

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Defense Medical Research and Development Program

**Joint Program Committee 8 /
Clinical and Rehabilitative Medicine Research Program**

Restoring Warfighters with Neuromusculoskeletal Injuries Research Award (RESTORE)

Announcement Type: Initial

Funding Opportunity Number: W81XWH-19-DMRDP-CRMRP-RESTORE

**Catalog of Federal Domestic Assistance Number: 12.420 Military Medical
Research and Development**

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), September 3, 2019
- **Invitation to Submit an Application:** October 2019
- **Application Submission Deadline:** 11:59 p.m. ET, December 16, 2019
- **End of Application Verification Period:** 5:00 p.m. ET, December 18, 2019
- **Peer Review:** February 2020
- **Programmatic Review:** March 2020

This Program Announcement must be read in conjunction with the General Application Instructions, version 20190530. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2019 (FY19) Defense Medical Research and Development Program (DMRDP) Joint Program Committee 8/Clinical and Rehabilitative Medicine Research Program (JPC-8/CRM RP), Restoring Warfighters with Neuromusculoskeletal Injuries Research Award (RESTORE) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The Congressionally Directed Medical Research Programs (CDMRP) provides DMRDP execution management support for DHP core research program areas, including JPC-8/CRM RP. This Program Announcement/ Funding Opportunity and subsequent awards will be managed and executed by CDMRP with strategic oversight from JPC-8/CRM RP.

The JPC-8/CRM RP is one of six major DHP core research program areas within the DHA J9, Research and Development Directorate, and focuses on innovations to reconstruct, rehabilitate, and provide definitive care for injured Service members. The ultimate goal is to return the Service members to duty and restore their quality of life. Innovations developed from JPC-8/ CRM RP-supported research efforts are expected to improve restorative treatments and rehabilitative care to maximize function for return to duty (RTD) or civilian life. The goal is to advance medical technologies (drugs, biologics, and/or devices) and treatment/rehabilitation strategies (methods, guidelines, standards, and information) that will significantly improve the medical care provided to our wounded Service members within the Department of Defense (DoD) healthcare system. Implementation of these technologies and strategies should improve the rate of RTD of Service members and the time to clinical workload (patient encounters, treatments, etc.), and reduce the initial and long-term costs associated with restorative and rehabilitative or acute care. Additional information about the JPC-8/CRM RP can be found at <https://crmp.amedd.army.mil/>.

II.A.1. RESTORE Focus Areas

The DMRDP JPC-8/CRM RP RESTORE will support research in the areas of optimal management, treatment, and restoration following Service-related neuromusculoskeletal injury, including **acute combat/non-combat injury, repetitive overuse injury, limb loss, and limb trauma**.

To meet the intent of the award mechanism, applications *must* address one or more of the following Focus Areas:

- Solutions that accurately diagnose neuromusculoskeletal injuries in training and operational environments to optimize management and treatment decisions

- Solutions to accelerate recovery and restore Warfighter performance in training and operational environments
- Objective support tools to enable providers to assess function and performance throughout treatment and predict long-term outcomes
- Pain management strategies following acute and/or chronic neuromusculoskeletal injury that are fast-acting, long-lasting, and free of adverse side effects
- Optimization of Warfighter performance following limb trauma or loss. Examples include, but are not limited to, prosthetics and orthotic solutions (e.g., intuitive control and sensation, interface, interoperability, prescription, and training), as well as regenerative rehabilitation solutions addressing peripheral nerves, skeletal muscle, and/or bone. Technology development is allowed. Regenerative studies without a rehabilitative component are not responsive to this funding opportunity.

II.B. Award Information

The intent of the RESTORE mechanism is to provide support for research of exceptional scientific merit that proposes solutions for optimal management, treatment, and restoration following Service-related neuromusculoskeletal injury. Research will accelerate progress toward returning Warfighters to combat readiness following neuromusculoskeletal injury and will ultimately benefit all patients with such injuries.

The JPC-8/CRM RP expects to allot a total of approximately **\$40 million (M)** of DHP RDT&E appropriations over the three fiscal years, FY19, FY20, FY21, to fund approximately 25 to 30 RESTORE applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program. The funding estimated for this Program Announcement is approximate and subject to realignment.

Research Scope: The RESTORE is structured with three different Research Levels. The levels are all designed to support research that will lead to clinical application. Each level has a defined research scope. *It is the responsibility of the applicant to select the Research Level that aligns with the scope of the proposed research.* The Research Level should be selected based on the research scope defined in the Program Announcement, and not on the funding limit. **Only one Research Level may be chosen per application.** Therefore, the research scope defined under each Research Level should be considered carefully before the pre-application is submitted. The following are generalized descriptions of the scope of research appropriate for each Research Level:

- **Research Level 1—New ideas that represent innovative approaches and have the potential to make an important contribution within the [RESTORE Focus Areas](#):** Although groundbreaking research often involves a degree of risk, applications should be based on a sound scientific rationale that is established through logical reasoning and/or critical review and analysis of the literature. Due to this Research Level’s emphasis on innovation, preliminary data are encouraged, but not required. Clinical trials are not

supported in this Research Level. *The anticipated total (direct and indirect) costs will not exceed \$500,000.*

- **Research Level 2—Advancement of laboratory discovery, population-based studies, or clinical knowledge into clinical application and acceleration toward a clinical solution:** Supported research may include preclinical studies in animal models and clinical research involving human subjects. Proposed research may include initial studies advancing to a pilot clinical trial in later aims, where limited clinical testing of a novel intervention or device is necessary to inform the next step in the continuum of translational research. Preliminary data are required. Research consisting only of a clinical trial should be submitted to Research Level 3. *The anticipated total (direct and indirect) costs will not exceed \$1.5M.*
- **Research Level 3—Clinical trials with the potential to have a significant impact on Warfighters who have incurred neuromusculoskeletal injuries:** Proposed projects may range from small proof-of-concept trials (e.g., pilot, first-in-human, Phase 0) to demonstrate feasibility or inform the design of more advanced trials through large-scale trials to determine efficacy in relevant patient populations. Preclinical research is not supported. Preliminary data are required. *The anticipated total (direct and indirect) costs will not exceed \$3M.*

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

Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Funding of applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the Government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this funding opportunity will be funded with FY19, FY20, and FY21 funds.

Awards initiated with FY19 funds will be made no later than September 30, 2020. Awards initiated with FY20 funds will be made no later than September 30, 2021. For additional information refer to [Section II.F.1, Federal Award Notices](#).

