

**BROAD AGENCY ANNOUNCEMENT  
FOR EXTRAMURAL RESEARCH  
(PROGRAM SPECIFIC)**

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**

**Extremity Regeneration Intervention**

**Funding Opportunity Number: W81XWH-16-R-CRM1**

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

**SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Proposal/Pre-Application Deadline:** 5:00 p.m. Eastern time (ET) December 15, 2015
- **Proposal/Application Submission Deadline:** 11:59 p.m. ET, December 22, 2015
- **End of Proposal/Application Verification Period:** 5:00 p.m. ET, December 29, 2015
- **Peer Review:** February 2016
- **Programmatic Review:** April 2016

*This Broad Agency Announcement is one of two documents with instructions to prepare and submit a proposal/application for this funding opportunity. The second document, the General Submission Instructions, is available for downloading from Grants.gov.*

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## I. OVERVIEW OF THE FUNDING OPPORTUNITY

### A. Administrative Overview

This Funding Opportunity Announcement is a Broad Agency Announcement (BAA) for the Fiscal Year (FY15) Joint Program Committee 8 (JPC-8)/Clinical and Rehabilitative Medicine Research Program (CRM RP) Extremity Regeneration Intervention Award (ERI). This BAA must be read in conjunction with the submission guidelines in [Grants.gov/Apply for Grants](https://www.grants.gov/apply-for-grants) (hereinafter called [Grants.gov/Apply](https://www.grants.gov/apply)). It must also be read in conjunction with the document titled “General Submission Instructions” available with this BAA in Grants.gov.

This BAA is intended to solicit extramural research and development ideas and is issued under the provisions of the Competition in Contracting Act of 1984 (Public Law 98-369), as implemented in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016. In accordance with FAR 35.016, projects funded under this BAA must be for basic and applied research and that part of development not related to the development of a specific system or hardware procurement. Projects must be for scientific study and experimentation directed toward advancing the state-of-the-art or increasing knowledge or understanding rather than focusing on a specific system or hardware solution. Research and development funded through this BAA is intended and expected to benefit and inform both military and civilian medical practice and knowledge. **This BAA is intended for extramural investigators only.**

- An *extramural investigator* is defined as all those not included in the definition of intramural investigators below.
- An *intramural investigator* is defined as a Department of Defense (DoD) military or civilian employee working within a DoD laboratory, DoD military treatment facility, or working in a DoD activity embedded within a civilian medical center.
- Submissions from intramural investigators to this BAA will be rejected. *It is permissible, however, for an intramural investigator to be named as a collaborator in a proposal/application submitted by an extramural investigator.* For more information, refer to the General Submissions Instructions, Section II.C.8.
- In accordance with FAR 35.017, Federally Funded Research and Development Centers (FFRDCs) are not eligible to directly receive awards under this BAA. However, teaming arrangements between FFRDCs and eligible organizations are allowed if permitted under the sponsoring agreement between the Federal Government and the specific FFRDC.

**Pre-Proposals/Pre-Applications:** All pre-proposals/pre-applications must be submitted through the electronic Biomedical Research Application Portal (eBRAP [<https://eBRAP.org/>]). A registration process through eBRAP must be completed before a pre-proposal/pre-application can be submitted.

- A Principal Investigator (PI) and the organization’s business official must register in eBRAP before submitting a pre-proposal/pre-application.
- Full proposals/applications (submitted through Grants.gov) will be available for viewing, modification, and verification in eBRAP, for a limited period.

**Full Proposals/Applications:** To submit a full proposal/application, the PI must submit a pre-application, including a letter of intent. The full proposal/application must be submitted electronically through Grants.gov (<http://www.grants.gov/>) using the SF-424 Research and Related (R&R) forms and the SF-424 (R&R) Application Guide. *Proposals/Applications will not be accepted by mail or in person.*

## **B. Program Overview**

Proposals/applications to the FY15 JPC-8/CRM RP ERI are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs [OASD(HA)], the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Materiel Command (USAMRMC), Congressionally Directed Medical Research Programs (CDMRP) provides Defense Medical Research and Development Program (DMRDP) execution management support for DHP core research program areas, including JPC-8/CRM RP. CDMRP is the execution management agent for this BAA and will provide management support for subsequent awards in partnership with the U.S. Army Medical Materiel Development Activity (USAMMDA) with strategic oversight from JPC-8/CRM RP.

