

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

**Program Announcement for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Defense Medical Research and Development Program**

**Joint Program Committee 8/**

**Clinical and Rehabilitative Medicine Research Program**

**Regenerative Medicine Focused Research Award**

**(AFIRM III)**

**Announcement Type: Initial**

**Funding Opportunity Number: W81XWH-19-DMRDP-RMFRA**

**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), August 7, 2019
- **Invitation to Submit an Application:** September 2019
- **Application Submission Deadline:** 11:59 p.m. ET, November 20, 2019
- **End of Application Verification Period:** 5:00 p.m. ET, November 25, 2019
- **Peer Review:** January 2020
- **Programmatic Review:** March 2020

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

## TABLE OF CONTENTS

<b>I. OVERVIEW OF THE FUNDING OPPORTUNITY.....</b>	<b>1</b>
<b>II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY.....</b>	<b>3</b>
II.A. Program Description.....	3
II.A.1. FY19 JPC-8/CRM RP RMFRA Focus Areas and Areas of Encouragement.....	4
II.A.2. History .....	4
II.B. Award Information .....	4
II.C. Eligibility Information.....	10
II.C.1. Eligible Applicants .....	10
II.C.2. Cost Sharing.....	10
II.C.3. Other .....	10
II.D. Application and Submission Information.....	11
II.D.1. Address to Request Application Package.....	11
II.D.2. Content and Form of the Application Submission .....	11
II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM) .....	47
II.D.4. Submission Dates and Times.....	47
II.D.5. Funding Restrictions.....	48
II.D.6. Other Submission Requirements .....	49
II.E. Application Review Information .....	50
II.E.1. Criteria .....	50
II.E.2. Application Review and Selection Process.....	59
II.E.3. Integrity and Performance Information.....	59
II.E.4. Anticipated Announcement and Federal Award Dates.....	60
II.F. Federal Award Administration Information .....	60
II.F.1. Federal Award Notices.....	60
II.F.2. Administrative and National Policy Requirements.....	61
II.F.3. Reporting.....	61
II.G. Federal Awarding Agency Contacts.....	62
II.G.1. CDMRP Help Desk .....	62
II.G.2. Grants.gov Contact Center .....	62
II.H. Other Information.....	63
II.H.1. Program Announcement and General Application Instructions Versions.....	63
II.H.2. Administrative Actions.....	63
II.H.3. Application Submission Checklist .....	65
<b>APPENDIX 1: ACRONYM LIST .....</b>	<b>69</b>
<b>APPENDIX 2: DOD AND VA WEBSITES.....</b>	<b>71</b>

## **II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY**

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

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

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

As part of the JPC-8/CRM RP, its regenerative medicine portfolio supports research aimed at providing solutions to repair, reconstruct, or regenerate tissue lost or damaged due to traumatic injury, particularly tissues of the extremities and craniomaxillofacial compartment. Regenerative medicine encompasses multiple approaches (engineered/synthetic, pharmacologic, biologic, and combinatorial) to the treatment of damaged tissues by using therapies that promote the self-regenerative capacity of the body. To address this effort, the JPC-8/CRM RP is offering the Regenerative Medicine Focused Research Award (RMFRA) as its next iteration of the Armed Forces Institute of Regenerative Medicine, AFIRM III, in FY19 to continue its effort to support the development of regenerative medicine solutions.

### **II.A.1. FY19 JPC-8/CRM RP RMFRA Focus Areas and Areas of Encouragement**

To meet the intent of the award mechanism, all projects submitted under the FY19 JPC-8/CRM RP RMFRA must address one or both of the following Focus Areas:

- Peripheral nerve regeneration
- Skeletal muscle regeneration

Efforts to regenerate peripheral nerve should focus on restoring maximal function. The goal for peripheral nerve regeneration should be accelerating functional recovery and/or reducing the need for autograft; efforts should not simply address metrics of nerve regrowth or conduits to cross nerve gaps. Similarly, efforts to regenerate skeletal muscle should extend beyond restoration of muscle bulk or structure and address restoration of maximal muscle function.

The Areas of Encouragement include:

- Immediate reconnection of severed peripheral nerves (e.g., preventing Wallerian degeneration)
- Regeneration of composite muscle and nerve injuries leading to improved function
- Regenerative therapies for volumetric muscle loss
- Preservation of denervated end organs
- Maintenance of the motor end plate or regeneration of the neuromuscular junction
- Improving the rate of peripheral nerve regeneration

### **II.A.2. History**

The initial award mechanism for AFIRM, which was first established in FY08, resulted in awards to Rutgers University and Wake Forest University. A second solicitation for AFIRM in FY13 (AFIRM II) resulted in one award to Wake Forest University.

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

The JPC-8/CRM RP RMFRA mechanism is intended to optimize research supporting the development of technical capabilities and solutions through collaborative partnerships and synergistic projects that inform and build on each other to accelerate regenerative medicine solutions and technical capabilities that repair, reconstruct, or regenerate tissue lost or damaged due to traumatic injury. The goal of the focused research to be funded under this award mechanism is to position the most promising solutions and technical capabilities (i.e., material or knowledge products) for advanced development and ultimately for transition to medical use and/or commercialization. Therefore, products resulting from the proposed focused research must have the potential for commercialization or adoption by clinicians as surgical and/or therapeutic options. Given the complex nature of peripheral nerve and skeletal muscle

regeneration, it is anticipated that the most effective solutions will involve a multifaceted approach spanning both Focus Areas and several Areas of Encouragement. Key aspects of this award include:

**Overarching Challenge:** JPC-8/CRM RP RMFRA applications must describe a unifying, overarching challenge that will be addressed by the proposed effort. The overarching challenge must be relevant to one or both of the FY19 JPC-8/CRM RP RMFRA Focus Areas.

**Research Team:** The JPC-8/CRM RP RMFRA is designed to accommodate either single Principal Investigator (PI) or Multiple PI submissions, though both should clearly demonstrate a focused approach to resolving the diverse barriers to restoring full peripheral nerve and/or muscle function after traumatic injury. Multi-institutional collaborations between/among academia, industry, and DoD and/or Department of Veterans Affairs (VA) facilities are highly encouraged.

- **Single PI Submissions:** Applications must include a single PI who leads a single project with a comprehensive and multifaceted approach to addressing the identified overarching challenge and the goal of restoring full peripheral nerve and/or skeletal muscle function after traumatic injury. The PI is required to devote a minimum of 20% effort to the proposed focused research to ensure maximum success. The PI should be highly qualified to lead this effort and should assemble a skilled team that can carry out the proposed work.
- **Multiple PI Submissions:** Applications must include two or more PIs who will collaborate as equal partners, each leading an independent research project that address complementary aspects of the identified overarching challenge, Focus Area(s), and Area(s) of Encouragement, if applicable. The ultimate goal is to restore full peripheral nerve and/or skeletal muscle function after traumatic injury. Each PI is required to devote a minimum of 10% effort to the proposed focused research to ensure maximum success. Partnerships should include highly qualified and multidisciplinary investigators that come together as a team to create an environment that fosters and supports collaboration and innovation in a way that engages each partner in all aspects of the research plan. The resources and expertise brought to the team by each partner should combine to create a robust, synergistic collaboration.

One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as Partnering PI(s). Initiating and Partnering PIs each have different submission requirements, as described in [Section II.D.2, Content and Form of the Application Submission](#); however, all PIs should contribute significantly to the development of the proposed focused research. If recommended for funding, each PI will be named to an individual award.

**Research Projects:** Applications shall include either a single comprehensive project (Single PI submissions) or a set of complementary independent projects (Multiple PI submissions). The project(s) should position the proposed solutions/products for advanced development and ultimately for transition to medical use and/or commercialization (e.g., early communications with the U.S. Food and Drug Administration (FDA); appropriate regulatory strategy and

milestones; Investigational New Drug (IND) and/or Investigational Device Exemption (IDE) pre-submission or submission; industry partners). Individual research projects should be at either the advanced preclinical stage, or an early stage clinical trial (Phase 0, I, or IIa) with the potential to reconstruct and rehabilitate injured Service members for RTD and/or restore of quality of life.

- **Single PI Submissions:** Applications shall include a single project that outlines a comprehensive and multifaceted approach that has the goal of restoring full peripheral nerve and/or skeletal muscle function after traumatic injury. It is anticipated that restoring full function will encompass multiple aspects of peripheral nerve and/or skeletal muscle regeneration, such as those listed in the FY19 JPC-8/CRM RP RMFRA Areas of Encouragement.
- **Multiple PI Submissions:** Applications shall include two or more independent research projects, each led by either the Initiating or a Partnering PI. While individual projects must be capable of standing on their own scientific merits, they must also be interrelated and synergistic with the other proposed project(s) and advance a solution beyond what would be possible through individual efforts. The exploration of multiple hypotheses or viewpoints of the same line of questioning is encouraged. This award mechanism is not intended to support a series of research projects that are dependent on the success of any other project. Each project should propose a unique approach to addressing the overall challenge and be capable of producing research findings with potential to impact the field and/or patient care. Together, the combined goal of the focused research projects is the restoration of full peripheral nerve and/or skeletal muscle function after traumatic injury.