The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of the DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a “thing of value” to a “state, local government,” or “other recipient” to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be

made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305) and the award will identify the specific substantial involvement. Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application as a stand-alone study. Submission to HRPO of protocols involving more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Applications that involve recruitment of human subjects must indicate the quarterly enrollment targets across all sites in [Attachment 5: Statement of Work \(SOW\)](#). Successful applicants will work with USAMRAA to establish milestones for human subjects recruitment. Continued support for the project will be based upon satisfactory progress in meeting the established milestones. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

This award mechanism supports preclinical research, clinical research, and clinical trials/testing according to the Research Level descriptions above. *New FY19 definition:* A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. Funded trials are required to post a copy of the IRB-approved informed consent form used to enroll subjects on a publicly available Federal website in accordance with Federal requirements described in the Code of Federal Regulations, Title 2, Part 219 (2 CFR 219).

Research proposed within this award may *not* be used to support fundamental basic research. For this award, basic research is defined as research directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward process or products in mind.

DoD and Department of Veterans Affairs (VA) Collaboration and Alignment Encouraged: Principal Investigators (PIs) are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with the DoD and/or VA is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DoD and VA areas of research interest or potential opportunities for collaboration can be found in [Appendix 2](#).

Use of DoD or VA Resources: If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Access to target active duty military patient population(s) and/or DoD resource(s) or database(s) should be confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs/Co-PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief. If appropriate, the application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the application should include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

Access to certain DoD or VA patient populations, resources, or databases may only be obtained by collaboration with a DoD or VA investigator who has a substantial role in the research and may not be available to a non-DoD or non-VA investigator if the resource is restricted to DoD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DoD or non-VA investigator collaborating with the DoD and/or VA. If access cannot be confirmed at the time of application submission, the Government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s). Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information.

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

relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at <https://journals.plos.org/plosone/article/file?type=supplementary&id=info:doi/10.1371/journal.pone.0146533.s001>.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled, “Research Involving Animals.” *Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies*. Refer to the General Application Instructions, Appendix 1, for additional information.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 2, Section K.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

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

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

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center.

Note: Applications from an intramural DoD organization or from an extramural Federal Government organization may be submitted to Grants.gov through a research foundation.

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

II.C.1.b. Principal Investigator

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

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

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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

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

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

II.D. Application and Submission Information

Submission of applications that are essentially identical or propose essentially the same research project to different Research Levels within this funding opportunity is prohibited and will result in administrative withdrawal of the duplicative application(s).

Extramural Submission: An application submitted by an organization to Grants.gov.

Intramural DoD Submission: An application submitted by a DoD organization to eBRAP.

II.D.1. Address to Request Application Package

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

Extramural Submissions:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at Grants.gov.

Intramural DoD Submissions:

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

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

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

Submission is a two-step process requiring both *pre-application* and *full application* as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-Application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (<https://eBRAP.org/>).

Full Application Submission: Full applications must be submitted through the online portals as described below.

Extramural Organization Submissions: Full applications from extramural organizations must be submitted through Grants.gov Workspace. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in [Section II.C.1, Eligible Applicants](#).

Intramural DoD Organization Submissions: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP.

For Both Extramural and Intramural Applicants: eBRAP allows an organization's representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Program Announcement requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement.

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

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

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

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

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

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

The applicant organization and associated PI identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

PIs with an ORCID identifier should enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B, for additional information on pre-application submission):

- **Tab 1 – Application Information**

Submission of application information includes assignment of primary and secondary research classification codes, which may be found at <https://ebrap.org/eBRAP/public/Program.htm>. Note that the codes have recently been revised. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this

application” in Block 5 of the Grants.gov SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

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

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

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

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

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

- **Tab 4 – Conflicts of Interest (COIs)**

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

- **Tab 5 – Pre-Application Files**

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

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

The Preproposal Narrative should include the following:

For All Research Levels:

- **Focus Area(s):** State which [RESTORE Focus Area\(s\)](#) the proposed work will address and how it could improve management, treatment, and restoration to function following Service-related neuromusculoskeletal injury.

- **Research Level:** State the developmental stage of the proposed research (preclinical, clinical study, etc.). Provide a rationale for the Research Level chosen based on the research scope.
- **Research Plan:** Concisely state the ideas and reasoning on which the proposed preclinical research, clinical study, or clinical trial is based. State the project’s hypothesis, objectives, and specific aims, and briefly describe the experimental approach. For preproposals with a clinical trial, provide a brief description of the intervention.
- **Military Benefit and Impact:** Describe how the proposed work will impact Warfighter health following neuromusculoskeletal injuries, specifically on returning injured Warfighters to combat readiness and/or restoring the highest levels of form, function, performance, and quality of life.
- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* and are limited to the following:
 - References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
 - Key Personnel Biographical Sketches (six-page limit per individual). *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **Tab 6 – Submit Pre-Application**

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

Pre-Application Screening

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the JPC-8/CRM RP, pre-applications will be screened based on the following criteria:

- **Alignment with Focus Area(s):** How well the project addresses at least one of the [RESTORE Focus Areas](#).

- **Research Level:** How appropriate the proposed research is for the Research Level chosen.
 - **Research Plan:** How well the proposed research addresses the intent of the award mechanism and the program. To what degree the rationale, objectives, and specific aims support the research idea.
 - **Military Benefit and Impact:** How the proposed work, if successful, would benefit Warfighter health and readiness following neuromusculoskeletal injuries.
- **Notification of Pre-Application Screening Results**

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

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

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

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

Each application submission must include the completed full application package for this Program Announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://www.grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Application Guidelines

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the *same version* of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
<p>Download application package components for W81XWH-19-DMRDP-CRMRP-RESTORE from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.</p>	<p>Download application package components for W81XWH-19-DMRDP-CRMRP-RESTORE from eBRAP (https://ebrap.org).</p>
Full Application Package Components	
<p>SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.</p>	<p>Tab 1 – Summary: Provide a summary of the application information.</p> <p>Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form (if applicable) 	<p>Tab 3 – Full Application Files: Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites <p>Tab 4 – Application and Budget Data: Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>
Application Package Submission	
<p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>Submit a Grants.gov Workspace Package. An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package at least</p>	<p>Submit package components to eBRAP (https://ebrap.org).</p> <p>Tab 5 – Submit/Request Approval Full Application: After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/</p>

Extramural Submissions	Intramural DoD Submissions
<p>24-48 hours prior to the close date to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p>Note: If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline.</p>	<p>Comptroller/Task Area Manager or equivalent Business Official by email.</p>
<p><u>Application Verification Period</u></p>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form</i>.</p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form</i>. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>
<p>Further Information</p>	
<p>Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

Both Extramural and Intramural Organizations: Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. *The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.* Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the

application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

Attachments:

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

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

- **Attachment 1: Project Narrative (page limit varies by Research Level; see below for page limit): Upload as “ProjectNarrative.pdf”.** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.
 - **Page Limit:** Page limits for the Project Narrative are correlated with the application’s Research Level:
 - **Research Level 1:** Twelve-page limit
 - **Research Level 2:** Fifteen-page limit
 - **Research Level 3:** Twenty-page limit

- **Outline for Projective Narrative:** Describe the proposed project in detail using *one* of the two outlines below, depending on the whether or not a clinical trial is proposed.