The CRM RP is one of six major program areas within the DHP and is administered with oversight from JPC-8, which consists of DoD and non-DoD medical and military technical experts relevant to the program area. The CRM RP 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 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 interest is in medical technologies (drugs, biologics, and 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 DoD health care system. Implementation of these technologies and strategies should improve the rate of RTD of Service members, the time to RTD, clinical outcome measures, and quality of life, as well as reduce the hospital stay lengths, clinical workload (patient encounters, treatments, etc.), and initial and long-term costs associated with restorative and rehabilitative or acute care. The CRM RP focuses its efforts on the following research areas: neuromusculoskeletal injury (including amputees), sensory systems (including hearing, balance, tinnitus, and vision), acute and chronic pain, and regenerative medicine.

The area of interest for this BAA is extremity regeneration to address complex blast and other traumatic injuries to Service members. The proposed research must have military relevance but is expected to improve both public and military health care outcomes. Unprotected extremities are at greatest risk for significant tissue damage and loss. These patients typically have multiple upper and lower mangled extremity injuries and often sustain damage to muscle, nerve, blood vessels, bone, and connective tissues. Consideration will be given to bone and soft tissue reconstruction, limb and tissue salvage technologies, and regenerative medicine technologies for the treatment of

trauma-induced damage to these tissues. The focus is on identifying innovative solutions to treating extremity injury that will transform the standard of care.

### C. Award Information

The FY15 JPC-8/CRM RP ERI is intended to support Phase I, II, or pivotal clinical trial phase development projects focused on extremity regeneration. The focus is on bone and soft tissue reconstruction, limb and tissue salvage technologies, and regenerative medicine technologies for the treatment of trauma-induced damage. All clinical trials must be responsive to the health care needs of military Service members and Veterans, as well as the general public. All proposals/applications must specifically and clearly address the military relevance of the proposed research.

Proposals/applications submitted to the FY15 JPC-8/CRM RP ERI *must* specifically address one or more of the Focus Areas listed below.

- ***The treatment of soft tissue injury***, specifically, nerve, muscle, and vascular injury to the extremities. The aim of these technologies is to: (a) maintain the structure and function of end organs distal to a nerve injury, (b) restore functional muscle tissue, and (c) restore vascular perfusion. Both innovative care solutions as well as innovative technologies that may better enable a definitive care solution to be delivered at some future time point, such as vascular shunting or stenting technologies, will be considered.
- ***The treatment for bone healing***, specifically technologies that create a wound environment more conducive to bone healing following injury to the extremities.

***Funding from this award mechanism must support a clinical trial and development-related efforts and may not be used for preclinical research studies.*** A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. The term “human subjects” is used in this BAA to refer to individuals who will be recruited for or who will participate in the proposed clinical trial. For more information, a Human Subject Resource Document is provided at [https://cdmrp.org/Program\\_Announcements\\_and\\_Forms/](https://cdmrp.org/Program_Announcements_and_Forms/).

**Use of 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 USAMRMC Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) of record. 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. Refer to the General Submission Instructions, Appendix 5, for additional information.

If the proposed study involves the use of a drug biologic or device that is not approved by the U.S. Food and Drug Administration (FDA), is not covered by an existing Investigational New Drug (IND) or Investigational Device Exemption (IDE), or uses a drug, biologic or device that is being used outside of its FDA-approved indication and population (e.g., off-label), ***evidence that an IND or IDE application has been submitted or will be submitted within 60 days of award*** is required.

- If the proposed study will use clinical sites located outside of the United States and uses an investigational or off-label drug, biologic, or device, ***evidence that submission of the appropriate application to the regional regulatory authority has been or will be submitted within 60 days of award date*** is required.
- The Government reserves the right to withdraw funding if the appropriate regulatory approval application (e.g., IND, IDE) has not been submitted to the FDA or regional regulatory authority within 60 days of the DoD award date or if the documented status of the regulatory approval has not been obtained within 6 months of the award date.
- A business plan that describes the product and industry development progression through FDA marketing application, and to the commercial market (if applicable), must be submitted within 60 days of the award.
- The Government reserves the right to withdraw funding if the business plan has not been submitted to the DoD within 60 days of the award date.

The following are important aspects of a submission for the ERI:

#### **Relevance and Feasibility**

- The proposal/application should describe how the proposed intervention to be tested will offer significant potential impact for military Service members, Veterans or the general public over current standard of care.
- The proposal/application should demonstrate availability of, and access to, a suitable patient population that will support a meaningful outcome for the study.
- The proposed clinical trial is initiated and can begin enrollment no later than 12 months after the award date.
- The proposal/application should demonstrate how accrual goals will be achieved and how standards of care may impact the study population.
- The proposal/application should demonstrate documented availability of and access to the drug, biologic, or device, if applicable, and/or other materials needed, as appropriate.