**Focused Research Strategy:** The plan to address the overarching challenge must be supported by a detailed focused research strategy that identifies critical milestones; outlines the knowledge, resources, and technical innovations that will be utilized to achieve the milestones; and explains how the outcomes will be translated to patients. A robust statistical plan and statistical expertise should be included where applicable. Similarly, an FDA-regulatory strategy and interaction plan should be included where applicable. A plan for assessing individual project performance and progress toward addressing the overarching challenge must be included in the focused research strategy. Plans for communication and data transfer between/among collaborating institutions, as well as how data, specimens, and/or imaging products obtained during the study will be handled, must be included. An intellectual and material property plan agreed to by participating organizations is required in the application's supporting documentation.

**Military Relevance:** The proposed focused research should be responsive to the healthcare needs of military Service members and/or Veterans recovering from traumatic injury, and/or other military health system beneficiaries. PIs are strongly encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with DoD or VA investigators is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DoD and VA areas of research interest or potential opportunities for collaboration can be found in [Appendix 2](#).

**In-Progress Review (IPR) Meetings:** RMFRA recipients will present research updates to the DoD at annual IPR meetings. The JPC-8/CRM RP will appoint members to a Regenerative

Medicine Oversight Committee, who will provide program recommendations to the Grants Officer Representative (GOR) following the IPRs. Based on advice from the Regenerative Medicine Oversight Committee, U.S. Army Medical Research and Development Command (USAMRDC) staff may also work with awardees to adjust milestones accordingly following feedback from the FDA or other regulatory agencies, or other key stakeholders.

The anticipated total costs budgeted for the entire period of performance for an FY19 JPC-8/CRM RP RMFRA award will not exceed **\$10 million (M)**. Costs should reasonably reflect the number of projects included in the application and the type and breadth of research proposed and be fully justified. Applications, as well as individual research projects (Multiple PI submissions), may range in size, scope, and duration (up to a maximum of 5 years), as appropriate for the work proposed, and will be equally considered. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

***The JPC-8/CRM RP expects to allot approximately \$20M to fund up to approximately five JPC-8/CRM RP RMFRA applications. Funding of applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the Government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY19 funding opportunity will be funded with FY19 funds, which will expire for use on September 30, 2025.***

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

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 assistance agreement for this funding opportunity will be a cooperative agreement, in which substantial DoD programmatic involvement with the recipient is anticipated during the performance of the project. Under the cooperative agreement, DoD’s purpose is to support and stimulate the recipient’s activities in and otherwise working jointly with the award recipient in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the project. The dominant role and prime responsibility reside with the direct recipient for the project as a whole.

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

***New FY19 definition:*** A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Funded trials are required to post a copy of the IRB approved informed consent form used to enroll subjects on a publicly available Federal website in accordance with Federal requirements described in Code of Federal Regulations, Title 32, Part 219 (32 CFR 219).

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

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs/Co-PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the

Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief. If appropriate, the application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the application should include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

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

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

**Rigor of Experimental Design:** All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 ([www.nature.com/nature/journal/v490/n7419/full/nature11556.html](http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html)). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Projects that include research on animal models are required to submit [Attachment 7: 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).

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

## **II.C. Eligibility Information**

### **II.C.1. Eligible Applicants**

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

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

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

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

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

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

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

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

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

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

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

### **II.C.2. Cost Sharing**

Cost sharing/matching is not an eligibility requirement.

### **II.C.3. Other**

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

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**

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

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

### **II.D.1. Address to Request Application Package**

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

***Extramural Submissions:***

- Pre-application content and forms must be accessed and submitted at [eBRAP.org](https://eBRAP.org).
- Full application packages must be accessed and submitted at [Grants.gov](https://Grants.gov).

***Intramural DoD Submissions:***

- Pre-application content and forms must be accessed and submitted at [eBRAP.org](https://eBRAP.org).
- Full application packages must be accessed and submitted at [eBRAP.org](https://eBRAP.org).

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

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

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

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

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

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

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

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

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

***Multiple PI Submission:*** The Initiating PI must complete the pre-application submission process and submit the contact information for each Partnering PI. Each Partnering PI will then be notified of the pre-application submission separately by email. ***Each Partnering PI must follow the link in the notification email in order to associate his/her full application package with that of the Initiating PI. After following the link, each Partnering PI must verify his/her contact information, organization, and designation as an extramural or intramural submission within eBRAP.*** If not previously registered, the Partnering PI(s) must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI(s). Applicants are urged to complete these steps as soon as possible. If they are not completed, each Partnering PI will not be able to view and modify his/her application during the verification period in eBRAP. If these steps are not completed, an intramural partner will not be able to submit the Partnering PI's required full application package components to eBRAP.

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

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

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

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

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

The applicant organization and associated PI(s) 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.

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

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

- **Tab 1 – Application Information**

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

- **Tab 2 – Application Contacts**

Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

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

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

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

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

[FY19 JPC-8/CRM RP RMFRA 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.

**Multiple PI Submission:** The Initiating PI must enter the contact information for each Partnering PI in the Partnering PI section.

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

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

- **Tab 5 – Pre-Application Files**

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

- **Preproposal Narrative (individual components of the preproposal narrative have page limits as described below; however, there is no overall 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 Overall Research Plan component, which includes descriptions of the overarching challenge and the focused research strategy, should appear first in assembly order for all submissions. This should be followed by the Research Project(s) description. For Multiple PI submissions, the Initiating PI's Research Project description should appear directly behind the Overall Research Plan component, followed by each Partnering PI's Research Project description in numerical order (P1, P2, etc.).

The Preproposal Narrative should include the following:

- **Overall Research Plan (one-page limit per submission):**

- **Overarching Challenge:** Describe the unifying challenge to be addressed by the focused research and how it is relevant to a critical problem or question in the field of research and/or patient care in one or both of the [FY19 JPC-8/CRM RP RMFRA Focus Areas](#). Where applicable, identify which [FY19 JPC-8/CRM RP RMFRA Area\(s\) of Encouragement](#) will be addressed. Clearly articulate the

rationale for selecting the identified overarching challenge, explain how each research project is integrated to address overarching challenge, and describe the goals to be achieved; include relevant preliminary data and literature citations.

- **Focused Research Strategy:** Describe the concept for the focused research strategy and how the proposed comprehensive project (Single PI submission) or set of collaborative and synergistic projects (Multiple PI submission) will successfully achieve the goals of the overarching challenge. Describe how the project(s) will accelerate regenerative medicine solutions and technical capabilities that repair, reconstruct, or regenerate tissue lost or damaged due to traumatic injury. Explain how the resulting product(s) will have the potential for commercialization or adoption by clinicians as surgical or therapeutic options. Include a description of the composition, expertise, and organization of the research team, and discuss how partnership interactions (as applicable) will foster robust, synergistic collaborations.
- **Research Project(s) (Single PI submission, three-page limit; Multiple PI submission, three-page limit per project):** *Each project should start on a new page with the project title and PI name identified.*
  - **Hypothesis and Objective:** State the hypothesis to be tested and the objectives to be reached. Describe how the project addresses the overarching challenge and contributes to the goals of the proposed focused research. If a single comprehensive project, describe how the multifaceted approach comes together to advance the goals of the focused research. If one of multiple projects, describe how the project interrelates to, and is synergistic with, the other project(s), aligns with the overarching challenge, and supports the goals of the focused research.
  - **Specific Aims and Study Design:** Concisely state the project’s specific aims and describe the scientific approach and how it will accomplish the study aims. Include a description of controls, as appropriate.
  - **Clinical Trial (if applicable):** If the project is a clinical trial, briefly state the clinical intervention(s), subject population(s), and the type and phase of the clinical trial (*only Phase 0, I, or IIa clinical trials are allowed*). Describe the objectives of the clinical trial, how it addresses the overarching challenge, and how it complements other proposed project(s) (if applicable).
  - **Impact, Focus Area, and Area(s) of Encouragement:** Describe how the potential immediate and long-term outcome(s)/product(s) (knowledge and/or material) of the proposed research will impact the regenerative medicine research field, patient care, and/or quality of life, including the impact on one or both of the [FY19 JPC-8/CRM RP RMFRA Focus Areas](#). If applicable, describe the potential impact on the [FY19 JPC-8/CRM RP RMFRA Area\(s\) of Encouragement](#).
  - **Military Relevance:** Describe how the proposed research project would impact the healthcare needs of military Service members and Veterans, as well as their

family members, caregivers, or clinicians. Describe any collaborations with military researchers and/or clinicians.

- **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 for the Overall Research Plan component; one-page limit for each Research Project): 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 (five-page limit per individual): *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **Tab 6 – Submit Pre-Application**

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

### Pre-Application Screening

- **Pre-Application Screening Criteria**

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

#### Review Criteria for the Overall Research Plan:

- **Overarching Challenge:** How well the unifying challenge identifies and addresses a critical problem or question in the field of research and/or patient care of one or both of the [FY19 JPC-8/CRM RP RMFRA Focus Areas](#) and, if applicable, the FY19 [JPC-8/CRM RP RMFRA Area\(s\) of Encouragement](#). How well the rationale, preliminary data, and literature support the identified overarching challenge as an area that needs to be addressed.
- **Focused Research Strategy:** How well the concept for the focused research strategy and the comprehensive project or set of collaborative and synergistic projects will support successfully achieving the goals of the overarching challenge. How well the proposed project(s) will accelerate regenerative medicine solutions that repair, reconstruct, or regenerate lost or damaged tissue. Whether the resulting product(s) will have the potential for commercialization or adoption into clinical practice. How well the research

team is qualified to conduct the proposed research and achieve the described goals. For Multiple PI submissions, how well the partnership interactions will foster robust, synergistic collaborations.

