

# **I. OVERVIEW OF THE FUNDING OPPORTUNITY**

**Program Announcement for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Peer Reviewed Orthopaedic Research Program**

**Applied Research Award**

**Announcement Type: Initial**

**Funding Opportunity Number: W81XWH-18-PRORP-ARA**

**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), July 30, 2018
- **Invitation to Submit an Application:** September 5, 2018
- **Application Submission Deadline:** 11:59 p.m. ET, October 24, 2018
- **End of Application Verification Period:** 5:00 p.m. ET, October 29, 2018
- **Peer Review:** December 2018
- **Programmatic Review:** February 2019

*This Program Announcement must be read in conjunction with the General Application Instructions, version 20180329. The General Applications 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**

***New for 2018: Application submission by extramural organizations through Grants.gov requires use of the Workspace interface, which separates the application package into individual forms. Applicants must create a Workspace in Grants.gov, complete the required forms, and submit their application Workspace package.***

### **II.A. Program Description**

Applications to the Fiscal Year 2018 (FY18) Peer Reviewed Orthopaedic Research Program (PRORP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement is the Congressionally Directed Medical Research Programs (CDMRP). The PRORP was initiated in 2009 to provide support for research of exceptional scientific merit on optimizing recovery and restoration of function for military personnel with orthopaedic injuries sustained in combat or combat-related duties. Appropriations for the PRORP from FY09 through FY17 totaled \$338.5 million (M). The FY18 appropriation is \$30M.

The FY18 PRORP challenges the scientific community to address the most significant gaps in care for the leading burden of injury and for facilitating return to duty by funding innovative, high-impact, clinically relevant research to advance optimal treatment and rehabilitation from neuromusculoskeletal injuries (excluding spinal cord injuries) sustained during combat or combat-related activities. It is expected that research findings would also benefit the general population. Applications involving multidisciplinary collaborations among academia, industry, the military Services, the Department of Veterans Affairs (VA), and other Federal agencies are highly encouraged.

#### **II.A.1. FY18 PRORP Emphasis**

An estimated 3,700 civilian amputations occur annually as a result of traumatic injury. In the military, extremity battle wounds comprise approximately 50% of injuries in the Joint Theater Trauma Registry. However, orthopaedic injuries and conditions that occur outside of combat (during training, leisure activities, resultant from old injuries, etc.) are the greatest threat to the readiness of our Service members and military. Early stabilization and treatment of orthopaedic injuries in both civilian and military populations have led to better outcomes, particularly in the prevention of secondary complications and in minimizing morbidity. Availability of orthopaedic care and treatment as early as possible, or as close to the point of injury as possible, also minimizes limb loss and loss of troop readiness. However, in potential future conflicts in rural areas, austere combat zones, or in mass casualty events, access to medical care may be delayed for hours, if not days or weeks.

The North Atlantic Treaty Organization (NATO) defines Prolonged Field Care (PFC) as field trauma care extended beyond doctrinal timelines until the patient can be transported from the point of injury to an appropriate level of care. PFC has been identified as the number one capability gap across the Army, and a major priority for other Services. Additional information regarding PFC can be found in the following documents:

[http://www.wemjournal.org/article/S1080-6032\(17\)30063-7/pdf](http://www.wemjournal.org/article/S1080-6032(17)30063-7/pdf) and

[http://mrmc.amedd.army.mil/index.cfm?pageid=media\\_resources.articles.prolonged\\_field\\_care\\_the\\_new\\_normal](http://mrmc.amedd.army.mil/index.cfm?pageid=media_resources.articles.prolonged_field_care_the_new_normal).

## **II.A.2. FY18 PRORP Applied Research Award (ARA) Focus Areas**

*All applications must address one of the following FY18 PRORP ARA Focus Areas as the primary Focus Area. Selection of the appropriate Focus Area is the responsibility of the applicant. Studies that propose nominal or iterative advancements are not encouraged.*

**Animal Models:** Develop animal models that replicate orthopaedic injuries or conditions that are challenging in a PFC scenario, such as ischemia reperfusion injury and compartment syndrome.

**Device Development:** Develop offloading and stability devices (e.g., braces, casting) for ligamentous injuries, small extremity fractures, and/or other non-severe common battlefield musculoskeletal injuries for immediate return to duty.

**Wound Infection:** Translate promising available clinical interventions in prevention and control of combat extremity wound infections (e.g., for long bone open fractures) to improve their durability to treat battlefield or trauma-related injuries as close as possible to the point of injury. Projects that further develop novel wound protectants for this population will also be considered.