Outline for projects without a clinical trial (Research Level 1 or Research Level 2 [if not including a pilot clinical trial]):

- **Focus Area(s):** State explicitly which [RESTORE Focus Area\(s\)](#) the proposed research will address and how it could improve management, treatment, and restoration to function following Service-related neuromusculoskeletal injury.
- **Research Level:** Describe how the Research Level chosen is appropriate for the proposed research.
- **Background:** Briefly describe the ideas and reasoning on which the proposed work is based. Preliminary data are encouraged, but not required, for Research Level 1 applications. For Research Level 2 applications, provide sufficient preliminary data to support the feasibility of the work proposed. Regardless of whether preliminary data are available, the application must demonstrate logical reasoning and provide a sound scientific rationale for the proposed project as established through a critical review and analysis of published literature. If proposing translational or clinical research, it is important to describe the studies showing proof of concept and, if applicable, efficacy in an in vivo system.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely state the project's specific aims to be funded by this award.
- **Innovation (Research Level 1 only):** Describe how the proposed research is innovative and proposes new paradigms, challenges existing paradigms, or is otherwise highly creative in one or more of the following ways: concept or question, research methods or technologies, adaptations of methods or technologies, or other ways. Describe how the proposed research represents more than an incremental advance beyond ongoing research and published data.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for evaluation. Explain how this research strategy will meet the research goals and milestones. Where relevant, describe the accessibility to the data, cohort(s), and/or critical reagents (e.g., therapeutic molecules, human samples) necessary for the project. Address potential pitfalls and problem areas and present alternative methods and approaches. As appropriate, include information on the endpoints/outcome measures to be used. If proposing translational research, provide a well-developed, well-integrated, and detailed research plan that supports the translational feasibility and promise of the approach. If the methodology is new or unusual, provide sufficient details for evaluation. Describe how data will be reported and how it will be assured that the documentation will support a

regulatory filing with the U.S. Food and Drug Administration (FDA), if applicable.

- **Statistical Plan:** Describe the statistical plan, including power analysis as appropriate, for the research proposed.

Outline for projects with a clinical trial (Research Level 2 [if including a pilot clinical trial] and Research Level 3). (Note: The Project Narrative is not the formal clinical trial protocol. If recommended for funding, the clinical trial protocol will be requested.):

- **Focus Area(s):** State explicitly which [RESTORE Focus Area\(s\)](#) the proposed research will address and how it could improve management, treatment, and restoration to function following Service-related neuromusculoskeletal injury.
- **Research Level:** Describe how the Research Level chosen is appropriate for the proposed research.
- **Background:** Describe in detail the rationale for the study and include a literature review, preliminary studies, and/or preclinical data that led to the development of the proposed clinical trial. Importantly, describe the studies showing proof of concept and efficacy in in vivo system(s) that led to the current proposed work. Provide a summary of relevant clinical trials and distinguish how the proposed study differs from other relevant ongoing or recently completed clinical trials. Include a discussion of any current clinical use of the intervention under investigation and/or details of its study in clinical trials for other indications (as applicable). The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or study hypotheses. This section should establish the relevance of the study and explain the applicability of the proposed findings.

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

- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely state the project's specific aims to be funded by this award.
- **Research Strategy (Research Level 2 only):** Describe the laboratory research studies that will be performed under this award and how they are clearly linked to the clinical trial. Describe the experimental design and methodology, including reagents, assay validation, potential pitfalls, and alternative approaches. Where relevant, describe the availability of and access to necessary data and/or critical reagents (e.g., therapeutic molecules, human samples) necessary for the proposed

research. Provide a well-developed, well-integrated research strategy that supports the feasibility of the approach. If the methodology is new or unusual, provide sufficient details for evaluation. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

- **Clinical Trial:** Provide detailed plans for initiating, conducting, and completing the clinical trial during the period of performance. As appropriate, outline a plan for obtaining Investigational New Drug/Investigational Device Exemption (IND/IDE) status (or other FDA approvals). It is expected that, if required, IND/IDE applications to the FDA will be submitted by the application submission deadline (provide details in the Regulatory Strategy, [Attachment 9](#)). Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and explain how it is appropriate to meet the project's objectives. Outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate. For Research Level 2, describe how the proposed pilot clinical trial is clearly linked to the preclinical/clinical research studies that will be performed through the award.
 - Briefly identify the intervention to be tested and describe the projected outcomes (further details should be provided in [Attachment 10](#)).
 - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
 - Describe the availability of and accessibility to critical reagents (e.g., therapeutic molecules) necessary for the clinical trial.
 - Briefly describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random). Provide information on the availability of and access to the appropriate patient population(s), as well as the ability to accrue sufficient subjects for the clinical trial (further details should be provided in [Attachment 11](#)).
 - Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
- **Statistical Plan:** For the preclinical studies, describe the statistical plan, including power analysis as appropriate, for the research proposed. For clinical trials, describe the statistical model and data analysis plan with respect to the study objectives. Specify the number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at

each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.

- **Clinical Team:** Describe the composition of the clinical trial team. Provide details on how the team (including investigator[s], study coordinator, statistician) possesses the appropriate expertise in conducting clinical trials.
 - **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. 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. Identify and provide justification for the inclusion of international sites, as appropriate. If applicable, identify the FDA regulatory sponsor and any external consultants or other experts who will assist with FDA applications. While there is no specified format for this information, a table(s) or diagram is recommended.
 - **Study Personnel Description:** Briefly describe the roles of the individuals listed in the organizational chart on the project. Describe relevant experience and qualifications that demonstrate appropriate expertise for the given role, including previous interactions with the FDA, if applicable. An external research monitor (if applicable) and study coordinator(s) should be included.
 - **Study Management Plan:** Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial is multi-institutional, clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. Provide a regulatory submission plan for the master protocol and master consent form by the lead organization; include a single IRB/EC pathway whenever possible. If applicable, describe how communication and data transfer between the collaborating institutions will occur, as well as how data, specimens, and/or imaging products obtained during the study will be handled and shared.
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

- References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support (two pages per letter is recommended): Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (if applicable) (two pages per letter is recommended): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.
- Letters of Commitment (if applicable): If the proposed study involves the use of a commercially produced investigational drug, device, or biologic, provide a letter of commitment from the commercial entity 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.
- Good Manufacturing Practice (GMP) Compliance (if applicable): Provide information regarding the resources available to aid in the development of sufficient quantities of the reagent under GMP. If the reagent is to be provided from industrial sources, evidence of a cost-sharing plan must also be provided.