### **Review Criteria for the Research Projects:**

- **Specific Aims/Study Design:** How well the specific aims are stated and supported through scientific rationale and referenced literature and how well the proposed research project's approach will address these aims. How well the project addresses the overarching challenge. If a Single PI submission, how well the comprehensive and multifaceted approach comes together to advance the goals of the focused research. For a Multiple PI submission, how well the project interrelates to, and is synergistic with, the other project(s) to support the goals of the focused research.
  - **Clinical Trials (if applicable):** Whether the proposed study is a Phase 0, I, or IIa clinical trial. How well the proposed clinical trial complements other proposed projects (as applicable).
  - **Impact, Focus Areas, and Areas of Encouragement:** Whether the potential immediate and long-term outcome(s)/product(s) (knowledge and/or material) of the proposed research, if successful, will impact the regenerative medicine research field, including the impact on one or both of the [FY19 JPC-8/CRM RP RMFRA Focus Areas](#) and, if applicable, the [FY19 JPC-8/CRM RP RMFRA Area\(s\) of Encouragement](#).
  - **Military Relevance:** How well the project will impact the healthcare needs of military Service members and Veterans, as well as their family members, caregivers, or clinicians.
- **Notification of Pre-Application Screening Results**

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

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

Applications will not be accepted unless notification of invitation has been received by the PI (Single PI submissions) or Initiating PI (Multiple PI submissions).

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

Each application submission must include the completed full application package for this Program Announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://www.grants.gov/>) for extramural

organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines.

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

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

**Table 1. Full Application Submission Guidelines**

Extramural Submissions	Intramural DoD Submissions
<b>Application Package Location</b>	
Download application package components for W81XWH-19-DMRDP-RMFRA from Grants.gov ( <a href="https://www.grants.gov">https://www.grants.gov</a> ) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-19-DMRDP-RMFRA from eBRAP ( <a href="https://ebrap.org/">https://ebrap.org/</a> ).
<b>Full Application Package Components</b>	
<b>SF424 Research &amp; Related Application for Federal Assistance Form:</b> Refer to the General Application Instructions, Section III.A.1, for detailed information.	<p><b>Tab 1 – Summary:</b> Provide a summary of the application information.</p> <p><b>Tab 2 – Application Contacts:</b> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>

Extramural Submissions	Intramural DoD Submissions
<p>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="#">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="#">Research &amp; Related Subaward Budget Attachment(s) Form</a> (if applicable)</li> </ul>	<p><b>Tab 3 – Full Application Files:</b> Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <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 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><b>Note:</b> If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline.</p>	<p><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>

Extramural Submissions	Intramural DoD Submissions
<b><u>Application Verification Period</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 may be modified <i>with the exception of the Project Narrative and Research &amp; Related Budget Form</i>.</p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI(s) will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research &amp; Related Budget Form</i>. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>
<b>Further Information</b>	
<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>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

**Both Extramural and Intramural Organizations:** Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. *The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.* Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

**Multiple PI Submissions:** The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned a unique eBRAP log number. Each full application package must be submitted using the unique eBRAP log number. **Note:** *All associated applications (Initiating PI’s and each Partnering PI’s) must be submitted by the full application submission deadline.*

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

**Attachments:**

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

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

- **Attachment 1: Project Narrative (individual components of the Project Narrative have page limits as described below; however, there is no overall 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.

The Overall Research Plan component, which includes descriptions of the overarching challenge and the focused research strategy, should appear first in assembly order for all submissions. This should be followed by the Research Project(s) description. For Multiple PI submissions, the Initiating PI’s Research Project should appear directly behind the Overall Research Plan component, followed by each Partnering PI’s Research Project description in numerical order (P1, P2, etc.).

Describe the proposed project in detail using the outline below.

#### **Overall Research Plan (10-page limit)**

- **Overarching Challenge:** Describe the unifying, overarching challenge to be addressed and how it is relevant to a critical problem or question in the field of regenerative medicine and/or patient care in one or both of the [FY19 JPC-8/CRM RP](#)

[RMFRA Focus Areas](#). If applicable, identify [FY19 JPC-8/CRM RP RMFRA Area\(s\) of Encouragement](#) to be addressed. Clearly articulate the rationale for selecting the identified overarching challenge and describe the goals to be achieved; include relevant preliminary data and literature citations.

- **Focused Research Strategy:** Describe the concept for the focused research strategy and how the proposed comprehensive project (Single PI submission) or set of collaborative and synergistic projects (Multiple PI submission) are designed to cooperatively achieve the goals of the overarching challenge. For Single PI submissions, describe how the multifaceted comprehensive study will hone in on the overarching challenge and advance the goal of restoring full peripheral nerve and/or skeletal muscle function after traumatic injury. For Multiple PI submissions, clearly describe how the proposed research projects are interrelated and synergistic and will advance a solution through a multidisciplinary research program. Describe how each project will address the overarching challenge in a unique but complementary way and how the combined efforts of the projects will address the overarching challenge more effectively than if the projects were conducted independently, with the ultimate goal of restoring full peripheral nerve and/or skeletal muscle function after traumatic injury.

Describe how the project(s) will accelerate regenerative medicine solutions and technical capabilities that repair, reconstruct, or regenerate tissue lost or damaged due to traumatic injury. Explain how the resulting product(s) will have the potential for commercialization or adoption by clinicians as surgical or therapeutic options. Include a description of the composition, expertise, and organization of the research team, and discuss how partnership interactions (as applicable) will foster robust, synergistic collaborations.

- **Research Team and Environment:** Identify the PI(s) and key personnel, list their role(s) in the proposed research, describe their relevant expertise, and explain how their combined expertise are synergistic and appropriate for the proposed focused research. Indicate the PI's level of effort on the award. For Single PI submissions, the PI must devote a minimum of 20% effort to this award; for Multiple PI submissions, each PI must devote a minimum of 10% effort to this award. Provide evidence of institutional support for resolving potential intellectual and material property issues (which should be discussed in greater detail in the Intellectual and Material Property Plan), and removing institutional barriers to achieving high levels of cooperation. For Multiple PI submissions, describe plans for regular communication and reciprocal flow of ideas and information.

#### **Research Projects: Basic, Preclinical, and Translational Studies (10-page limit per project)**

- **Background/Rationale/Readiness:** Describe the research problem, question, or knowledge gap related to one or both of the [FY19 JPC-8/CRM RP RMFRA Focus Areas](#) to be addressed by the proposed research project. Where applicable, identify which [FY19 JPC-8/CRM RP RMFRA Area\(s\) of Encouragement](#) will be addressed.

Present the ideas and scientific rationale behind the proposed project, and clearly demonstrate that there is sufficient evidence to support the proposed stage of research. *Preliminary and/or published data that are relevant to regenerative medicine and the proposed project must be included.*

- **Hypothesis and Objective:** State the hypothesis to be tested and the objectives to be reached.
- **Specific Aims:** Concisely state the project’s specific aims. If the proposed work is part of a larger study, then present only tasks that would be funded under this effort.
- **Study Design and Feasibility:**
  - Describe the study design, methods, and analyses, including appropriate controls, in sufficient detail for evaluation of appropriateness and feasibility.
  - 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, and identification of primary endpoints.
  - 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.
  - Describe the statistical analysis plan and rationale for this statistical methodology. Provide a sample size estimate and the method by which it was derived, including power analysis calculations, as applicable. Include any plans for blinding and randomization.
  - Address potential problem areas and present alternative methods and approaches.
  - If animal studies are proposed, clearly describe the key elements of the study/studies as they relate to the overall project; detailed information is required in [Attachment 7: Animal Research Plan](#).
  - If human subjects or human anatomical substances will be used, describe the plan for recruitment of subjects or acquisition of samples. A detailed plan must be included in [Attachment 8: Human Subject Recruitment and Safety Procedures](#). Consent forms for all samples collected under this project should include permission for the samples to be used in future studies without the need for re-consent. The availability of the proposed study population and past successes in recruiting similar populations should be discussed.

**Research Projects: Clinical Trials (if applicable; 20-page limit per project)**

*The project narrative is NOT the formal clinical trial protocol. Instead, all essential elements of the proposed clinical trial necessary for scientific review must be included as directed in Attachment 1 (the project Narrative), Attachment 6, and Attachments*

***8-12 described below. Failure to submit these attachments as part of the application package may result in removal of the project from the application.***

- **Background/Rationale/Readiness:** Describe in detail the rationale for the study. Provide a literature review and describe the preliminary studies and/or preclinical data that led to the development of the proposed clinical trial. Provide a summary of other relevant ongoing, planned, or completed clinical trials and describe how the proposed study differs. Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications (as applicable). The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or study hypotheses. This section should establish the relevance of the study and explain the applicability of the proposed findings.
- **Hypothesis and Objective:** State the hypothesis to be tested and the objectives to be reached. (Note that the clinical trial must be a stand-alone project with no accompanying preclinical studies.)
- **Specific Aims/Study Design:** State the specific aims of the clinical trial and ensure that they agree with the primary aims and associated tasks described in the SOW ([Attachment 5](#)). If the proposed clinical trial is part of a larger study, then present only tasks that would be funded under this effort. Describe the type of study to be performed (e.g., treatment, prevention, diagnostic), the study phase (Phase 0, I, or IIa) or class, as applicable, and the study model (e.g., single group, parallel, crossover). Outline the proposed methodology in sufficient detail to show a clear course of action. Include the following details:
  - Identify the intervention to be tested and describe the projected results.
  - State whether an IND or IDE is required for the clinical trial, and whether the agent/device has been cleared to proceed. (Please note: IND/IDE applications must be submitted within 60 days of award start date and must be cleared to proceed within 6 months of award start date.)
  - Define the primary and any secondary or interim endpoints/outcome measures, outline why they were chosen, and describe how and when they will be measured. Include a description of appropriate controls. Outline the timing and procedures planned during the follow-up period.
  - Describe the study population and the inclusion and exclusion criteria that will be used.
  - Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random).
  - Define each arm/study group of the proposed trial, if applicable. Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating groups,

or other procedures). Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).

