**	☐
Additional Application Materials	
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach Biographical Sketch for Senior/Key Persons (Biosketch_LastName.pdf)	☐
Attach Current/Pending Support for Senior/Key Persons (Support_LastName.pdf)	☐
Research & Related Budget	☐
Project/Performance Site Location(s)	☐
Research & Related Subaward Budget Attachment(s) ***(if applicable)***	☐

Appendix 2. Acronym List

CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CRA	Clinical Research Award
DHA	Defense Health Agency
DHA R&D	Defense Health Agency Research and Development
DHACA	Defense Health Agency Contracting Activity
DOD	U.S. Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DOW	U.S. Department of War
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
ORP	Orthopaedic Research Program
ORRC	Office of Research and Regulatory Compliance
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
R&D	Research and Development
RL1	Research Level 1
RL2	Research Level 2
RPPR	Research Performance Progress Report
SAM	System for Award Management
SF424 R&R	Standard Form 424 (Application for Federal Assistance, Research & Related)
SOW	Statement of Work
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USC	United States Code
VA	U.S. Department of Veterans Affairs