- Intellectual Property: Information can be found in 2 CFR 200.315, “Intangible Property.”
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about CDMRP expectations for making data and research resources publicly available.
- Use of DoD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military populations and/or DoD resources or databases.
- Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the ACOS/R&D or Clinical Service Chief, confirming access to VA patients, resources, and/or research space. For VA PIs, if the VA NPC is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- Quad chart: Provide a quad chart for the project using the template provided on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>).
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Use the outline below.

- **Focus Area(s):** State explicitly which [RESTORE Focus Area\(s\)](#) will be addressed.
- **Background:** Present the ideas and reasoning behind the proposed work.
- **Objective/Hypothesis:** State the objective to be reached/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- **Specific Aims:** State the specific aims of the study.
- **Research Strategy:** State the Research Level of the proposed study. Briefly describe the study design, including appropriate controls.

- **Impact:** Briefly describe how the proposed project, if successful, will have an impact and accelerate progress toward returning Warfighters to combat readiness and/or restoring the highest levels of form, function, performance and quality of life following neuromusculoskeletal injury, as well as ultimately benefiting individuals with neuromusculoskeletal injury in the general population.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. **Do not include proprietary or confidential information.** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. Clearly describe, in a manner readily understood by readers without a background in science or medicine, the rationale, objective, and aims of the application. Do not duplicate the technical abstract.
 - Describe the ultimate applicability of the research.
 - Which [RESTORE Focus Area\(s\)](#) does this research address?
 - What types of patients will it help and how will it help them?
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected time it may take to achieve a patient-related outcome on returning Warfighters to combat readiness and/or restoring the highest levels of form, function, performance and quality of life following neuromusculoskeletal injury?
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the RESTORE mechanism, use the SOW format example titled, “SOW (Statement of Work) Generic Format” if a clinical trial is not proposed, or the “SOW for Clinical Research (Including Trials, Special Populations)” if a clinical trial is proposed. The SOW must be in PDF format prior to attaching.

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

- Include the name(s) of the key personnel and contact information for each study site/subaward site.
- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.

- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
 - Identify cell line(s) and commercial or organizational source(s) to be used, if applicable.
 - If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., IND/IDE applications) by the FDA or other Government agency.
 - The SOW should include a feasible plan and timeline to conduct the research. The SOW must include specific research milestones to be accomplished by the end of each year in the period of performance.
- **Attachment 6: Military Benefit and Impact Statement (one-page limit): Upload as “MilBen.pdf”.** Describe how the proposed work will impact Warfighter health following neuromusculoskeletal injuries, specifically on returning injured Warfighters to combat readiness and/or restoring the highest levels of form, function, performance, and quality of life. Describe how the proposed research will ultimately benefit patients with neuromusculoskeletal injuries. Explain how the proposed research will move beyond a minor advancement and will lead to a new approach that is fundamentally better than interventions already approved or in clinical development. *(Do not restate the research strategy as part of the Military Benefit and Impact Statement.)*
 - **Attachment 7: Transition Plan (two-page limit, not required for Research Level 1, required for Research Levels 2 and 3): Upload as “Transition.pdf”.** Provide information on the methods, strategies, and anticipated timeline proposed to advance the anticipated outcomes to the next phase of research. The Transition Plan attachment should include the components listed below.
 - Details of the strategy to transition to the next level of development (e.g., further development of the intervention, clinical trials, commercialization and/or delivery to the civilian or military market). Include plans for the funding strategy to transition to the next level of development, clinical testing and/or commercialization (e.g., specific industry partners, specific funding opportunities to be applied for).
 - Provide a description of collaborations and other resources that will be used to provide continuity of development. For knowledge products this may include proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. (A “Knowledge Product” is a non-materiel product that addresses an identified need, topic area, or capability gap; is based on current evidence and research; aims to transition into medical practice, training, tools, or support for materiel solutions [systems to develop, acquire, provide, and sustain medical solutions and capabilities]; and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.)

- For planned peer-reviewed publications generated from clinical research or trials, identify and explain the level of evidence that will contribute toward evidence-based clinical practice. Generally grades are:
 - Level 1 – Large randomized controlled trials (RCTs) with clear results or meta-analyses
 - Level 2 – Small RCTs with unclear results
 - Level 3 – Cohort and case-control studies
 - Level 4 – Historical cohort or case-control studies
 - Level 5 – Case series, studies with no controls

(Sackett DL, Rules of evidence and clinical recommendations on the use of antithrombotic agents, *Chest* 1989, 95:2S–4S).

- Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the Government’s ability to access such products or technologies in the future.
- If applicable, a risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 8: Animal Research Plan (as applicable for Research Levels 1 and 2; three-page limit): Upload as “AnimalResPlan.pdf”.** If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. The Animal Research Plan should not be an exact replica of the protocol(s) submitted to the IACUC. The Animal Research Plan should address the following points for each proposed animal study:
 - Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study’s relevance to human biology. Describe how the animal model chosen reproduces the human injury of interest.
 - Summarize the procedures to be conducted and state the endpoints/outcome measures to be assessed. Describe how the study will be controlled.
 - Describe the randomization and blinding procedures for the study, as well as any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
 - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.

- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
- **Attachment 9: Regulatory Strategy (required for all Research Level 3 submissions and for all Research Level 2 submissions that include a clinical trial; no page limit):** If submitting multiple documents, start each document on a new page. Combine and upload as a single file named “Regulatory.pdf”.

Describe the regulatory strategy using the following outline and provide supporting documentation as applicable.

- State the product/intervention name.
- State how many months into the award the anticipated clinical trial would be initiated after the award begins, taking into account any required advanced preclinical work (e.g., GMP production; pharmacokinetics and toxicity testing) and/or clinical trial preparation (IRB and DoD HRPO approval).

For products/interventions that do not require regulation by the FDA or an international regulatory agency:

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

For products/interventions that require regulation by the FDA or an international regulatory agency:

- State whether the product is FDA-approved, -licensed, or -cleared and marketed in the U.S.
- If the product/intervention ***has*** already received FDA approval:
 - Provide a copy of the acceptance letter from the FDA.
 - If the product is marketed in the U.S., state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).