- Describe any data collection instruments (e.g., surveys, questionnaires) to be used, as applicable.
  - Outline whether subjects, clinicians, data analysis, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias.
  - If using psychometric measures, describe their reliability and validity.
  - Describe potential problem areas and discuss alternative methods/approaches that may be employed to overcome them. Estimate the potential for subject loss to follow-up and how such loss will be handled/mitigated.
  - Detail the plans for safety reporting, including adverse events and serious adverse events.
- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to study objectives. Specify the approximate number of human subjects to be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.
- **Access to Target Population/Enrollment Strategy:** Describe access to the target population for the proposed clinical trial. State the projected quarterly enrollment for each study site, and provide a contingency plan, including a threshold at which the plan will be implemented if enrollment fails to meet expectations. The projected quarterly enrollment should take into account the inclusion/exclusion criteria of the study site, multiple visits, and any other factors that may affect enrollment into and completion of the trial. Additional details can be included in [Attachment 8: Human Subject Recruitment and Safety Procedures](#).
- **Study Personnel and Organization:** Provide an organizational chart that identifies key members of the study team and provides an outline of the governing structure for multi-institutional studies. Identify collaboration organizations, centers, and/or departments and name each person's position on the project. Include any separate laboratory or testing centers. Identify the data and clinical coordinating center(s) and notes any involvement from Contract Research Organizations, as appropriate. If applicable, identify the FDA regulatory sponsor and any external consultants or other experts who will assist with FDA applications.

Briefly describe the roles of the individuals listed in the organizational chart on the project. Describe relevant experience and qualifications that demonstrate appropriate

expertise for the given role, including previous interactions with the FDA, if applicable. An external research monitor (if applicable) and study coordinator(s) should be included.

Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial is multi-institutional, clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. Provide a regulatory submission plan for the master protocol and master consent form by the lead organization; include a single IRB/EC pathway whenever possible. If applicable, describe how communication and data transfer between the collaborating institutions will occur, as well as how data, specimens, and/or imaging products obtained during the study will be handled and shared.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

The Overall Research Plan component, which includes descriptions of the overarching challenge and the focused research strategy, should appear first in assembly order for all submissions. This should be followed by the Research Project(s) description. For Multiple PI submissions, the Initiating PI’s Research Project description should appear directly behind the Overall Research Plan component, followed by each Partnering PI’s Research Project description in numerical order (P1, P2, etc.).

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under

which the facilities or equipment items are now accountable. There is no form for this information.

- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: 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): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.
- Letters of Commitment (if applicable): If the proposed study involves use of a commercially produced investigational drug, device, or biologic, provide a letter of commitment from the commercial entity indicating availability of the product for the duration of the study, support for the proposed phase of research, and support for the indication used.
- Intellectual Property: Information can be found in 2 CFR 200.315, "Intangible Property."
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
- Use of DoD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military populations and/or DoD resources or databases.
- Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the 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 for the Overall Research Plan; one-page limit for each Research Project; no overall 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 provided for the Overall Research Plan and for each Research Project using the outline below. Each technical abstract should begin on a new page and identify the project title and PI name. The abstract for the Overall Research Plan should appear first in assembly order, followed by the Research Project(s). For Multiple PI submissions, the Initiating PI’s Research Project abstract should appear directly behind Overall Research Plan abstract, followed by each Partnering PI’s Research Project abstract in numerical order (P1, P2, etc.).

#### **Overall Research Plan:**

- **Overarching Challenge:** Describe the unifying, overarching challenge to be addressed and how it is relevant to a critical problem or question in the field of regenerative medicine and/or patient care in one or both [FY19 JPC-8/CRM RP RMFRA Focus Areas](#). If applicable, identify [FY19 JPC-8/CRM RP RMFRA Area\(s\) of Encouragement](#) to be addressed. Clearly articulate the rationale for the overarching challenge, as well as the goals to be achieved.
- **Focused Research Strategy:** Describe the concept for the focused research strategy and how the proposed comprehensive project (Single PI submission) or set of collaborative and synergistic projects (Multiple PI submission) will successfully achieve the goals of the overarching challenge. For Single PI submissions, describe how the multifaceted comprehensive study will hone in on the overarching challenge and advance the goal of restoring full peripheral nerve and/or skeletal muscle function. For Multiple PI submissions, clearly describe how the proposed research project(s) are interrelated and synergistic and will advance a solution through focused multidisciplinary research. Describe how the project(s) will accelerate regenerative medicine solutions and technical capabilities that repair, reconstruct, or regenerate tissue lost or damaged due to traumatic injury, with the ultimate goal of restoring full peripheral nerve and/or skeletal muscle function. Explain how the resulting product(s) will have the potential for commercialization or adoption by clinicians as surgical or therapeutic options.

## Research Projects: Basic, Preclinical, and Translational Studies

- **Background/Rationale:** Describe the research problem, question, or knowledge gap to be addressed by the proposed research project. Present the ideas and scientific rationale behind the proposed project.
- **Hypothesis/Objective:** State the hypothesis to be tested and the objective(s) to be reached.
- **Study Aims/Study Design:** Concisely state the specific aims of the proposed research project, and briefly describe the study design, including appropriate controls.
- **Impact and Focus Area(s):** Briefly describe the short- and long-term impact of this study on the regenerative medicine research field, patient care, and/or quality of life, including the impact on one or both of the [FY19 JPC-8/CRM RP RMFRA Focus Areas](#) and, if applicable, on the [FY19 JPC-8/CRM RP RMFRA Area\(s\) of Encouragement](#).
- **Military Relevance:** Briefly describe how the proposed research project will impact the healthcare needs of military Service members and Veterans, as well as their family members, caregivers, or clinicians. Describe any collaborations with military or VA researchers and/or clinicians.

## Research Projects: Clinical Trials

- **Background/Rationale:** Identify the type of trial and phase proposed. Present the ideas and rationale behind the proposed clinical trial, including the scientific evidence to support moving this research into the proposed clinical trial phase.
- **Hypothesis/Objective:** State the hypothesis to be tested and the objective(s) to be reached.
- **Study Aims:** State the specific aims of the proposed clinical trial.
- **Study Design:** Briefly describe the study design including the intervention to be applied, appropriate controls, the study population, subject recruitment strategies and accrual goals, timelines, outcome measures, and primary and secondary endpoints (if applicable).
- **Clinical Impact:** Briefly describe the short- and long-term impact of this study on patient care and/or quality of life, including the impact on one or both of the [FY19 JPC-8/CRM RP RMFRA Focus Areas](#), and if applicable, on the [FY19 JPC-8/CRM RP RMFRA Area\(s\) of Encouragement](#).
- **Military Relevance:** Briefly describe how the proposed research project will impact the healthcare needs of military Service members and Veterans, as well as their family members, caregivers, or clinicians. Describe any collaborations with military or VA researchers and/or clinicians.

- **Attachment 4: Lay Abstract (one-page limit for the Overall Research Plan; one-page limit for each Research Project; no overall 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.

Lay abstracts should be provided for the Overall Research Plan and for each Research Project using the outline below. Each lay abstract should begin on a new page and identify the project title and PI name. The abstract for the Overall Research Plan should appear first in assembly order, followed by the Research Project(s). For Multiple PI submissions, the Initiating PI’s Research Project lay abstract should appear directly behind the Overall Research Plan lay abstract, followed by each Partnering PI’s Research Project lay abstract in numerical order (P1, P2, etc.).

**Overall Research Plan:**

- Clearly describe the unifying, overarching challenge to be addressed, and how it is relevant to a critical problem or question in the field of regenerative medicine and/or patient care.
- Clearly describe how the proposed focused research addresses the overarching challenge in a manner readily understood by readers without a background in science or medicine.
- Identify the [FY19 JPC-8/CRM RP RMFRA Focus Area\(s\)](#) and, if applicable, the [FY19 JPC-8/CRM RP RMFRA Area\(s\) of Encouragement](#) to be addressed.
- Describe the ultimate applicability and impact of the proposed focused research and how it will benefit the healthcare needs of military Service members and Veterans, as well as the needs of their family members, caregivers, or clinicians.

**Research Project(s):**

- Clearly describe the objectives and rationale for the proposed study/intervention in a manner readily understood by readers without a background in science or medicine.
- Identify the [FY19 JPC-8/CRM RP RMFRA Focus Area\(s\)](#) and, if applicable, the [FY19 JPC-8/CRM RP RMFRA Area\(s\) of Encouragement](#) to be addressed.
  - Describe the ultimate applicability and impact of the research:
    - ❖ What types of patients will the research help, and how will it help them? Include the current available statistics to the related injury/condition.
    - ❖ What are the potential clinical applications, benefits, and risks?