**Tissue Regeneration:** Develop and conduct preclinical testing of therapies for volumetric muscle loss due to traumatically damaged tissues of the extremities.

## **II.B. Award Information**

The FY18 PRORP ARA seeks applied research applications focused on advancing optimal treatment and restoration of function for individuals with musculoskeletal injuries sustained during combat or combat-related activities. Applicants are encouraged to address how the proposed research will support patient care closer to the point of injury and/or allow patients to more quickly return to duty/work. It is expected that any research findings would also provide benefit to the general population. To meet the intent of the award mechanism, applications **must** specifically address a primary FY18 PRORP ARA Focus Area, listed in [Section II.A.2](#), above.

Applications proposing sports injury research will not meet the intent of the award mechanism and will not be considered for funding unless the proposed research involves sports injuries that are related to a combat injury. Applicants are encouraged to address how the proposed research will support patient care closer to the point of injury and/or allow patients to more quickly return to duty/work.

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

The FY18 PRORP ARA is focused on **applied research**, defined as work that refines concepts and ideas into potential solutions with a view toward evaluating technical feasibility of promising new knowledge products, pharmacologic agents, behavioral and rehabilitation interventions, diagnostic and therapeutic techniques, clinical guidance, and/or emerging approaches and technologies.

The anticipated total costs budgeted for the entire period of performance for an FY18 PRORP ARA will not exceed **\$750,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

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 Department of Defense (DoD) during project performance is the key factor in determining whether to award a grant or cooperative agreement.

***Extramural Organizations:*** 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 Scope:** Research proposed under the FY18 PRORP ARA may include small- to large-scale projects. These awards are expected to yield potential health products, approaches, or technologies positioned for human testing. Upon successful completion, the proposed research is expected to yield knowledge products, approaches, or technologies that have the potential to advance toward clinical translation. Strong transition plans are expected. Applicants to the FY18 PRORP ARA are asked to consider, where appropriate, the inclusion of large animal studies in their research plan.

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

Studies allowed under the FY18 PRORP ARA may include, but are not limited to:

- Refinement of concepts and ideas into potential solutions, or research tools, with a view toward evaluating technical feasibility of emerging approaches, technologies, and promising new knowledge products.
- Evaluation, maturation, and/or down-selection of potential product candidates (drugs, biologic constructs, or devices/systems) in vitro and/or in vivo.
- Preparation activities needed to support a future clinical trial or regulatory submission.

***Awards may not be used to support clinical trials.*** A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. For more information on how to distinguish clinical research from clinical trials, see the Human Subject Resource Document at <https://ebrap.org/eBRAP/public/Program.htm>. Investigators seeking support to conduct a clinical trial should apply to one of the other FY18 PRORP award mechanisms, which can be accessed at <http://cdmrp.army.mil/funding/default.shtml>.

**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 Materiel Command (USAMRMC) 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. 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.

**Guidelines for Animal Research:** All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of

preclinical research. The standards are described in Landis, S.C., et al., A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 (<http://www.nature.com/nature/journal/v490/n7419/nature11556/>). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Projects that include research on animal models are required to submit [Attachment 8: Animal Research Plan](#), as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE (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 [http://www.elsevier.com/\\_data/promis\\_misc/622936arrive\\_guidelines.pdf](http://www.elsevier.com/_data/promis_misc/622936arrive_guidelines.pdf).

**Research Involving Animals:** All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC 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. Principal Investigators (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.

**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 PI is responsible for demonstrating such access at the time of application submission and should develop 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 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.

**Encouraged DoD and/or VA Collaboration and Alignment:** Military relevance is a key feature of this award. Therefore, PIs are strongly encouraged to collaborate, integrate, and/or align their projects with military and/or VA research laboratories and programs. Although not a comprehensive list, the following websites may be useful in identifying information about ongoing DoD and VA areas of research interest, ongoing research, or potential opportunities for collaboration:

Air Force Office of Scientific Research  
<http://www.wpafb.af.mil/afri/afosr/>

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

Armed Forces Radiobiology Research Institute  
<http://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  
<http://cdmrp.army.mil>

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

Defense Technical Information Center  
<http://www.dtic.mil>

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

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

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

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

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

Navy and Marine Corps Public Health Center  
<http://www.nmcpbc.med.navy.mil/>

Office of Naval Research  
<http://www.med.navy.mil/>

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

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

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

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

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

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

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.