- If the product/intervention ***has not*** already received FDA approval:
 - State the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification.
 - Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor’s understanding of all sponsor responsibilities and commitment to oversee execution of the study.
 - Describe the overall regulatory strategy and product development plan that will support the planned product indication. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, and the types of FDA meetings that will be held/planned. Include considerations for compliance with current GMP, Good Laboratory Practice (GLP), and Good Clinical Practice (GCP) guidelines.
 - If the clinical trial involves the use of a drug that has not been approved by the FDA for the proposed investigational use, then an IND application to the FDA that meets all requirements under 21 CFR 312 may be required and must be submitted to the FDA by the application submission deadline. If the investigational product is a device, evidence that an IDE application that meets all requirements under 21 CFR 812 has been submitted to the FDA by the application submission deadline, or that the device is exempt or qualifies for an abbreviated IDE, is required. The Government reserves the right to withhold or withdraw funding if an IND or IDE is necessary but has not been submitted to the FDA by the application submission deadline, or if documented status of the IND or IDE has not been obtained within 18 months of the award date.
- If a drug is to be used in the proposed clinical trial, describe the current status for manufacturing development (e.g., manufacturer’s name, GMP-compliant lots available, status of stability testing), non-clinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support Phase I testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).
- If a device is to be used in the proposed clinical trial, indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights for the conduct of the clinical trial.
- **Attachment 10: Intervention (required for all Research Level 3 submissions and for all Research Level 2 submissions that include a clinical trial; no page limit): Upload as “Intervention.pdf”.** The Intervention attachment should include the components listed below.
 - **Description of the Intervention:** Identify the intervention to be tested and describe the particular outcomes. As applicable, the description of the intervention should include the following components: complete name and composition, storage and

handling information, source and availability, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed. Description of devices should include general concept of design, detailed operational instructions, any potential risks to users, and intended benefits. Other types of interventions should be fully described. A description of how the intervention compares with currently available interventions and/or standards of care should be specified. Research procedures should be clearly delineated from routine clinical procedures. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights for conduct of the clinical trial.

Summarize key preclinical pharmacological findings, dosage studies, and other clinical studies (if applicable) that examine the safety and stability (as appropriate) of the intervention.

- **Study Procedures:** Describe the interaction with the human subject, including the study intervention that he/she will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will experience. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures. Clearly delineate research procedures from routine clinical procedures. Discuss how compliance with current GLP guidelines, GMP, and other regulatory considerations will be established, monitored, and maintained, as applicable.
- **Clinical Monitoring Plan:** Describe how the study will be conducted by and monitored for current ICH E6 (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) GCP compliance by an independent clinical trial monitor (or clinical research associate). The monitoring plan should describe the types of monitoring visits to be conducted, the intervals (based on level of risk), how corrective actions will be reported to the Sponsor and PI, and how they will be corrected and prevented by the clinical trial site/PI.
- **Attachment 11: Human Subject Recruitment and Safety Procedures (Required for all Research Level 3 submissions and for all Research Level 2 submissions that include a clinical trial; no page limit): Upload as “HumSubProc.pdf”.** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.
 - **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). Provide a table of anticipated enrollment counts at each study site. Demonstrate that the research team has access to the proposed study population at each site and describe the efforts that will be made to achieve accrual goals. Furthermore, discuss past efforts in recruiting human subjects from the target population 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. Identify ongoing clinical trials that may compete for the same patient population and how they may impact enrollment progress. Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender. ***For clinical trials proposing to include military personnel, refer to the General Application Instructions, Appendix 1, for more information.***

- **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

Inclusion of Women and Minorities in Study. Consistent with the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects,” and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded from the clinical trial.

- **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, healthcare provider identification).
 - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
 - If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan.
 - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.
- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.
 - ***For the proposed study, provide a draft, in English, of the Informed Consent Form.***
 - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects’ questions will be addressed during the consent process and throughout the trial.
 - Include information regarding the timing and location of the consent process.

- Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
 - Address how privacy and time for decision-making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
 - Consider the need for obtaining ongoing consent or reassessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
 - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. *Note:* In compliance with 10 USC 980 (<https://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf>), the application must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial. If applicable, refer to the General Application Instructions, Appendix 1, for more information.
 - *Assent.* If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.
- **Screening Procedures:** 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. *Note:* Some screening procedures may require a separate consent or a two-stage consent process.
 - **Risks/Benefits Assessment:**
 - **Effects on Daily Life:** Describe how participation in the study will affect the daily life of subjects (e.g., Will human subjects still be able to take their regular medications while participating in the study? Are human subjects required to stay overnight in a hospital?).
 - **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Study risks include any risks that the human subject is exposed to as a result of participation in the clinical trial. Consider psychological, legal, social, and economic risks as well as physical risks. If the

risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.

- **Risk management and emergency response:**
 - ❖ Describe how safety surveillance and reporting to the IRB and FDA (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. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
 - ❖ 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 cost of such care.
 - ❖ Address any 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).
 - ❖ 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 the IRB determines that a trial presents greater than minimal risk to human subjects, the DoD requires an independent research monitor with expertise consistent with the nature of risk(s) identified within the research protocol. If applicable, refer to the General Application Instructions, Appendix 1, Section B (Research Monitor Requirement), for more information on study reporting authorities and responsibilities of the research monitor.
- **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 12: Data Management (required for Research Level 3; no page limit): Upload as “Data_Manage.pdf”.** The Data Management attachment should include the components listed below.
 - **Data Management:** Describe all methods used for data collection, including the following:
 - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.

- **Confidentiality:**
 - ❖ Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
 - ❖ Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of the DoD are eligible to review study records.
 - ❖ Address requirements for reporting sensitive information to state or local authorities.
- **Data capture, verification, and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, the process for locking the database at study completion, and the length of time data will be stored. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. Describe the database lock process. For FDA-regulated studies, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) are required.
- **Data reporting:** Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.
- **Laboratory Evaluations:**
 - **Specimens to be collected, schedule, and amount:** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.
 - **Evaluations to be made:** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
 - **Storage:** Describe specimen storage, including location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the plan to store specimens for future use, including

considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.

- **Labs performing evaluations and special precautions:** Identify the laboratory performing each evaluation, the applicable quality standard, and any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.
- **Attachment 13: Surveys, Questionnaires, and Other Data Collection Instruments, if applicable (no page limit): Upload as “Surveys.pdf”.** The Surveys, Questionnaires, and Other Data Collection Instruments attachment should include a copy of the most recent version of surveys, questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study. Describe how and when the instrument(s) will be administered. Describe how the instrument(s) will be adapted to the subject population, if applicable.
- **Attachment 14: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- **Attachment 15: DoD Military Budget Form(s), if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the DoD Military Budget Form, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.
- **Extramural and Intramural Applications**

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

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

eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

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

- PI Biographical Sketch (six-page limit): Upload as “Biosketch_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.
- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.
- Key Personnel Biographical Sketches (six-page limit each): Upload as “Biosketch_LastName.pdf”.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.