- ❖ What is the plan for achieving a patient-related outcome, and what is the projected time it may take to reach it?
- ❖ What are the likely contributions of the proposed research to advancing regenerative medicine solutions to repair, reconstruct, or regenerate lost or damaged tissue due to traumatic injury?
- Briefly describe how the proposed project will benefit the healthcare needs of military Service members and Veterans, as well as the needs of their family members, caregivers, or clinicians.
- **Attachment 5: Statement of Work (three-page limit per basic/preclinical/translational research project; five-page limit for each clinical trial; no overall 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 RMFRA mechanism, use the SOW format example titled “SOW Generic Format” if no animal or human subjects are to be utilized; “SOW for Advanced Tech Development Research” if animal subjects are to be utilized and/or if the project includes plans for interactions with the FDA; and “SOW for Clinical Research (Including Trials, Special Populations)” for clinical research or a clinical trial. For Multiple PI submissions, each new project section in the overall SOW should begin on a new page, include the project title and PI name, and be assembled in numerical order (i.e., Initiating PI, P1, P2, etc.) 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., IND/IDE applications by the FDA or other Government agency).

- **Attachment 6: Impact and Military Relevance Statement (two-page limit for the Overall Research Plan; one-page limit for each Research Project; no overall page limit): Start each document on a new page, combine into one document, and upload as “ImpactMilRef.pdf”.** The Impact and Military Relevance Statement for the proposed focused research should appear first in assembly order, followed by the Impact and Military Relevance Statement for the research project(s). For Multiple PI submissions, the Impact and Military Relevance Statement for the Initiating PI’s research project should follow directly behind the one for the Overall Research Plan, followed by each Partnering PI’s Impact and Military Relevance Statement in numerical order (P1, P2, etc.). Each Statement should identify the project title and PI name.

### **Overall Research Plan**

- Describe the short- and long-term impact of the proposed focused research on accelerating regenerative medicine solutions to repair, reconstruct, or regenerate lost or damaged tissue due to traumatic injury.
- Address the impact of the proposed focused research on one or both of the [FY19 JPC-8/CRM RP RMFRA Focus Areas](#) and, if applicable, the [FY19 JPC-8/CRM RP RMFRA Area\(s\) of Encouragement](#).
- Demonstrate how the proposed focused research is responsive to the healthcare needs of military Service members and Veterans, as well as the needs of their family members, caregivers, or clinicians.
- Describe any collaborations with military or VA researchers and/or clinicians, and any efforts to integrate and/or align research projects with military and/or VA research laboratories and programs.

### **Research Projects**

- Describe the short- and long-term impact of the proposed research project on the regenerative medicine field, patient care, and/or quality of life, including an assessment of the likelihood that a successful outcome will lead to a practical application in individuals recovering from traumatic injury.

Although not all inclusive, the following are examples of ways in which a research project, if successful, may have an impact:

- It has the potential to advance the field of regenerative medicine research.
  - It has the potential to change standard of care.
  - It contributes to the development or validation of evidence-based policy or guidelines for patient evaluation and care.
- Address the impact on one or both of the [FY19 JPC-8/CRM RP RMFRA Focus Areas](#) and, if applicable, the [FY19 JPC-8/CRM RP RMFRA Area\(s\) of Encouragement](#).

- Describe any relevant controversies that will be addressed by the proposed project, or potential issues that might limit the impact.
  - Demonstrate how the proposed research is responsive to the healthcare needs and quality of life of military Service members and Veterans, as well as their family members, caregivers, or clinicians.
  - Describe any collaborations with military or VA researchers and/or clinicians, and any efforts to integrate and/or align research projects with military and/or VA research laboratories and programs.
- **Attachment 7: Animal Research Plan (required for projects conducting animal research; five-page limit per project; no overall page limit): Start each document on a new page, combine into one document, and upload as “AnimalPlan.pdf”.** For Multiple PI submissions, the Animal Plan for the Initiating PI’s Research Project should appear first in assembly order, followed by each Partnering PI’s Animal Plan in numerical order (P1, P2, etc.). Each Animal Plan should be clearly labeled with the PI’s name and project number (Initiating, P1, P2, etc.). For each research project that involves animals, the applicant is required to detail the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:
- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study’s relevance to human biology.
  - Summarize the procedures to be conducted. Describe how the study will be controlled.
  - Describe the randomization and blinding procedures for the study and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
  - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
  - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
  - Discuss how compliance with current Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), and other regulatory considerations will be established, monitored, and maintained, as applicable.

- State whether these studies are intended to support an FDA submission. If an FDA submission is the goal, provide evidence that the study would actually support the submission (e.g., FDA communications, etc.).
- o **Attachment 8: Human Subject Recruitment and Safety Procedures** (*required for projects conducting clinical trials or clinical research; no page limit*): **Start each document on a new page, combine into one document, and upload as “HumSubProc.pdf”**. For Multiple PI submissions, the Human Subject Recruitment and Safety Procedures attachment for the Initiating PI’s Research Project should appear first in assembly order, followed by each Partnering PI’s attachment in numerical order (P1, P2, etc.). Each should be clearly labeled with the PI’s name and project number (Initiating, P1, P2, etc.). Each research project proposing prospective human subject enrollment is required to submit an attachment describing the human subject recruitment and safety procedures. The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.
  - **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). Provide a table of anticipated enrollment counts at each study site. Demonstrate that the research team has access to the proposed study population at each site, and describe the efforts that will be made to achieve accrual goals. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays. Identify ongoing clinical trials that may compete for the same patient population and how they may impact enrollment progress. Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender. *For clinical trials proposing to include military personnel, refer to the General Application Instructions, Appendix 1, for more information.*
  - **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

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

- **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, healthcare provider identification).
  - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
  - If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan.
  - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.
  
- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.
  - *For the proposed study, provide a draft, in English, of the Informed Consent Form.*
  - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.
  - Include information regarding the timing and location of the consent process.
  - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
  - Address how privacy and time for decision-making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
  - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
  - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial 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, for more information.

- **Assent.** If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.
- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Note that some screening procedures may require a separate consent or a two-stage consent process.
- **Risks/Benefits Assessment:**
  - **Effect on daily life:** Describe how participation in the study will affect the daily life of subjects (e.g., Will human subjects still be able to take their regular medications while participating in the study? Are human subjects required to stay overnight in a hospital?).
  - **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Study risks include any risks that the human subject is subjected to as a result of participation in the clinical trial. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
  - **Risk management and emergency response:**
    - ❖ Describe how safety surveillance and reporting to the IRB, HRPO, and FDA (if applicable) will be managed and conducted.
    - ❖ Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
    - ❖ Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the cost of such care.
    - ❖ Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).

- ❖ Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
- ❖ If the IRB determines that a trial presents greater than minimal risk to human subjects, the DoD requires an independent research monitor with expertise consistent with the nature of risk(s) identified within the research protocol. If applicable, refer to the General Application Instructions, Appendix 1, for more information on study reporting authorities and responsibilities of the research monitor.
- **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.
- **Attachment 9: Data Management Plan (no page limit): Start each document on a new page, combine into one document, and upload as “Data\_Manage.pdf”. A Data Management Plan should be submitted for each Research Project.** For Multiple PI submissions, the Data Management Plan for the Initiating PI’s Research Project should appear first in assembly order, followed by one for each Partnering PI’s Research Project in numerical order (P1, P2, etc.). Each should be clearly labeled with the PI’s name and project number (Initiating, P1, P2, etc.). The Data Management Plan attachment should include the components listed below.
  - **Data Management:** Describe all methods used for data collection, including the following:
    - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
    - **Confidentiality:**
      - ❖ Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
      - ❖ Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of the DoD are eligible to review study records.
      - ❖ Address requirements for reporting sensitive information to state or local authorities.

- **Data capture, verification, and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, the process for locking the database at study completion, and the length of time data will be stored. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. Describe the database lock process. For FDA-regulated studies, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) are required.
  - **Data reporting:** Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
  - **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.
- **Laboratory Evaluations:**
- **Specimens to be collected, schedule, and amount:** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.
  - **Evaluations to be made:** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
  - **Storage:** Describe specimen storage, including location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the plan to store specimens for future use, including considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.
  - **Labs performing evaluations and special precautions:** Identify the laboratory performing each evaluation, the applicable quality standard, and any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.
- **Attachment 10: Regulatory Strategy (no page limit):** Start each document on a new page, combine into a one document, and upload as “Regulatory.pdf”. *A Regulatory Strategy should be submitted for each product, as applicable.* For Multiple PI submissions, the Regulatory Strategy for products within the Initiating PI’s Research Project should appear first in assembly order, followed by one for products within each

Partnering PI's Research Project in numerical order (P1, P2, etc.). Each should be clearly labeled with the PI's name and project number (Initiating, P1, P2, etc.). If the focused research strategy intends for two or more products to be used in conjunction with each other in a way that requires the FDA to review them together as a unit, then a regulatory strategy should be provided for this combination use as well. Such a regulatory strategy should be labeled with the PIs' names and project numbers, and clearly indicate that multiple products are to be reviewed together. FDA tasks should also be factored into the SOWs, timelines, and milestones for each project. The Regulatory Strategy attachment should provide the information requested below and include supporting documentation as applicable.

- State the product/intervention name.

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

- Explain why the product/intervention is exempt from FDA oversight. For clinical trials, provide confirmation that the trial does not require regulation by the FDA in writing from the IRB of record or the FDA. If the clinical trial will be conducted at international sites, provide equivalent information relevant to the host country(ies) regulatory requirements. No further information for this Attachment is required.