Awards will be made no later than September 30, 2019. For additional information refer to [Section II.F.1, Federal Award Notices](#).

## **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, Government, 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 organization may be submitted through a research foundation.

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

### **II.C.1.b. Principal Investigator**

Independent investigators at all academic levels (or equivalent) may be named as a PI in the application.

An eligible applicant, 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 <http://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 funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).*

*Extramural Submission* is defined as an application submitted by an organization to Grants.gov.

*Intramural DoD Submission* is defined as 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](http://eBRAP.org). Full application packages must be accessed and submitted at Grants.gov.

*Intramural DoD Submissions:* Pre-application content and forms and full application packages must be accessed and submitted at [eBRAP.org](http://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.

**Submitting Extramural Organizations:** Full applications from extramural organizations must be submitted through a 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](#).

**Submitting Intramural DoD Organizations:** 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:** A key feature of eBRAP is the ability of 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](mailto: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, each submission is assigned a unique log number by eBRAP. 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](mailto: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.

PIs and organizations 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](mailto:help@eBRAP.org) or 301-682-5507.

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 (R&R) 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 (R&R) 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.

[FY18 PRORP Programmatic Panel](#) members should not be involved in any pre-application or application. For questions related to Panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

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 pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY18, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Pre-applications or applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- **Tab 4 – Conflicts of Interest**

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). Refer to the General Application Instructions, Appendix 3, Section C, for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

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

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

The Preproposal Narrative should include the following:

- **Alignment with Focus Areas:** Explain how the proposed work addresses an FY18 PRORP ARA Focus Area.
- **Research Idea:** State the hypothesis to be tested or the objective to be reached. State how this project addresses an important problem relevant to combat-related

- orthopaedic injuries. State the ideas and reasoning on which the proposed work is based.
- **Research Strategy:** Clearly describe the research strategy for the proposed project. Concisely state the specific aims and ultimate goals of the project. Describe the proposed methods and how they will accomplish the project’s aims.
  - **Impact:** State explicitly how the proposed work may have an immediate and long-term impact on patient care and/or restoration of function for those who have sustained traumatic orthopaedic injuries.
  - **Military Benefit:** Describe how the proposed work would impact unit readiness and the healthcare needs of Service members and/or Veterans who have sustained combat-related orthopaedic injuries, as well as the treatment of non-battle injuries that significantly impact return to duty/work rates. Also describe how the proposed research, if successful, may benefit their families, caregivers, and the general public, as applicable.
  - **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the described research (detailed key personnel biographical sketches [six pages per individual] are allowed as part of pre-application supporting documentation, as described below). Note any DoD or VA collaborations.
- **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.
    - **Quad Chart:** Upload as “QuadChart.pdf.” The Quad Chart template is a one-page PowerPoint file that must be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm> in the “Generic Forms for Application Submission” section, then completed and saved as a PDF file.

- **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 PRORP, pre-applications will be screened based on the following criteria:

- **Alignment with Focus Areas:** How well the project addresses an FY18 PRORP ARA Focus Area. To what degree the proposed project addresses the intent of the award mechanism and addresses an important problem relevant to the PRORP.
- **Research Idea and Strategy:** How well the rationale, objectives, and specific aims support the research idea. Whether the proposed methodology is appropriate to the specific aims. Whether the endpoints to be measured are appropriate for the proposed study.
- **Impact:** To what extent the potential immediate and long-range outcome(s) of the proposed study, if successful, will produce results that are likely to translate into improved patient care and/or restoration of function for those who have sustained traumatic orthopaedic injuries.
- **Military Benefit:** How well the proposed study will directly or indirectly impact unit readiness and the healthcare needs of Service members and/or Veterans who have sustained combat-related orthopaedic injuries, as well as their families, caregivers and the general public.
- **Personnel:** How the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed research.

- **Notification of Pre-Application Screening Results**

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated time frame 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 the PI has received notification of invitation.