#### **Clinical Trial Elements**

- The proposed clinical trial should include clearly defined, measurable, and appropriate endpoints.
- The proposal/application should include a clearly articulated statistical analysis plan, availability of appropriate statistical expertise, and a power analysis reflecting sample size projections that will clearly answer the objectives of the study and support an FDA marketing application, if applicable.

- The proposal/application should indicate the availability of a study coordinator(s) who will guide the clinical protocol through the local IRB or EC of record and other regulatory approval processes, coordinate activities from all sites participating in the trial, and coordinate participant accrual.
- If an IND or IDE application is required to be submitted to the FDA, the proposal/application should describe the availability of appropriate support to prepare, submit, and maintain the IND or IDE application.
- If submission to a non-U.S. regional regulatory authority is required, the proposal/application should describe the availability of appropriate region-specific support to prepare, submit, and maintain the relevant application.
- Inclusion of preliminary data relevant to the proposed research project and FDA marketing application is required. Examples of preliminary data include preclinical toxicology, manufacture validation, quality systems audit/gap analysis, a summary of preclinical studies, and any prior clinical experience inside or outside of the United States.
- In addition to requisite preliminary data, the proposed research project must be based on sound scientific rationale that is established through logical reasoning and critical review and analysis of the literature.

#### **Institutional Elements**

- The proposal/application should include a post-award transition plan (including potential funding and resources) showing how the product would progress to the next clinical trial phase and/or delivery to the market after the successful completion of the work associated with this proposed award.
- The proposal/application should clearly demonstrate strong institutional support.

#### **D. Eligibility Information**

- Independent extramural investigators at all academic levels (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Eligible extramural investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Submission Instructions, Appendix 1, for general eligibility information.

**Recipient Qualification:** In addition to other information provided herein, by submitting a proposal/application and accepting an award, the organization is: (1) certifying that the investigators' credentials have been examined; and (2) verifying that the investigators are qualified to conduct the proposed study and to use humans or animals as research subjects, if proposed. Investigators include all individuals, regardless of ethnicity, nationality, or citizenship status, who are employed by, or affiliated with, an eligible organization.

Investigators are cautioned that awards are made to organizations, not individuals. A PI must submit a proposal/application through an organization in order to receive support.

**NOTE:** In accordance with FAR 35.017, FFRDCs are not eligible to directly receive awards under this BAA. However, teaming arrangements between FFRDCs and eligible organizations are allowed if permitted under the sponsoring agreement between the Federal Government and the specific FFRDC.

The USAMRMC is committed to supporting small businesses. Small business, Veteran-owned small business, Service-disabled Veteran-owned small business, HUBZone small business, small disadvantaged business, and woman-owned small business concerns must be given the maximum practical opportunity to participate through subawards on research proposals/applications submitted through the BAA.

## **E. Funding**

- The maximum period of performance is **4** years.
- The anticipated **total** costs (direct and indirect) budgeted for the entire period of performance will not exceed **\$4.9 million (M)**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding \$4.9M total costs or using an indirect rate exceeding the organization's negotiated rate.
- Option periods may be utilized for contracts, subject to the availability of funds.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.

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

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

- Travel costs for the PI(s) to attend an In-Progress Review (IPR) meeting anticipated to be held near the end of 1-year anniversary of the award Government location (to be determined) and annually for the remainder of the period of performance. Costs associated with travel to this meeting should be included in each year of the budget. For planning purposes, it should be assumed that a 2-day IPR meeting will be held in the National Capital/Maryland/Northern Virginia area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research-related subject costs
- Support for multidisciplinary collaborations
- Equipment
- Research supplies
- Travel between collaborating institutions, including travel to military/Government facilities
- Travel costs to attend scientific/technical meetings in addition to the required IPR meeting described above

***This BAA is intended for extramural investigators only.***

An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center.

It is permissible for an intramural investigator to be named as a collaborator in a proposal/application submitted by an extramural investigator under this BAA. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

Subawards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR] or Funding Authorization Document [FAD] process). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Submission Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for proposals/applications involving Federal agencies.