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

**Research Projects: Basic, Preclinical, Translational Studies**

- Describe any interactions with the FDA that have already taken place (e.g., request for designation, pre-IND/IDE meeting, IND/IDE submission, etc.) as well as the outcome of those interactions. Provide documentation for all submissions and responses, as well as meeting minutes.
- Provide the current status for manufacturing development (e.g., manufacturer's name, GMP-compliant lots available, status of stability testing, etc.), non-clinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support Phase I testing, etc.), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials). Provide relevant data and/or proof of compliance.
- Describe the overall regulatory strategy and product development plan that will support the planned product indication, including a timeline and narrative of how the strategy will be achieved. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy. Include considerations for compliance with current GMP, GLP, and Good Clinical Practice (GCP) guidelines.
- If the product is marketed in the U.S., state the product label indication. State whether the proposed research involves a change to the approved label indication for

the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is intended for an off-label use.

### **Research Projects: Clinical Trials (if applicable)**

- State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the U.S.
- If the product is marketed in the U.S., state the product label indication. State whether the proposed research involves a change to the approved label indication (e.g., route of administration, dosage level, subject population, etc.). Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is intended for an off-label use.
- If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification. Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.
- For the FY19 JPC-8/CRM RP RMFRA, ***if an IND or IDE is required, it must be submitted to the FDA within 60 days of award.*** The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed clinical trial. If already submitted, provide the date of submission, application number, and sponsor for any existing FDA applications in place. If there are any existing cross-references in place, provide the application number and associated sponsor. Provide an explanation of the status of the application (e.g., past the critical 30-day period, pending response to questions raised by the FDA, on clinical hold, etc.). Provide a summary of previous meetings with the FDA on development of this product, if appropriate. A copy of all submissions and Agency responses, as well as meeting minutes, should be included. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application. If not yet submitted, indicate when the IND/IDE application will be submitted to the FDA and describe how the application will comply with electronic Common Technical Document (eCTD) submission standards.
- If an IND or IDE has already been obtained for the investigational product, provide a copy of the acceptance from the FDA.
- If the clinical trial will be conducted at international sites, provide equivalent information and supporting documentation relevant to the product indication/label. Demonstrate that the FDA will accept the data from the international study and that it will be applicable to a FDA regulatory filing.

- Provide the current status for manufacturing development (e.g., manufacturer’s name, GMP-compliant lots available, status of stability testing, etc.), non-clinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support Phase I testing, etc.), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).
- Describe the overall regulatory strategy and product development plan that will support the planned product indication. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy. Include considerations for compliance with current GMP, GLP, and GCP guidelines.
- **Attachment 11: Transition Plan (no page limit): Upload as “Transition.pdf”. A *single cohesive and integrated Transition Plan should be submitted for the proposed focused research.***

The Transition Plan for the proposed focused research should describe the methods and strategies that will be used to move the proposed product(s) to the next phase of development (i.e., clinical trials, commercialization, and/or delivery to the military or civilian market) after successful completion of the award. If multiple products are proposed in the focused research, the Transition Plan should clearly indicate the strategies and methods for each product, as well as the overall plan for how the products will come together to achieve the ultimate goal of restoring full peripheral nerve and/or skeletal muscle function (e.g., one product may need to transition first before the second product can be transitioned; multiple products may transition separately but be used in conjunction during a treatment regimen; etc.). Applicants should provide supporting documentation for their methods and strategies, 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 post-award Transition Plan should include the components listed below.

- Details of the funding strategy to transition to the next level of development and/or commercialization (e.g., specific industry partners, specific funding opportunities to be applied for). Include a description of collaborations and other resources that will be used to provide continuity of development.
- 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 and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. A “Knowledge Product” is a non-materiel product that addresses an identified need, topic area, or capability gap, is based on current evidence and research, aims to transition into medical practice, training, tools, or to support materiel solutions systems to develop, acquire, provide,

- and sustain medical solutions and capabilities), and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.
- A brief schedule and milestones for transitioning the product to the next phase of development (i.e., clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by the FDA).
  - 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 risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 12: Intervention (required for projects conducting clinical trials; no page limit): Start each document on a new page, combine into one document, and upload as “Intervention.pdf”.** Each application proposing a clinical trial is required to submit an attachment describing the intervention, which should be clearly labeled with the PI’s name and project number (Initiating, P1, P2, etc.). If multiple clinical trials are proposed, the Intervention attachment should be assembled in numerical order (Initiating, P1, P2, etc.). The Intervention attachment should include the components listed below.
- **Description of the Intervention:** Identify the intervention to be tested and describe the particular outcomes. As applicable, the description of the intervention should include the following components: complete name and composition, storage and handling information, source and availability, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed. Measures to ensure consistency of dosing of active ingredients for nutritional supplements should be described, if applicable. Description of devices should include general concept of design, detailed operational instructions, any potential risks to users, and intended benefits. Other types of interventions should be fully described. A description of how the intervention compares with currently available interventions and/or standards of care should be specified. Research procedures should be clearly delineated from routine clinical procedures. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights for conduct of the clinical trial.
- Summarize key preclinical pharmacological findings, dosage studies, and other clinical studies (if applicable) that examine the safety and stability (as appropriate) of the intervention.
- **Study Procedures:** Describe the interaction with the human subject, including the study intervention that he/she will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will experience. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures. Clearly delineate research procedures from routine clinical procedures. Discuss how compliance with current GCP, GMP,

and other regulatory considerations will be established, monitored, and maintained, as applicable.

- **Clinical Monitoring Plan:** Describe how the study will be conducted by and monitored for current ICH E6 (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) GCP compliance, by an independent clinical trial monitor (or clinical research associate). The monitoring plan should describe the types of monitoring visits to be conducted, the intervals (based on level of risk), how corrective actions will be reported to the Sponsor and PI, and how they will be corrected and prevented by the clinical trial site/PI.
- **Attachment 13: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- **Attachment 14: DoD Military Budget Form(s), if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the DoD Military Budget Form, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.
- **Extramural and Intramural Applications**

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

**Research & Related Personal Data:** For extramural submissions (via [Grants.gov](https://www.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](https://www.grants.gov)), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- PI Biographical Sketch (five-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 (NIH) Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.
- PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.
- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch\_LastName.pdf”.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.

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

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

*Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s) even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.*

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

- **Extramural Applications Only**

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

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 14. (Refer to the General

Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DoD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

**DoD Military Budget Form:** A military facility collaborating in the performance of the project (but not participating as a Partnering PI) should be treated as a subaward for budget purposes. *Note:* Applicants should complete the **DoD Military Budget Form (Attachment 14)** to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

### Application Components for each Partnering PI

Each Partnering PI must follow the link in the email from eBRAP and, if not registered in eBRAP, complete the registration process prior to the application submission deadline in order to associate his/her full application package with that of the Initiating PI.

For each Partnering PI, the Initiating PI must identify if each Partnering PI will be named on an extramural or intramural application (in accordance with the guidelines in [Section II.C.1.a, Organization](#)) and the appropriate mode of submission (Grants.gov for extramural and eBRAP for intramural). Each Partnering PI must verify his/her contact information and mode of submission within eBRAP to ensure proper submission of his/her application.

The application submission process for each Partnering PI uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications**

**Attachments:**

- **Attachment 5: Statement of Work (three-page limit per basic/preclinical/translational research project; five-page limit per clinical trial; no overall page limit): Upload as “SOW.pdf”.** Refer to the General Application Instructions, Section III.A.2, for detailed information on completing the SOW. Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and each Partnering PI should be noted for each task.
- **Attachment 13: Representations (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- **Attachment 14: DoD Military Budget Form: Upload as “MFBudget.pdf”.** Refer to the General Application Instructions, Section IV.A.4, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.

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

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

- PI Biographical Sketch (five-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 NIH 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 (5-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, refer to the General Application Instructions, Section III.A.5, and for intramural submissions, refer to the General Application Instructions, Section IV.A.4, for detailed information.

**Budget Justification (no page limit):** Upload as “BudgetJustification.pdf”.

*Initiating and Partnering PIs must each submit a budget and justification specific to his/her own portion of the efforts as part of his/her separate Grants.gov or eBRAP application packages. The Research & Related Budget for each Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.*

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

- **Extramural Applications Only**

**Research & Related Subaward Budget Attachment(s) Form:**

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.)
- **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 14. (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

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

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

**II.D.4. Submission Dates and Times**

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

**Applicant Verification of Full Application Submission in eBRAP**

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

***Extramural Submission:*** The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the

application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified.

***Intramural DoD Submission:*** After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI(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 the application package prior to the application verification deadline.

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

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

The maximum period of performance is **5** years.

The anticipated total costs (direct plus indirect) budgeted for the entire period of performance will not exceed **\$10M** for both Single PI and Multiple PI submissions. ***Submissions may range in size, scope, and duration (up to 5 years) as appropriate for the work proposed, and will be equally considered. Submissions with a total budget of less than the maximum of \$10M are encouraged.*** 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 **\$10M** 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 **5** years.

***For Multiple PI submissions, a separate award will be made to each PI's organization.***

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

- Travel costs for the PI(s) to present project information or disseminate project results at annual IPR meetings during the period of performance of the award. For planning purposes, it should be assumed that the meeting will be held at Fort Detrick, Maryland. These travel costs are in addition to those allowed for annual scientific/technical meetings.
- Travel costs for the PI(s) to present project information or disseminate project results at one DoD-sponsored meeting (e.g., Military Health System Research Symposium) per year during the period of performance. The travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Research-related subject costs
- Clinical trial and clinical research costs
- Support for multidisciplinary collaborations, including travel
- Travel costs for one investigator per Research Project to travel to one scientific/technical meeting per year in addition to the required meetings described above. The intent of travel costs to scientific/technical meeting(s) is to present project information or disseminate project results.