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

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

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

- **Extramural Applications Only**

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

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

- **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 15. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DoD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)

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

II.D.4. Submission Dates and Times

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

Applicant Verification of Full Application Submission in eBRAP

Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate retrieved files against the specific Program Announcement requirements, and discrepancies will be noted in both the email and in the “Full Application Files” tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the Program Announcement. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

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

Intramural DoD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of the status and will be able to view and modify

application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

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

II.D.5. Funding Restrictions

It is the responsibility of the applicant to select the Research Level that is most appropriate for the proposed research project. The requested budget level should be appropriate for the scope of the research proposed.

For Research Level 1 Applications:

- The maximum period of performance is **3** years.
- The anticipated total costs budgeted for the entire period of performance will not exceed **\$500,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$500,000** total costs or using an indirect cost rate exceeding the organization's negotiated rate.

For Research Level 2 Applications:

- The maximum period of performance is **4** years.
- The anticipated total costs budgeted for the entire period of performance will not exceed **\$1.5M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$1.5M** total costs or using an indirect cost rate exceeding the organization's negotiated rate.

For Research Level 3 Applications:

- The maximum period of performance is **4** years.
- The anticipated total costs budgeted for the entire period of performance will not exceed **\$3.0M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$3.0M** total costs or using an indirect cost rate exceeding the organization's negotiated rate.

For All Research Levels:

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years for **Research Level 1** applications, or **4** years for **Research Level 2 and 3** applications.

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

- Travel costs for the PI to present project information or disseminate project results at one DoD-sponsored scientific meeting (e.g., Military Health System Research Symposium) during the period of performance in Year 2 or beyond should be requested. These travel costs are in addition to those allowed for annual scientific/technical meetings.
- Travel costs for the PI to present project information at one DoD-sponsored In-Progress Review meeting during the period of performance in Year 2 or beyond should be requested. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Research-related subject costs
- Clinical research costs
- Clinical trial costs (for Research Levels 2 and 3 only)
- Support for multidisciplinary collaborations, including travel
- Travel costs for up to two investigators to travel to no more than one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the RESTORE.

Must not be requested for:

- Clinical trial costs in Research Level 1
- Preclinical research costs in Research Level 3

Awards made to extramural organizations will consist solely of assistance agreements (grants and cooperative agreements). For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other

Federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

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

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. The time is considered when establishing the award's period of performance. It is anticipated that awards made from this funding opportunity will be funded with FY19, FY20, and FY21 funds.

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

Research Level 1:

- **Innovation**
 - To what degree the proposed research is innovative and proposes new paradigms, challenges existing paradigms, or is otherwise highly creative in one or more of the following ways: concept or question, research methods or technologies, adaptations of methods or technologies, or other ways.
 - To what degree the proposed research represents more than an incremental advance beyond ongoing research and published data.
- **Impact**
 - To what degree the proposed research could lead to a solution for a [RESTORE Focus Area](#).
 - To what degree the project, if successful, could accelerate progress toward returning Warfighters to combat readiness following neuromusculoskeletal injury.

- Whether the proposed research will move beyond a minor advancement and will lead to a new approach that is fundamentally better than interventions already approved or in clinical development.
- Whether the proposed research would ultimately benefit patients with neuromusculoskeletal injuries.
- **Research Strategy and Feasibility**
 - How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of published literature, logical reasoning, and preliminary data, if provided (preliminary data are not required under Research Level 1).
 - How well the hypothesis, objectives, specific aims, experimental design, methods, and analyses are developed.
 - How well the application acknowledges potential problems and addresses alternative approaches.
 - If applicable, how well the animal study (or studies) is (are) designed to achieve the objectives, including the endpoints/outcome measures to be used.
 - How well the proposed research is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, statistical analysis, and data handling.
 - Whether there is documented availability of, access to, and quality control for all data, cohort(s), and/or critical reagents.
 - Whether there are resources available for the development of sufficient quantities of critical reagents under GMP, if applicable.
 - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
 - How well the SOW indicates a feasible plan and timeline to conduct the research and provides clearly defined milestones.
- **Statistical Plan**
 - Whether an appropriate statistical plan is provided, including power analysis.
- **Personnel**
 - Whether the research personnel have the appropriate background and neuromusculoskeletal-related expertise to enable successful conduct of the project.
 - How appropriate the levels of effort are for successful conduct of the proposed work.

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

- **Environment**

- Whether the scientific environment is appropriate for the proposed research.
- How well the research requirements are supported by the availability of and access to facilities and resources (including collaborative arrangements).
- Whether the quality and extent of institutional support are appropriate for the proposed research.
- If applicable, to what degree the intellectual and material property plan is appropriate.

- **Budget**

- Whether the **total** maximum costs are equal to or less than the allowable total maximum costs as published in the Program Announcement.
- Whether the budget is appropriate for the proposed research.

- **Application Presentation**

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

Research Level 2 without a clinical trial:

- **Impact**

- To what degree the proposed research could lead to a solution for a [RESTORE Focus Area](#).
- To what degree the project, if successful, could accelerate progress toward returning Warfighters to combat readiness following neuromusculoskeletal injury.
- Whether the proposed research will move beyond a minor advancement and will lead to a new approach that is fundamentally better than interventions already approved or in clinical development.
- Whether the proposed research would ultimately benefit patients with neuromusculoskeletal injuries.

- **Research Strategy and Feasibility**

- How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of published literature, logical reasoning, and preliminary data (preliminary data are required under Research Level 2).

- How well the hypothesis, objectives, specific aims, experimental design, methods, and analyses are developed.
 - How well the application acknowledges potential problems and addresses alternative approaches.
 - If applicable, how well the animal study (or studies) is (are) designed to achieve the objectives, including the endpoints/outcome measures to be used.
 - How well the proposed research is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, statistical analysis, and data handling.
 - Whether there is documented availability of, access to, and quality control for all data, cohort(s), and/or critical reagents.
 - Whether there are resources available for the development of sufficient quantities of critical reagents under GMP, if applicable.
 - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
 - How well the SOW indicates a feasible plan and timeline to conduct the research and provides clearly defined milestones.
- **Transition Plan**
 - To what degree the application demonstrates feasible methods and strategies to move the research findings to the next phase of development including, as applicable, further development of the intervention, clinical trials, changes in clinical practice, and/or delivery to the military or commercial market after successful completion of the award.
 - Whether the application has a plan to distribute the findings or intervention. For planned peer-reviewed publications generated from clinical research or trials, how well is the level of evidence that will contribute toward evidence-based clinical practice described and explained.
- **Statistical Plan**
 - Whether an appropriate statistical plan is provided, including power analysis.
- **Personnel**
 - Whether the research personnel have the appropriate backgrounds and neuromusculoskeletal-related expertise to enable successful conduct of the project.
 - How appropriate the levels of effort are for successful conduct of the proposed work.