***The JPC-8 expects to allot approximately \$4.9M of the FY15 DHP RDT&E appropriation to fund one to three ERI proposal(s)/application(s), depending on the quality and number of proposals/applications received. Funding of proposals/applications received in response to this BAA is contingent upon the availability of Federal funds for this program.***

## **F. Mechanisms of Support**

The DHP executes its extramural research program primarily through the award of contracts and assistance agreements (grants and cooperative agreements). The type of instrument used to reflect the business relationship between the organization and the Government is at the discretion of the Government based on the Statement of Work submitted in the proposal/application.

The USAMRAA will negotiate the award types for proposals/applications selected for funding. The Federal Grant and Cooperative Agreement Act of 1977, 31 USC<sup>1</sup> 6301-6308, provides the legal criteria to select a procurement contract or an assistance agreement. Refer to the General Submission Instructions, Appendix 3, for additional information.

Any assistance agreement (grant or cooperative agreement) awarded under this BAA will be governed by the award terms and conditions that conform to the DoD's implementation of Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of awards made after December 26, 2014, may include revisions to reflect DoD implementation of new OMB guidance in 2 CFR<sup>2</sup> part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

## **G. Other Review Information**

The following information will be reviewed prior to the award of a contract or assistance agreement:

- 1. "Exclusions" Identified in System for Award Management (SAM):** *To protect the public interest, the Federal Government ensures the integrity of Federal programs by striving to conduct business only with responsible organizations. The USAMRAA uses the "Exclusions" within the Performance Information functional area of the SAM; data from the Federal Awardee Performance and Integrity Information System, a component within SAM, is used to verify that an organization is eligible to receive Federal awards. More information about the "Exclusions" reported in SAM is available at <https://www.sam.gov/>. Refer to the General Submission Instructions, Section II.A.2., for additional information.*
- 2. Conflicts of Interest:** *All conflicts of interest (COIs) or potential COIs must be disclosed with the proposal/application submission, along with a plan to resolve them. All COIs on the part of an organization or individual investigators that could bias the research project must be resolved prior to the award of a contract or assistance agreement. Refer to the General Submission Instructions, Appendix 1, for additional information.*
- 3. Review of Risk:** *The following areas may be reviewed in evaluating the risk posed by the applicant: Financial stability; quality of management systems and operational controls; history of performance; reports and findings from audits; ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities; degree of institutional support; integrity; adequacy of facilities; and conformance with safety and environmental statutes and regulations.*
- 4. Subcontracting Plan:** *If the resultant award is a contract that exceeds \$650,000 and the offeror is other than a small business, the contractor will be required to submit a subcontracting plan for small business disadvantaged business concerns, in accordance with FAR 19.7.A mutually agreeable plan will be incorporated as part of the resultant contract.*

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<sup>1</sup> United States Code

<sup>2</sup> Code of Federal Regulations

## II. SUBMISSION INFORMATION

### A. Where to Obtain the Submission Package

To obtain the complete Grants.gov proposal/application package (hereinafter, submission package), including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number **W81XWH-16-R-CRM1** in Grants.gov (<http://www.grants.gov/>).

Submission is a two-step process requiring both: (1) Pre-proposal/pre-application submission through eBRAP (<https://eBRAP.org/>); and (2) full proposal/application submission through Grants.gov (<http://www.grants.gov/>).

### B. Pre-proposal/Pre-Application Submission and Content

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

PIs and organizations identified in the pre-proposal/pre-application should be the same as those intended for the subsequent proposal/application submission. If any changes are necessary after submission of the pre-proposal/pre-application, the PI must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507. A change in PI or organization after submission of the pre-proposal/pre-application will be allowed only at the discretion of the USAMRAA Contracting or Grants Officer.

The organization, Business Official, and PI must register in eBRAP before submitting a pre-proposal/pre-application. Upon completion of an organization's registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization's Business Officials and PIs as they register. The organization, Business Officials, and PIs must all be registered and affiliated in eBRAP. (See *eBRAP User Guide* at <https://eBRAP.org/eBRAP/public/UserGuide.pdf>.)

Pre-proposals/pre-applications must be submitted by the deadline specified on the [title page](#) of this BAA. *Proprietary information should not be included in the pre-proposal/pre-application.*

The pre-proposal/pre-application consists of the following components, which are organized in eBRAP by separate tabs. Refer to the General Submission Instructions, Section II.B., for additional information on pre-proposal/pre-application submission.

- **Application Information – Tab 1:** Enter the information as described in eBRAP before continuing the pre-proposal/pre-application.
- **Application Contacts – Tab 2:** Enter contact information for the PI and the organization's Business Official responsible for sponsored program administration (or equivalent). This is the individual listed as "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF-424 Form. The Business Official must either be named or invited in order for the pre-proposal/pre-application to

be submitted. If the organization's Business Official is not in eBRAP, an invitation to the Business Official to register in eBRAP must be sent. In addition, it is recommended that the PI identify an Alternate Submitter in the event that assistance with pre-proposal/pre-application submission is needed.