Awards made to extramural organizations will consist solely of assistance agreements (cooperative agreements only). For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other Federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators. Application packages from associated extramural partners will be funded through assistance agreements (cooperative agreements only).

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

Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. The time is considered when establishing the award's period of performance. It is anticipated that awards made from this FY19 funding opportunity will be funded with FY19 funds, which will expire for use on September 30, 2025.

#### **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 proposed focused research applications will be evaluated according to the following **scored criteria**, which are of equal importance:

#### **Review Criteria for the Overall Research Plan**

- **Overarching Challenge**
  - How well the unifying challenge identifies and addresses a critical problem or question in the field of research and/or patient care of on one or both of the [FY19 JPC-8/CRM RP RMFRA Focus Areas](#) and, if applicable, the [FY19 JPC-8/CRM RP RMFRA Area\(s\) of Encouragement](#).
  - How well the rationale, preliminary data, and literature support the overarching challenge as an area that needs to be addressed.
- **Focused Research Strategy**
  - How well the concept for the focused research strategy and the comprehensive project or set of collaborative and synergistic projects will support successfully achieving the goals of the overarching challenge.
  - How well the proposed research project(s) will accelerate regenerative medicine solutions that repair, reconstruct, or regenerate lost or damaged tissue.
  - Whether the resulting product(s) will have the potential for commercialization or adoption into clinical practice.
  - For **Single PI submissions**, how well the proposed project provides a comprehensive multifaceted approach that hones in on the overarching challenge and supports the goal of restoring full peripheral nerve and/or skeletal muscle function after traumatic injury.
  - For **Multiple PI submissions**, how well the proposed set of research projects are interrelated and synergistic, with each project addressing the overarching challenge in a unique but complementary way. How the combined efforts of the projects will address the overarching challenge more effectively than if the projects were conducted independently, and will support the goal of restoring full peripheral nerve and/or skeletal muscle function after traumatic injury.
- **Research Team and Environment**
  - How well the research team is qualified to address the overarching challenge and achieve the described goals.

- Whether the combined expertise of the research team is synergistic and appropriate for the proposed focused research.
- Whether the PI(s) will devote a minimum of 10% (Multiple PI submission) or 20% (Single PI submission) effort to this award.
- Whether there is evidence of institutional support for resolving potential intellectual and material property issues, and removing institutional barriers to achieving high levels of cooperation.
- **Multiple PI submissions:**
  - How well the partnership interactions will foster robust, multidisciplinary, and synergistic collaborations.
  - Whether there is a plan for regular communications and reciprocal flow of ideas and information.

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

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

### **Review Criteria for the Basic, Preclinical, and Translational Research Projects**

To determine technical merit, all basic, preclinical, and translational research projects will be evaluated according to the following **scored criteria**, which are listed in decreasing order of importance:

- **Study Design**
  - How well the preliminary data and scientific rationale support the proposed research project and demonstrate sufficient evidence to support moving into the proposed stage of research.
  - How well the hypotheses and objectives, study aims, study design, methods, data collection procedures, and analyses are developed, appropriate, and integrated into the project.

- The extent to which the proposed project is feasible as described.
- As applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
- As applicable, the degree to which the intellectual and material property plan is appropriate.
- How well potential problems are acknowledged and alternative approaches are addressed.

***For applications involving animal research:***

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

***For applications involving human subjects and/or human anatomical substances:***

- The degree to which the plan to study human subjects and human anatomical substances is designed to achieve the objectives and is appropriate and feasible, including demonstrated access to the selected population(s) or resource(s).

***For applications involving military Service members or Veteran populations:***

- The degree to which the plan to study military Service members or Veteran populations is appropriate and feasible, including demonstrated access to the selected population.

- **Statistical Plan**

- The degree to which the statistical plan and power analysis is appropriate for the proposed project, as applicable.
- How well the proposed study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.

- **Impact**

- How effectively the proposed research project addresses one or both of the [FY19 JPC-8/CRM RP RMFRA Focus Areas](#) and, if applicable, the [FY19 JPC-8/CRM RP RMFRA Area\(s\) of Encouragement](#).
- How well the proposed project addresses a critical problem in, and will make important contributions to, regenerative medicine research, patient care, and/or quality of life.
- How likely that a successful outcome of the proposed study will lead to a practical application in individuals recovering from tissue loss or damage due to traumatic injury.

- **Personnel**
  - How the background and expertise of the Research Project PI and key personnel demonstrate their ability to perform the proposed work.
  - How well the PI's record of accomplishment demonstrates the ability to accomplish the proposed Research Project.
  - How the levels of effort by the Research Project PI and other key personnel are appropriate to ensuring the successful conduct of the project.
  
- **Transition Plan**
  - How appropriate and well described the proposed methods and strategies are to move the proposed product(s) to the next phase of development.
  - Whether the identified next level of development and/or commercialization is realistic.
  - Whether the funding strategy described to bring the product(s) to the next level of development (e.g., clinical trial, transition to industry, delivery to market, progression toward incorporation into standard practice) is appropriate.
  - To what extent the collaborations and other resources (established or planned) described are appropriate and will provide continuity of development.
  - How the schedule and milestones for bringing the product(s) to the next level of development (e.g., clinical trial, transition to industry, delivery to market, progression toward incorporation into standard practice) are appropriate and feasible.
  - How well the application identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization, describes an appropriate intellectual and material property plan between/among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent Governmental access to products supported by this Program Announcement.
  - If applicable, how well the risk analysis for cost, schedule, manufacturability, and sustainability is developed and is realistic and reasonable.
  - For Knowledge Products, how well the plan supports further development and dissemination, if applicable, as well as the incorporation into clinical practice/care.
  
- **Regulatory Strategy**
  - How the overall regulatory strategy and development plan to support the product indication or product label change, if applicable, are appropriate and well described.

- Whether the tasks and milestones in the SOW include appropriate interactions with the FDA (e.g., pre-IND/IDE meetings and/or submissions, requests for designation, IND/IDE submissions, etc.), as applicable.
- Whether the application includes documentation that the study is exempt from FDA or other international agency regulation, or that the IND or IDE application and/or international equivalent has been submitted to the FDA and/or relevant international regulatory agency, or that the SOW indicates that the IND or IDE application and/or international equivalent will be submitted within 60 days of the award date, as appropriate. Whether it has been demonstrated that the FDA will accept the data from the international study, if applicable, and that it will be applicable to an FDA filing.
- If applicable, whether plans to comply with GMP, GLP, and/or GCP guidelines are appropriate.

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

- **Budget**

- Whether the budget is appropriate for the proposed research.

- **Application Presentation**

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

### **Review Criteria for Clinical Trial Research Projects (if applicable)**

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

- **Impact**

- How effectively the proposed clinical trial addresses one or both of the [FY19 JPC-8/CRM RP RMFRA Focus Areas](#) and, if applicable, the [FY19 JPC-8/CRM RP RMFRA Area\(s\) of Encouragement](#).
- How relevant the anticipated outcomes of the proposed clinical trial are to individuals recovering from tissue loss or damage due to traumatic injury.
- How well the sample population represents the targeted patient population that might benefit from the proposed intervention.
- How the potential outcomes of the proposed clinical trial will provide/improve short-term benefits for individuals.

- How significantly the long-term benefits for implementation of the intervention may impact patient care and/or quality of life.
- **Study Design**
  - How well the scientific rationale for clinically testing the intervention is supported by the preliminary data, critical review and analysis of the literature, and/or laboratory/preclinical evidence.
  - How well the study aims, hypotheses and/or objective(s), experimental design, methods, data collection procedures, and analyses are designed to answer clearly the clinical objective.
  - How well the inclusion and randomization criteria meet the needs of the proposed clinical trial.
  - How well the exclusion criteria are justified.
  - How well plans to collect specimens and conduct laboratory evaluations are addressed, if applicable.
  - To what degree the data collection instruments (e.g., surveys, questionnaires), if applicable, are appropriate to the proposed study.
  - As applicable, the degree to which the intellectual and material property plan is appropriate.
- **Statistical Plan**
  - To what degree the statistical model and data analysis plan are suitable for the planned study.
  - How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
  - Whether the statistical plan compensates for the use of a subpopulation of a recruited sample population to ensure appropriate power can be achieved within the subpopulation study.
- **Intervention**
  - Whether there is evidence of support, indicating availability of the intervention from its source, for the duration of the proposed clinical trial (if applicable).
  - To what degree the intervention addresses the clinical need(s) described.
  - How the intervention compares with currently available interventions and/or standards of care.