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

- **Environment**

- Whether the scientific environment is appropriate for the proposed research.
- How well the research requirements are supported by the availability of and access to facilities and resources (including collaborative arrangements).
- Whether the quality and extent of institutional support are appropriate for the proposed research.
- If applicable, to what degree the intellectual and material property plan is appropriate.

- **Budget**

- Whether the **total** maximum costs are equal to or less than the allowable total maximum costs as published in the Program Announcement.
- Whether the budget is appropriate for the proposed research.

- **Application Presentation**

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

Research Level 2 with a clinical trial:

- **Impact**

- To what degree the proposed research could lead to a solution for a [RESTORE Focus Area](#).
- To what degree the project, if successful, could accelerate progress toward returning Warfighters to readiness and combat following neuromusculoskeletal injury.
- Whether the proposed research will move beyond a minor advancement and will lead to a new approach that is fundamentally better than interventions already approved or in clinical development.
- Whether the proposed research would ultimately benefit patients with neuromusculoskeletal injuries.

- **Research Strategy and Feasibility**

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

- How well the hypothesis, objectives, specific aims, experimental design, methods, and analyses are developed.
 - How well the application acknowledges potential problems and addresses alternative approaches.
 - If applicable, how well the animal study (or studies) is (are) designed to achieve the objectives, including the endpoints/outcome measures to be used.
 - How well the proposed research is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, statistical analysis, and data handling.
 - Whether there is documented availability of, access to, and quality control for all data and/or critical reagents.
 - Whether there are resources available for the development of sufficient quantities of critical reagents under GMP, if applicable.
 - Whether the proposed laboratory research studies are clearly linked to the proposed clinical trial.
 - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
 - How well the SOW indicates a feasible plan and timeline to conduct the research and provides clearly defined research milestones to be accomplished by the end of each year in the period of performance.
- **Clinical Strategy**
 - How clearly linked the proposed pilot clinical trial is to the preclinical research studies that will also be performed through this award.
 - Whether the type of clinical trial (e.g., prospective, randomized, controlled) proposed is appropriate to meet the project's objectives.
 - How well the clinical trial is designed with appropriate study variables, controls, and endpoints.
 - How well the application demonstrates the availability of and access to the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects.
 - Whether the clinical trial design, methods, and analysis plan meet the requirements for applying for and obtaining IND/IDE status (or other FDA approval), if appropriate.
 - Whether potential challenges and alternative strategies are appropriately identified.

- To what degree the SOW indicates a feasible plan and timeline to conduct the clinical trial and provides clearly defined milestones to be accomplished by the end of each year in the period of performance.
- **Regulatory Strategy**
 - How the regulatory strategy and development plan to support the product indication or product label change, if applicable, are appropriate and well described.
 - Whether the application includes documentation that the study is exempt from FDA regulation or that the IND or IDE application has been submitted to the FDA, as appropriate.
 - For investigator-sponsored regulatory exemptions (e.g., IND, IDE), whether there is evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the FDA.
 - Whether plans to comply with GMP, GLP, and GCP guidelines are appropriate.
- **Transition Plan**
 - Whether the application states a realistic timeline for clinical investigation.
 - To what degree the application demonstrates feasible methods and strategies to move the research findings to the next phase of development including, as applicable, further development of the intervention, clinical trials, changes in clinical practice, and/or delivery to the military or commercial market after successful completion of the award.
 - Whether the application has a plan to distribute the findings or intervention. For planned peer-reviewed publications generated from clinical research or trials, how well is the level of evidence that will contribute toward evidence-based clinical practice described and explained.
- **Statistical Plan**
 - Whether an appropriate statistical plan is provided, including power analysis.
 - Whether the clinical trial is designed with enough statistical power to lead to meaningful results.
- **Personnel**
 - Whether the research personnel have the appropriate backgrounds and neuromusculoskeletal-related expertise to enable successful conduct of the project.
 - How appropriate the levels of effort are for successful conduct of the proposed work.

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

- **Environment**
 - To what degree the scientific environment, clinical setting, and accessibility of institutional resources support the clinical trial at each participating center or institution (including collaborative arrangements).
 - Whether there is evidence for appropriate institutional commitment from each participating institution.
 - If applicable, whether the intellectual and material property plan that is agreed upon by each participating institution is appropriate for the proposed clinical trial.
- **Budget**
 - Whether the **total** maximum costs are equal to or less than the allowable total maximum costs as published in the Program Announcement.
 - Whether the budget is appropriate for the proposed research.
- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influence the review.

Research Level 3:

- **Impact**
 - To what degree the proposed research could lead to a solution for a [RESTORE Focus Area](#).
 - To what degree the project, if successful, could accelerate progress toward returning Warfighters to combat readiness following neuromusculoskeletal injury.
 - Whether the proposed research will move beyond a minor advancement and will lead to a new approach that is fundamentally better than interventions already approved or in clinical development.
 - Whether the proposed research would ultimately benefit patients with neuromusculoskeletal injuries.
- **Clinical Strategy**
 - Whether the type of clinical trial (e.g., prospective, randomized, controlled) proposed is appropriate to meet the project's objectives.
 - How well the clinical trial is designed with appropriate study variables, controls, and endpoints.

- How well the application demonstrates the availability of and access to the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects.
- Whether the clinical trial design, methods, and analysis plan meet the requirements for applying for and obtaining IND/IDE status (or other FDA approval), if appropriate.
- Whether potential challenges and alternative strategies are appropriately identified.
- How well the proposed research is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, statistical analysis, and data handling.
- To what degree the SOW indicates a feasible plan and timeline to conduct the clinical trial and provides clearly defined milestones to be accomplished by the end of each year in the period of performance.
- **Regulatory Strategy**
 - How the regulatory strategy and development plan to support the product indication or product label change, if applicable, are appropriate and well described.
 - Whether the application includes documentation that the study is exempt from FDA regulation, or that the IND or IDE application has been submitted to the FDA, as appropriate.
 - For investigator-sponsored regulatory exemptions (e.g., IND, IDE), whether there is evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the FDA.
 - Whether plans to comply with GMP, GLP, and GCP guidelines are appropriate.
- **Transition Plan**
 - Whether the application states a realistic timeline for clinical investigation.
 - To what degree the application demonstrates feasible methods and strategies to move the research findings to the next phase of development including, as applicable, further clinical trials, changes in clinical practice, and/or delivery to the military or commercial market after successful completion of the award.
 - Whether the application has a plan to distribute the findings or intervention. For planned peer-reviewed publications generated from clinical research or trials, how well the level of evidence will contribute toward evidence-based clinical practice is described and explained.
- **Statistical Plan**
 - Whether an appropriate statistical plan is provided, including power analysis.