*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 (<http://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 the 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
<b>Application Package Location</b>	
Extramural Submissions	Intramural DoD Submissions
<b>Application Package Location</b>	
Download application package components for W81XWH-18-PRORP-ARA from Grants.gov ( <a href="http://www.grants.gov">http://www.grants.gov</a> ) and create a Grants.gov Workspace. The Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-18-PRORP-ARA from eBRAP ( <a href="https://ebrap.org/">https://ebrap.org/</a> ).
<b>Full Application Package Components</b>	
<b>SF424 (R&amp;R) Application for Federal Assistance Form:</b> Refer to the General Application Instructions, Section III.A.1, for detailed information.	<b>Tab 1 – Summary:</b> Provide a summary of the application information. <b>Tab 2 – Application Contacts:</b> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components:	<b>Tab 3 – Full Application Files:</b> Upload files under each Application Component in

Extramural Submissions	Intramural DoD Submissions
<ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">R&amp;R Subaward Budget Attachment(s) Form</a> (if applicable)</li> </ul>	<p>eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Key Personnel</a></li> <li>• <a href="#">Budget</a></li> <li>• <a href="#">Performance Sites</a></li> </ul> <p><b>Tab 4 – Application and Budget Data:</b> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>
<b>Application Package Submission</b>	
<p><b>Create a Grants.gov Workspace.</b> Add participants (investigators and Business Officials) to the Workspace, complete all required forms, and check for errors before submission.</p> <p><b>Submit a Grants.gov Workspace Package.</b> 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 <b>at least 24-48 hours prior to the close date</b> 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 prior to the application submission deadline.</p>	<p><b>Submit package components to eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</b></p> <p><b>Tab 5 – Submit/Request Approval Full Application:</b> After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email.</p>
<b><u><a href="#">Application Verification Period</a></u></b>	
<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, <b>with the exception of the Project Narrative and Budget Form</b>, may be modified.</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, <b>with the exception of the Project Narrative and Budget Form</b>, may</p>

Extramural Submissions	Intramural DoD Submissions
	be modified. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.
Further Information	
<p><b>Tracking a Grants.gov Workspace Package.</b> 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>	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. ***The Project Narrative and Budget 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.

***Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.***

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

Describe the proposed project in detail using the outline below.

- **Background:** Establish the relevance of the study to an FY18 PRORP ARA Focus Area and explain the applicability of the proposed findings to the intended patient population. Describe in detail the rationale for the study questions and/or study hypotheses. Cite relevant literature. Include pilot or preliminary data that led to the development of the proposed project. State how the proposed work is a refinement or maturation of any existing work or research.
- **Hypotheses/Objectives/Specific Aims:** State the hypotheses to be tested or the objectives to be reached. Concisely explain the specific aims of the project to be funded by this award.
- **Research Strategy:** Describe the study design, methods, and models, including appropriate controls, in sufficient detail for assessment of the application. Explain how this research strategy will meet the research goals and milestones. Provide a well-developed, well-integrated, and detailed research plan that supports the translational feasibility and promise of the approach.
- **Technical Risks:** Identify and describe potential problem areas in the proposed approach and alternative methods and approaches that will be employed to mitigate any risks that are identified.
- **Statistical and Data Analysis Plan:** Describe the statistical model and data analysis plan with respect to the study objectives as appropriate to the type of study. Include a

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

- If any biological material will be used in the proposed studies, the name, definition, pathological classification, and source of the material must be provided.
  - If human anatomical samples will be used, include a detailed plan for the acquisition of samples.
  - If applicable, describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA).
- **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 publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- Current Quad Chart: Provide a current Quad Chart (<https://ebrap.org/eBRAP/public/Program.htm>). If no changes have been made to the project, the same Quad Chart submitted with the pre-application may be used.
- Letters of Organizational Support (one-page limit per letter is recommended): Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (if applicable; one-page limit per letter): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.
- Intellectual Property: Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), "Intangible Property."
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
  - Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
    - ❖ Clearly identify all such property;
    - ❖ Identify the cost to the Federal government for use or license of such property, if applicable; or
    - ❖ Provide a statement that no property meeting this definition will be used on this project.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
- **Use of DoD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military patient 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 VA 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.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.” The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. *Do not include proprietary or confidential information.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Technical abstracts should be written using the outline below. Abstracts of all funded research projects will be posted on the CDMRP website (<http://cdmrp.army.mil>); therefore, proprietary or confidential information should not be included.

- **Background:** State the FY18 PRORP ARA Focus Area addressed by the proposed research. State how the proposed research addresses the intent of the award mechanism. Present the ideas and reasoning behind the proposed work.
- **Objective/Hypothesis:** State the objective to be reached/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design, including appropriate controls.
- **Military Benefit:** Briefly explain how the proposed project, if successful, will have an immediate and/or long-term impact on patient care closer to the point of injury, and/or optimizing recovery and restoration of function for Service members and/or Veterans with orthopaedic injuries sustained in combat or combat-related activities, as well as their families, caregivers, and the general public.
- **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.
  - Describe the objectives and rationale for the application in a manner that will be readily understood by readers without a background in science or medicine. ***Do not duplicate the technical abstract.*** Abstracts of all funded research projects will be posted on the CDMRP website (<http://cdmrp.army.mil>); therefore, proprietary or confidential information should *not* be included.