- To what degree the applicant has provided preclinical and/or clinical evidence to support the safety of the intervention.
- How well research procedures are clearly delineated from routine clinical procedures.
- Whether measures are described to ensure the consistency of dosing of active ingredients for nutritional supplements (if applicable).
- **Regulatory Strategy**
  - How the regulatory strategy and development plan to support the product indication or product label change, if applicable, are appropriate and well described.
  - Whether the application includes documentation that the study is exempt from FDA or other international agency regulation, or that the IND or IDE application and/or international equivalent has been submitted to the FDA and/or relevant international regulatory agency, or that the SOW indicates that the IND or IDE application and/or international equivalent will be submitted within 60 days of the award date, as appropriate. Whether it has been demonstrated that the FDA will accept the data from the international study, if applicable, and that it will be applicable to an FDA filing.
  - For investigator-sponsored regulatory exemptions (e.g., IND, IDE, or other international equivalent), whether there is evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the FDA or relevant international regulatory agency.
  - Whether plans to comply with GMP, GLP, and/or GCP guidelines are appropriate.
- **Recruitment, Accrual, and Feasibility**
  - How well the application addresses the availability of human subjects for the clinical trial and the prospect of their participation.
  - Whether the application has demonstrated access to the proposed human subjects population.
  - The degree to which the recruitment, informed consent, screening, and retention processes for human subjects will meet the needs of the proposed clinical trial.
  - How well the application identifies possible delays (e.g., slow accrual, attrition) and presents adequate contingency plans to resolve them.
  - To what extent the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study (e.g., Will human subjects still be able to take their regular medications while participating in the clinical trial? Are human subjects required to stay overnight in a hospital?).

- **Transition Plan**

- Whether the identified next level of development and/or commercialization is realistic.
- Whether the funding strategy described to bring the product(s) to the next level of development (e.g., specific industry partners, specific funding opportunities to be applied for) is reasonable and achievable.
- For Knowledge Products, whether the proposed collaborations and other resources for providing continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications, are established and/or achievable.
- Whether the schedule and milestones for bringing the intervention to the next level of development (next-phase clinical trials, transition to industry, delivery to the market, incorporation into standard practice, and/or approval by the FDA) are achievable.
- Whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
- How well the application identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent Government access to products supported by this Program Announcement.

- **Ethical Considerations**

- Whether the population selected to participate in the trial stands to benefit from the knowledge gained.
- If applicable, how well the inclusion of international sites is justified.
- How the level of risk to human subjects is minimized and how the safety monitoring and reporting plan is appropriate for the level of risk.
- Whether a research monitor with expertise consistent with the nature of the potential risk(s) is identified, if applicable.
- How well the evidence shows that the procedures are consistent with sound research design and, when appropriate, that these procedures are already in use for diagnostic or treatment purposes.
- To what degree privacy and confidentiality issues are appropriately considered.

- To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.

- **Personnel and Communication**

- Whether the composition of the study team (e.g., study coordinator, statistician) is appropriate.
- To what degree the study team's background and expertise are appropriate to accomplish the proposed work (e.g., statistical expertise, expertise in the disease/condition/injury, and clinical studies).
- How the levels of effort of the study team members are appropriate for successful conduct of the proposed trial.
- How well the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, standardization of procedures) meet the needs of the proposed clinical trial.
- For multi-site clinical trials, how well the lead site responsibilities and human research protections regulatory coordination are defined and planned for.

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

- **Environment**

- To what degree the scientific environment, clinical setting, and the accessibility of institutional resources support the clinical trial at each participating center or institution (including collaborative arrangements).
- How the quality and extent of organizational support are appropriate for the proposed clinical trial and support multi-institutional collaborations (if applicable).

- **Budget**

- Whether the budget is appropriate for the proposed clinical trial.

- **Application Presentation**

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

### **II.E.1.b. Programmatic Review**

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY19 JPC-8/CRM RP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Programmatic relevance to one or both of the [FY19 JPC-8/CRM RP RMFRA Focus Areas](#)
  - Relative impact and military relevance
  - Relative value in budget

### **II.E.2. Application Review and Selection Process**

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC, on behalf of the DHA and the OASD(HA). *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section II.E.1.b, Programmatic Review](#).* Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.army.mil/about/2tierRevProcess>. A PI Information Paper describing the funding recommendations and review process for the FY19 JPC-8/CRM RP RMFRA will be provided to the PI and posted on the CDMRP website.

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

### **II.E.3. Integrity and Performance Information**

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, over the period of performance, the

Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

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

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

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

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

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

### **II.F. Federal Award Administration Information**

#### **II.F.1. Federal Award Notices**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

### **II.F.3. Reporting**

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

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

Quarterly technical progress reports and quad charts will be required.

In addition to written progress reports, in-person presentations at annual IPR meetings 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 Representations (see General Application Instructions, Appendix 5, Section B).

## **II.G. Federal Awarding Agency Contacts**

### **II.G.1. CDMRP Help Desk**

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

Phone: 301-682-5507

Email: [help@eBRAP.org](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 20190530a. The Program Announcement numeric version code will match the General Application Instructions version code 20190530.

### **II.H.2. Administrative Actions**

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

#### **II.H.2.a. Rejection**

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

- A Preproposal Narrative component exceeds the specified 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.
- A Project Narrative component exceeds the specified 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 FY19 JPC-8/CRM RP RMFRA 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 FY19 JPC-8/CRM RP RMFRA Programmatic Panel members can be found at [https://cdmrp.army.mil/dmr dp/panels/19jpc8\\_rm fra](https://cdmrp.army.mil/dmr dp/panels/19jpc8_rm fra).*

- The application fails to conform to this Program Announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY19, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The invited application proposes a different research project than that described in the pre-application.
- For Multiple PI submissions, all associated (Initiating and Partnering PI) applications are not submitted by the deadline.

#### **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

#### Checklist for Mechanisms with Single PIs

Application Components	Action	Completed
SF424 Research & Related 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 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 Relevance Statement: Upload as Attachment 6 with file name "ImpactMilRef.pdf"	
	Animal Research Plan: Upload as Attachment 7 with file name "AnimalPlan.pdf" if applicable	
	Human Subject Recruitment and Safety Procedures: Upload as Attachment 8 with file name "HumSubProc.pdf" if applicable	
	Data Management: Upload as Attachment 9 with file name "DataManage.pdf"	
	Regulatory Strategy: Upload as Attachment 10 with file name "Regulatory.pdf" if applicable	
	Transition Plan: Upload as Attachment 11 with file name "Transition.pdf"	
	Intervention: Upload as Attachment 12 with file name "Intervention.pdf" if applicable	
	Representations (extramural submissions only): Upload as Attachment 13 with file name "RequiredReps.pdf" if applicable	

<b>Application Components</b>	<b>Action</b>	<b>Completed</b>
	DoD Military Budget Form(s): Upload as Attachment 14 with file name “MFBudget.pdf” if applicable	
Research & Related Personal Data	Complete form as instructed	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field	
Research & Related Budget ( <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	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed	

## Checklist for Mechanisms with Partnering PIs

Application Components	Action	Initiating PI Completed	Partnering PI Completed
SF424 Research & Related 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 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 Relevance Statement: Upload as Attachment 6 with file name "ImpactMilRef.pdf"		
	Animal Research Plan: Upload as Attachment 7 with file name "AnimalPlan.pdf" if applicable		
	Human Subject Recruitment and Safety Procedures: Upload as Attachment 8 with file name "HumSubProc.pdf" if applicable		
	Data Management: Upload as Attachment 9 with file name "DataManage.pdf"		
	Regulatory Strategy: Upload as Attachment 10 with file name "Regulatory.pdf" if applicable		
	Transition Plan: Upload as Attachment 11 with file name "Transition.pdf"		
	Intervention: Upload as Attachment 12 with file name "Intervention.pdf" if applicable		

<b>Application Components</b>	<b>Action</b>	<b>Initiating PI Completed</b>	<b>Partnering PI Completed</b>
	Representations (extramural submissions only): Upload as Attachment 13 with file name "RequiredReps.pdf" if applicable		
	DoD Military Budget Form(s): Upload as Attachment 14 with file name "MFBudget.pdf" if applicable		
Research & Related Personal Data	Complete form as instructed		
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field		
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field		
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field		
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field		
Research & Related Budget ( <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		
Research & Related Subaward Budget Attachment(s) Form	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
AFIRM	Armed Forces Institute of Regenerative Medicine
ARRIVE	Animal Research: Reporting <i>In Vivo</i> Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
CRM RP	Clinical and Rehabilitative Medicine Research Program
DHA	Defense Health Agency
DHP	Defense Health Program
DMRDP	Defense Medical Research and Development Program
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
eCTD	Electronic Common Technical Document
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GOR	Grants Officer Representative
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
ICH E6	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDE	Investigational Device Exemption
IND	Investigational New Drug
IPR	In-Progress Review
IRB	Institutional Review Board
JPC-8	Joint Program Committee 8

LAR	Legally Authorized Representative
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
NPC	Non-Profit Corporation
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
RMFRA	Regenerative Medicine Focused Research Award
RTD	Return to Duty
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs

## APPENDIX 2: DOD AND VA WEBSITES

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

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

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

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

Armed Forces Institute of Regenerative  
Medicine  
<https://www.afirm.mil>

Center for Neuroscience and Regenerative  
Medicine  
<https://www.cnrnstudies.org/>

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

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

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

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

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

Defense Health Agency (DHA) J9, Research  
and Development Directorate  
<https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/Research-and-Development>

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

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

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

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

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

National Center for Telehealth and  
Technology  
<https://t2health.dcoe.mil>

National Museum of Health and Medicine  
<https://www.medicalmuseum.mil/index.cfm>

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

Naval Medical Research Center  
[www.med.navy.mil/sites/nmrc](http://www.med.navy.mil/sites/nmrc)

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

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

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

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

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

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

U.S. Army Aeromedical Research  
Laboratory  
[www.usaarl.army.mil](http://www.usaarl.army.mil)

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

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

U.S. Army Medical Research Acquisition  
Activity  
<https://www.usamraa.army.mil/>

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

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

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

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

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

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

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

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

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