- Whether the clinical trial is designed with enough statistical power to lead to meaningful results.

- **Personnel**

- Whether the application includes an appropriate and robust research/clinical team with the combined backgrounds and neuromusculoskeletal-related expertise to enable successful conduct of the project.
- How appropriate the levels of effort are for successful conduct of the proposed work.

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

- **Ethical Considerations**

- Whether the population selected to participate in the trial stands to benefit from the knowledge gained.
- If applicable, how well the inclusion of international sites is justified.
- 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.
- Whether a research monitor with expertise consistent with the nature of the potential risk(s) is identified, if applicable.
- How well the evidence shows that the 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 privacy and confidentiality issues are appropriately considered.
- To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.

- **Environment**

- To what degree the scientific environment, clinical setting, and accessibility of institutional resources support the clinical trial at each participating center or institution (including collaborative arrangements).
- Whether there is evidence for appropriate institutional commitment from each participating institution.
- If applicable, whether the intellectual and material property plan that is agreed upon by each participating institution is appropriate for the proposed clinical trial.

- **Budget**
 - Whether the **total** maximum costs are equal to or less than the allowable total maximum costs as published in the Program Announcement.
 - Whether the budget is appropriate for the proposed research.
- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY19 DMRDP JPC-8/CRM RP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio balance
 - Relative innovation (Research Level 1) and impact
 - Military relevance

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC, on behalf of the DHA and the OASD(HA). ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section II.E.1.b, Programmatic Review](#).*** Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.army.mil/about/2tierRevProcess>. A PI Information Paper describing the funding recommendations and review process for the DMRDP JPC-8/CRM RP RESTORE will be provided to the PI and posted on the CDMRP website.

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

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

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

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

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

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

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY19 and FY20 funds are anticipated to be made no later than September 30, 2020 and September 30, 2021, respectively. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

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

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

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

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

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

The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

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

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

II.F.2. Administrative and National Policy Requirements

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

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

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

Refer to the full text of the latest [DoD R&D General Terms and Conditions](#); the [USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations](#); Addendum to the DoD R&D General Terms and Conditions; and the

[USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

II.F.3. Reporting

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

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

Quarterly technical progress reports will be required for Research Level 3.

Quarterly technical progress reports may be requested for Research Levels 1 and 2 at the discretion of the Grants Officer.

In-person presentations and in-progress reviews may be requested.

Annual quad charts as well as a final quad chart will be required.

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

Awards resulting from this Program Announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to Program Announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP

should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

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

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

Email: support@grants.gov

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

II.H. Other Information

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

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 20190530a. The Program Announcement numeric version code will match the General Application Instructions version code 20190530.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

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

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- For Research Level 2 submissions with a clinical trial and all Research Level 3 submissions: Regulatory Strategy ([Attachment 9](#)) is missing.
- For Research Level 2 submissions with a clinical trial and all Research Level 3 submissions: Intervention ([Attachment 10](#)) is missing.
- For Research Level 2 submissions with a clinical trial and all Research Level 3 submissions: Human Subject Recruitment and Safety Procedures ([Attachment 11](#)) is missing.
- For Research Level 3 submissions: Data Management ([Attachment 12](#)) is missing.

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

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

- A RESTORE Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the RESTORE Programmatic Panel members can be found at https://cdmrp.army.mil/dmrdp/panels/19jpc8_restore.*
- The application fails to conform to this Program Announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY19, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The invited application proposes a different research project than that described in the pre-application.
- A clinical trial is proposed for **Research Level 1**.
- Preclinical research is proposed for **Research Level 3**.
- The PI does not meet the eligibility criteria.

II.H.2.d. Withhold

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

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance (Extramural submissions only)	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) (Intramural submissions only)	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Military Benefit and Impact Statement: Upload as Attachment 6 with file name "MilBen.pdf"	
	Transition Plan: Upload as Attachment 7 with file name "Transition.pdf"	
	Animal Research Plan: Upload as Attachment 8 with file name "AnimalResPlan.pdf" if applicable	
	Regulatory Strategy: Upload as Attachment 9 with file name "Regulatory.pdf" if applicable	
	Intervention: Upload as Attachment 10 with file name "Intervention.pdf" if applicable	
	Human Subject Recruitment and Safety Procedures: Upload as Attachment 11 with file name "HumSubProc.pdf" if applicable	
	Data Management: Upload as Attachment 12 with file name "Data_Manage.pdf" if applicable	
	Surveys, Questionnaires, and Other Data Collection Instruments: Upload as Attachment 13 with file name "Surveys.pdf"	
Representations (extramural submissions only): Upload as Attachment 14 with file name "RequiredReps.pdf" if applicable		

Application Components	Action	Completed
	DoD Military Budget Form(s): Upload as Attachment 15 with file name “MFBudget.pdf” if applicable	
Research & Related Personal Data	Complete form as instructed	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field	
Research & Related Budget (Extramural submissions only)	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field	
Budget (Intramural submissions only)	Complete the DoD Military Budget Form and justification	
Project/Performance Site Location(s) Form	Complete form as instructed	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed	

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
ARRIVE	Animal Research: Reporting <i>In Vivo</i> Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
CRM RP	Clinical and Rehabilitative Medicine Research Program
DHA	Defense Health Agency
DHP	Defense Health Program
DMRDP	Defense Medical Research and Development Program
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
ICH E6	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
JPC-8	Joint Program Committee 8
LAR	Legally Authorized Representative
M	Million
MIPR	Military Interdepartmental Purchase Request
NPC	Non-Profit Corporation
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator

RCT	Randomized Controlled Trial
RDT&E	Research, Development, Test, and Evaluation
RESTORE	Restoring Warfighters with Neuromusculoskeletal Injuries Research Award
RTD	Return to Duty
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs

APPENDIX 2: DOD AND VA WEBSITES

PIs are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with DoD and/or VA investigators is also encouraged. Below is a list of websites that may be useful in identifying additional information about DoD and VA areas of research interest, ongoing research, or potential opportunities for collaboration.

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

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

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

Clinical and Rehabilitative Medicine
Research Program
<https://crmrp.amedd.army.mil>

Combat Casualty Care Research Program
<https://ccc.amedd.army.mil>

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

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

Defense Health Agency
<https://health.mil/dha>

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

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

Military Health System Research
Symposium
<https://mhsrs.amedd.army.mil>

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

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

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

Naval Health Research Center
<https://www.med.navy.mil/sites/nhrc>

Naval Medical Research and Development
<https://www.med.navy.mil/sites/nmrc>

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

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

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

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

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

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

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

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

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

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

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

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

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

U.S. Army Sharp, Ready & Resilient
Directorate
<https://readyandresilient.army.mil>

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

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

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

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