- Describe the ultimate applicability of the research.
  - Which FY18 PRORP ARA Focus Area will be addressed?
  - How will the proposed research impact the ARA Focus Area addressed?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected timeline to achieve the expected patient-related outcome?
- Describe how the proposed project will benefit Service members and/or Veterans who sustained combat related or non-battle orthopaedic injuries that affect readiness or return to duty/work. Also describe benefits to their families, caregivers, and the general public, as applicable.
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the ARA mechanism, use the SOW format example titled, “SOW Generic Format.” The SOW must be in PDF format prior to attaching.

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

- Include the name(s) of the key personnel and contact information for each study site/subaward site.
- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
- 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, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the FDA or other Government agency.

- **Attachment 6: Impact and Military Benefit Statement (three-page limit):** Upload as “MilBen.pdf.”
  - Describe the immediate impact, as well as the anticipated long-term benefits, of the proposed research on the lives of individuals with traumatic orthopaedic injuries. Include details about the anticipated patient care and/or restoration of function-relevant outcomes that will be directly attributed to the results of the proposed research.
  - Describe how the proposed study may impact PFC, point of injury care, and/or unit readiness.
  - Describe how the proposed study is responsive to the healthcare needs of military Service members and the Veteran population that sustained orthopaedic injuries. Provide information about the incidence and/or prevalence of the project-relevant orthopaedic injuries in military Service members and/or Veterans, if appropriate and available.
  - If active duty military and/or Veteran population(s) or dataset(s) will be used in the proposed research, describe the population(s)/dataset(s), the appropriateness of the population(s)/dataset(s) for the proposed study, and the feasibility of using the population(s)/dataset(s). If a non-military population will be used for the proposed research, explain how the population simulates the targeted population (i.e., military Service members or Veterans). If applicable, show how the proposed study complements ongoing DoD and/or VA areas of orthopaedic research interest. Describe how the study design will replicate field conditions, if applicable.
- **Attachment 7: Transition Plan (two-page limit):** Upload as “Transition.pdf.” Describe/discuss the methods and strategies proposed to move the anticipated research outcomes to the next phase of development (e.g., clinical trials, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Outline the regulatory strategy, as applicable. Applicants are encouraged to work with their organization’s Technology Transfer Office (or equivalent) to develop the transition plan. PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development. The plan for post-award transition of the anticipated research outcome should include the components listed below, as appropriate and applicable to the research proposed.
  - The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication.
  - A detailed FDA regulatory strategy, including considerations for compliance with Good Manufacturing Practice, Good Laboratory Practice, and Good Clinical Practice (GCP) guidelines (if appropriate).

- Details of the funding strategy to transition to the next level of development and/or commercialization (e.g., partners, internal/external funding opportunities to be applied for).
- For Knowledge Products, a description of collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of Clinical Practice Guidelines (CPGs) 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-material 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 material 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.
- A brief schedule and milestones for transitioning the anticipated research outcomes to the next phase of development (e.g., next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, approval by the FDA), including identification of the FDA regulatory strategy (if appropriate).
- A description of ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the Government’s ability to access such products or technologies in the future.
- A description of collaborations and other resources that will be used to provide continuity of development.
- If applicable, a risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 8: Animal Research Plan, if applicable (five-page limit):** Upload as “AnimalPlan.pdf.”
  - When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:
    - Briefly describe the research objective(s) of the animal study. Explain how and why the proposed animal species, strain, and model(s) are appropriate for addressing the scientific objectives and, where appropriate, the study’s relevance to human biology.
    - Summarize the procedures to be conducted. Describe how the study will be controlled.

- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
  - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
  - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
  - Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- **Attachment 9: Human Sample Acquisition and Safety Procedures (if applicable; required for all studies recruiting human subjects) (no page limit):** Upload as “HumSamAcq.pdf.” The Human Sample Acquisition and Safety Procedures attachment should include the components listed below.
- **Study Population and Design:** 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 (population from whom the samples were obtained). *Use of military or Veteran populations is preferable, but not required.* If the project proposes inclusion of a military population, the appropriate letter of support must be included in the supporting documentation. If a military population is not used, describe how the identified population serves as a surrogate to the military experience.
    - Demonstrate that the research team has access to the proposed study population.
    - If applicable, discuss past effort(s) in recruiting human subjects from the target population from previous interventional or observational studies. Address any potential barriers to accrual and plan for addressing unanticipated delays. Include justification of any age, race, ethnicity, or sex limitations provided.
    - For some in vitro diagnostics, the link between analytical performance and clinical performance is not well defined. In these circumstances, clinical information may be required.
    - The FDA rarely requires prospective clinical studies for in vitro diagnostics, but regularly requests clinical samples with sufficient laboratory and/or clinical characterization to allow an assessment of the clinical validity of a new device. This is usually expressed in terms of clinical sensitivity and clinical specificity or agreement.

- Note that the study design may include identification of surrogate endpoints to establish the device performance (clinical sensitivity and specificity or agreement) with relation to the identified endpoints in corollary studies using randomly collected clinical studies. Use of laboratory samples from military populations is preferable, but not required.
- **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical research. 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 USAMRMC. 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 study.

- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study inclusion and the diagnostic criteria for entry. Note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.
- **Description of the Informed Consent Process:** In certain cases, Federal regulations allow the IRB to approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent, or to waive the requirement to obtain any informed consent. Most complete waivers of consent involve studies in which there are minimal risks to subjects. 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 study.
  - Include information regarding the timing and location of the consent process.
  - Describe the biological origin of the samples to be tested (e.g., primary fibroblast cells from adults with and without disease).
  - The narrative should also describe the sample source(s), such as purchased human samples obtained from a clinical repository, or previously collected as part of a research effort. If samples will be or have been collected as part of a research

activity, the application should state whether donors provided consent for use of their samples in future research consistent with this proposed effort.

- Describe the plan, if appropriate, for obtaining waivers of informed consent or the informed consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study.
  - **Waiver of Informed Consent**, described in 45 CFR 46.116(d), establishes four criteria for waiving consent or altering the elements of consent in minimal risk studies. These four criteria must be addressed.
  - **Waiver of Documentation of Consent**, described in 45 CFR 46.117(c), allows the IRB to waive the requirement for obtaining signed consent if it finds that either:
    - ❖ The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (these criteria cannot be used for FDA-regulated studies), or
    - ❖ The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. This paragraph only also applies to FDA-regulated studies per 21 CFR 56.109(c)(1).
  - 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: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed research to be in compliance with 10 USC 980 (<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf>). If applicable, refer to the General Application Instructions, Appendix 1, Regulatory Requirements, for more information.
- **Risks/Benefits Assessment:**
- **Foreseeable risks:** Clearly identify all study risks. Study risks include any risks that the human subject is subjected to (including retroactively, as identified by the ORP and IRB) as a result of participation in the research. 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 all safety measures to minimize and/or eliminate risks to human subjects and study personnel, or to manage unpreventable risks.

- **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society.
- **Attachment 10: Data Management (if applicable; required for all studies recruiting human subjects) (no page limit):** Upload as “Data\_Manage.pdf.” The Data Management attachment should include the components listed below.
  - **Data Management:** Describe all methods used for data collection to include the following:
    - **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 study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
      - ❖ Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRMC are eligible to review study records.
      - ❖ Address requirements for reporting sensitive information to state or local authorities.
    - **Data capture, verification and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored.
    - **Data reporting:** Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
    - **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, to include 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, to include location of storage, how long specimens will be stored, any special conditions required, labeling, and disposition. Outline the plan to store specimens for future use to include considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.
  - **Laboratories performing evaluations and special precautions:** Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. 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 11: Representations, if applicable (extramural submissions only):** Upload as “MandatoryReps.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 12: 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 and Related Budget form under subaward costs. Refer to the General Application Instructions, Section III.A.7, 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, 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.2, 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 the PDF format that is not editable.
- 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.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, 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.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only**

**R&R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section III.A.6, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, 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 12. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Intramural DoD

Collaborator(s) costs per year should be included on the Grants.gov Research and 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’s 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.