**NOTE:** The eBRAP system does not require an approval of the pre-proposal/pre-application by the PI's organization.

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

- Enter the name, organization, and role of all collaborators and key personnel associated with the application (including co-investigators, mentors, collaborators, consultants, and subrecipients/subawardees) associated with the proposal/application.
- FY15/16 JPC-8/CRM RP Extremity Regeneration Steering Committee (ERSC) members should not be involved in any pre-application or application including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. A list of the FY15/16 JPC-8 ERSC members can be found at <http://cdmrp.army.mil/dmrpd/panels/ERpanel15>. *If formal collaboration with Military Facility personnel is planned (i.e., included in the proposal/application in performance of the research), this prohibition is not applicable. However, these Military Facility personnel may not be involved in the review process and/or with making funding recommendations.* For questions related to JPC-8 ERSC members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

- **Conflicts of Interest – Tab 4:**

- List all individuals other than collaborators and key personnel who may have a COI in the review of the proposal/application (including those with whom the PI has a personal or professional relationship).
- Federal agency personnel involved in the review process and/or with making funding recommendations are prohibited from assisting in any proposal/application, including, but not limited to, concept design, proposal/application development, budget preparation, and the development of any supporting documentation. *If formal collaboration with Military Facility personnel is planned (i.e., included in the proposal/application in performance of the research), this prohibition is not applicable. However, these individuals may not be involved in the review process and/or with making funding recommendations.*

- **Pre-Application Files- Tab 5:**

*Note: Upload document(s) 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.*

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the Focus Area(s) under which the application will be submitted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review.

Refer to the General Submission Instructions, Section II.B., for detailed information.

- **Submit Pre-Application – Tab 6:**

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

### **C. Full Proposal/Application Submission Content and Forms**

*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 proposal/application submission must include the completed application package provided in Grants.gov for this BAA. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

After proposal/application submission to Grants.gov, eBRAP will retrieve and validate the submission. eBRAP will notify the organizational representatives and PI via email and instruct them to log into eBRAP to review, modify, and verify the proposal/application. During this verification period, the PI may upload missing files (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the verification period.

*Note: The Project Narrative and Budget Form cannot be changed after the proposal/application submission deadline.* If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID *prior to the application submission deadline.*

Proprietary information should *be included* in the full proposal/application *only if necessary for evaluation purposes.* Conspicuously and legibly, mark any proprietary information that is included in the full proposal/application.

**Grants.gov Application Package Components: For the W81XWH-16-R-CRM1, the Grants.gov application package includes the following components (refer to the General Submission Instructions, Section II.C., for additional information on proposal/application submission):**

1. **SF-424 (R&R) Application for Federal Assistance Form:** Refer to the General Submission Instructions, Section II.C., for detailed information.

## 2. Attachments Form

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Submission Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (25-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, etc.) 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 will result in administrative withdrawal of the proposal/application.

Describe the proposed project in detail using the outline below.

- **Background:** State the relevance of the proposed clinical trial to at least one of the FY16 DMRDP CRM RP ERI Focus Areas and explain the applicability of the proposed findings to improving clinical outcomes for injured Service members.
- **Intervention Rationale:** Describe in detail the rationale for the study and include a literature review, preliminary studies, and/or preclinical data that led to the development of the proposed clinical trial.
- **Supportive Clinical Studies:** Provide a summary of relevant clinical trials and distinguish how the proposed study differs from other relevant or recently completed clinical trials. Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications (as applicable). Clearly support the choice of study variables and explain the basis for the study questions and/or study hypotheses.
- **Experience:** Describe previous experience of the PI and key members of the research team most pertinent to this project.
- **Product Indication or Target Treatment:** Provide a description of the proposed product indication.
- **Objectives/Specific Aims/Hypotheses/Milestones:** Provide a description of the purpose and objectives of the clinical trial and development plan with detailed specific aims and/or study questions/hypotheses/milestones.