***New Requirement:*** In March 2018, the General Services Administration (GSA) implemented fraud prevention security measures in the SAM that require every ***new*** contractor registrant to provide a written (hard copy), notarized letter confirming the entity’s Administrator authorized to register the entity in the SAM database or to make changes to its registration. Effective April 29, 2018, the notarized letter process is now mandatory on all ***current*** registrants at SAM who have a requirement to update data on their SAM record. The notarized letter is mandatory and is required before the GSA Federal Service Desk (FSD) will activate the entity’s registration. The Office of the Secretary of Defense and GSA realize the length of time needed to transmit, receive, process, and approve the notarized letters presents a significant impact on the ability of the contracting activity to make timely awards, but these steps must be taken to mitigate fraud concern. ***Notarized letters are required for all new and existing SAM-registered entities.*** The notarized letters must be postal service mailed (not emailed or faxed) to the “Federal Service Desk” and must contain the information outlined in the SAM-posted Frequently Asked Questions (FAQs) at: <https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/sam-update>. Instructions for domestic entities and instructions for international entities with embedded templates for use are also provided within the SAM Update notice with frequently asked questions at <https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/sam-update>.

### **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(s) 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 prior to the application verification deadline.

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

### **II.D.5. Funding Restrictions**

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

The anticipated total (direct plus indirect) costs budgeted for the entire period of performance will not exceed **\$750,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the Government exceeding **\$750,000** total costs or using an indirect cost rate exceeding the organization’s negotiated rate.

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

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

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

- Travel costs for one PI to disseminate project results at one Military Health System Research Symposium meeting. For planning purposes, it should be assumed that the meeting will be held in the Central Florida Area. Costs associated with travel to this meeting should be included in Year 2 or 3 of the budget. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research supplies and equipment
- Research-related subject costs
- Clinical research costs
- Preparatory activities for a near-future clinical trial directly related to the proposed study
- Support for multidisciplinary collaborations, including travel
- Travel costs for one investigator to travel to one scientific/technical meeting per year in addition to the required symposium meeting described above to present project outcomes from the FY18 PRORP ARA.

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 fund 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.4, 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.4.***

***The CDMRP expects to allot approximately \$4.5M of the \$30M FY18 PRORP appropriation to fund approximately six Applied Research Award 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.***

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 FY18 funds, which will expire for use on September 30, 2024.

#### **II.D.6. Other Submission Requirements**

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

### **II.E. Application Review Information**

#### **II.E.1. Criteria**

##### **II.E.1.a. Peer Review**

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

- **Research Strategy and Feasibility**
  - How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, logical reasoning, and the presentation of preliminary data or published data.
  - How well the hypotheses or objectives, aims, experimental design, data management plan (if applicable), methods, and analyses are developed and integrated into the project and how well they address the study questions described.
  - How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, power analysis, blinding, randomization, and data handling.
  - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
  - If applicable, whether the animal model to be developed is appropriate for the context of use.
  - How consistent the methods and procedures are with sound research design.
  - If applicable, to what degree the statistical plan and power analysis are appropriate for the proposed project and future transition to the next level of development.
  - How well the potential problem and risk areas in the experimental approach are identified and the extent to which the proposed alternative methods and approaches address those areas.
- **Impact and Military Benefit**
  - How well the proposed study addresses the selected FY18 PRORP ARA Focus Area.

- How relevant the anticipated research outcomes are to the selected FY18 PRORP ARA Focus Area addressed in the application.
  - How well the applicant describes the potential immediate and/or long-term impact of the proposed research on patient care and restoration of function from orthopaedic injuries sustained during combat or combat-related activities.
  - The potential immediate or long-term benefit and applicability of the proposed research on the health and well-being of orthopaedically injured Service members and/or Veterans, as well as their families, caregivers, and the general public.
  - How well the study addresses a critical issue in the treatment of combat-related injuries, as well as non-battle orthopaedic injuries that impact unit readiness and the ability to return to work/duty, if applicable.
- **Transition Plan**
    - Whether the identified next level of development and/or commercialization is well-described and realistic.
    - Whether the funding strategy described to bring the anticipated research outcomes to the next level of development is reasonable and realistic.
    - If applicable, whether the proposed collaborations and other resources for providing continuity of development for Knowledge Products, including proposed development or modification of CPGs and recommendations, provider training materials, patient brochures and other clinical support tools, scientific journal publications, models, simulations, and applications, are established and/or achievable.
    - Whether the schedule and milestones for bringing the study results to the next level of development (e.g., higher phase clinical trial, transition to industry, delivery to the market, incorporation into standard practice, approval by the FDA) are achievable.
    - If applicable, whether the risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
    - How well the application identifies intellectual property ownership, describes an appropriate intellectual and material property plan among all participating organizations (if applicable), and addresses impact of any intellectual property issues on product or technology development and subsequent Government access to products or technologies supported by this Program Announcement.
  - **Personnel**
    - How well the background and expertise of the PI and other key personnel demonstrate their ability to successfully complete the proposed research.

- How appropriate the composition of the research or study team is to accomplishing the proposed work (e.g., statistical expertise, expertise in orthopaedic research).
- How appropriate the levels of effort by the PI and other key personnel are to ensuring success of this project.

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

- **Ethical Considerations**

- If applicable, whether the level of risk to human subjects is minimized, and how the safety monitoring and reporting plan is appropriate for the level of risk.
- 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.
- If applicable, to what degree privacy issues are appropriately considered.
- If applicable, 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 and the accessibility of institutional resources support the proposed research project.
- How well the research requirements are supported by the availability of and the accessibility to facilities and resources (including collaborative arrangements).
- How the quality and extent of institutional support are appropriate for the proposed project.

- **Budget**

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

- **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 FY18 PRORP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Relative impact and 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 of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and PRORP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***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 <http://cdmrp.army.mil/about/fundingprocess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement 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 will be made no later than September 30, 2019. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

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

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 Organizations:*** Awards 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**

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

### **II.F.2. Administrative and National Policy Requirements**

In-person presentations may be requested.

Applicable requirements in the DoDGARs found in 32 CFR, Chapter 1, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement.

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

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

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

Quarterly technical progress reports, quad charts, annual progress reports, as well as a final progress report will be required.

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 Terms and Conditions (see General Application Instructions, Section III.A.4).

## **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](mailto: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](mailto: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 20180329g. The Program Announcement numeric version code will match the General Applications Instructions version code 20180329.

### **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.

### **II.H.2.b. Modification**

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

### **II.H.2.c. Withdrawal**

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

- An FY18 PRORP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the FY18 PRORP Programmatic Panel members can be found at <http://cdmrp.army.mil/prorp/panels/panels18>.*
- The application fails to conform to this Program Announcement description to the extent that appropriate review cannot be conducted.
- 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 FY18, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless

plans to manage COIs are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- 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.
- Applications may be administratively withdrawn from further consideration if the applicant cannot demonstrate access to the relevant study population or resources.
- The invited application does not propose the same research project described in the pre-application.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.
- The application proposes a clinical trial.

#### **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 (R&R) Application for Federal Assistance <b>(Extramural submissions only)</b>	Complete form as instructed.	
Summary (Tab 1) and Application Contacts (Tab 2) <b>(Intramural submissions only)</b>	Complete these tabs as instructed.	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Impact and Military Benefit Statement: Upload as Attachment 6 with file name "MilBen.pdf."	
	Transition Plan: Upload as Attachment 7 with file name "Transition.pdf."	
	Animal Research Plan: Upload as Attachment 8 with file name "AnimalPlan.pdf," if applicable.	
	Human Sample Acquisition and Safety Procedures: Upload as Attachment 9 with file name "HumSamAcq.pdf," if applicable.	
	Data Management: Upload as Attachment 10 with file name "Data_Manage.pdf," if applicable.	
	Representations (Extramural submissions only): Upload as Attachment 11 with file name "MandatoryReps.pdf," if applicable.	
DoD Military Budget Form(s): Upload as Attachment 12 with file name "MFBudget.pdf," if applicable.		
Research & Related Personal Data	Complete form as instructed.	

Application Components	Action	Completed
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget ( <b>Extramural submissions only</b> )	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Budget ( <b>Intramural submissions only</b> )	Complete the DoD Military Budget Form and justification.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R&R 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
ARA	Applied Research Award
ARRIVE	Animal Research: Reporting <i>In Vivo</i> Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
CPG	Clinical Practice Guideline
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FAQs	Frequently Asked Questions
FDA	U.S. Food and Drug Administration
FSD	Federal Service Desk
FY	Fiscal Year
GSA	General Services Administration
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IPR	In-Progress Review
IRB	Institutional Review Board
LAR	Legally Authorized Representative
M	Million
MIPR	Military Interdepartmental Purchase Request
NATO	North Atlantic Treaty Organization

OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
OMB	Office of Management and Budget
ORP	Office of Research Protections
PFC	Prolonged Field Care
PI	Principal Investigator
PRORP	Peer Reviewed Orthopaedic Research Program
RDT&E	Research, Development, Test, and Evaluation
RM	Resource Manager
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, Mathematics
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
VA	Department of Veterans Affairs