- **Preliminary Data:** Provide preliminary data relevant to the proposed project such as preclinical toxicology, manufacture validation, quality systems audit/gap analysis, a summary of preclinical studies, and any prior clinical experience inside or outside of United States.
- **Project Design:** Describe the type of clinical study to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action.
  - Describe potential challenges and alternative strategies where appropriate.
  - Identify the intervention to be tested and describe the projected outcomes, including how they will be measured.
  - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
  - Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random).
  - Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers). Discuss blinding procedures as applicable and how the blind will be maintained. Describe other methods to control for the introduction of potential bias into the study.
- Acknowledge commitment to file the study in the National Institutes of Health (NIH) clinical trials registry, <http://www.clinicaltrials.gov>. Proposals/applications for clinical studies that meet the definition of an “applicable clinical trial” (see note below) are required to comply with Section 801 of the Food and Drug Administration Amendments Act (FDAAA) regarding registering and/or reporting of results of the study on [ClinicalTrials.gov](http://ClinicalTrials.gov). Applicable clinical trials include:
  - Trials of drugs and biologics: Controlled clinical investigations, other than Phase 1 clinical investigations, of drugs or biological products subject to FDA regulation
  - Trials of devices: Controlled trials subject to FDA regulation, other than small feasibility studies

**NOTE:** Applicable clinical trials generally include interventional studies (with one or more arms) of FDA-regulated drugs, biologics, or devices that meet one of the following conditions:

  - Has one or more sites in the United States
  - Is conducted under an FDA IND or IDE
  - Involves a drug, biologic, or device that is manufactured in the United States or its territories

- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate and sufficient to meet the objectives of the study.
- **Manufacturing and Testing Support:** Describe the product manufacturing methods and associated product testing or release criteria. Describe the maturity and scale of manufacturing with respect to current Good Manufacturing Practices (cGMP).
- **Project Milestones:** Identify timelines for critical events that must be accomplished in order for the project to be successful in terms of cost, schedule, and performance.

Refer to the General Submission Instructions, Appendix 5, for additional regulatory information.

- **Attachment 2: Supporting Documentation: Start each document on a new page. Combine and upload as a single file named “Support.pdf.”** If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *There are no page limits for any of these components unless otherwise noted. Include only those components described below; items not requested will be removed and may result in administrative withdrawal of the proposal/application.*
  - **Bibliography and References Cited:** List the references in the order they appear in the Project Narrative. Use a reference format that gives the title of the citation. Do not send or attach copies of articles in print. There is no form for this information. The attachments should be in PDF in accordance with the formatting guidelines specified for full proposal/application preparation.
  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
  - **Facilities and Other Resources:** Describe the facilities available for performance of the proposed request and any additional resources proposed for acquisition at no cost to the Government. Indicate if a Government-owned facility is proposed for use. Reference should be made to the original or present award under which the facilities or resources are now accountable. There is no form for this information. The attachments must be in PDF in accordance with the formatting guidelines outlined for full proposal/application preparation.
  - **Equipment:** Include a description of existing equipment to be used for the proposed research project.
  - **Publications and/or Patent Abstracts (five-document limit):** Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be attached.

- 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. A letter for each organization involved in the project should be provided.
- Collaboration: Provide letter(s) supporting stated collaborative efforts necessary for the project's success, even if provided at no cost. ***If the project involves collaboration with a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center), special requirements apply.*** A DoD researcher must obtain a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the research project. This letter must be included with the proposal/application. (Refer to the General Submission Instructions, Section II.C.8., for additional information.)
- Joint Sponsorship (if applicable): Describe present or prospective joint sponsorship of any portion of the program outlined in the proposal/application. In the absence of agreements among sponsors for joint support, the proposal/application should be structured so that the research can be carried out without the resources of any other sponsor. If, however, it is desirable to request partial support from another agency, the proposed plan should be stated and the reasons documented. If the plan cannot be formulated at the time the proposal/application is submitted, information should be sent later as an addendum to the proposal/application. Prior approval from both agencies must be secured for research to be undertaken under joint sponsorship. Provide letters of support related to recruitment, subject access, and data access plans.
- Intellectual Property: Refer to the General Submission Instructions, Appendix 3, for additional information. Provide the following:
  - Background and Proprietary Information: Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.
  - Intellectual and Material Property Plan: If applicable, provide a plan for resolving intellectual and material property issues among participating organizations.
  - All software and technical data first produced under the award are subject to a Federal purpose license. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.

- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”**

Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. Use the outline below. Abstracts of all funded proposals/applications may be posted online; *therefore, proprietary information should not be included in the abstracts.*

- **Background:** Provide a brief statement of the ideas and theoretical reasoning behind the proposed work.
- **Proposed indication and expected FDA regulatory pathway.**
- **Objective/Hypothesis:** State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- **Specific Aims/Milestones:** State concisely the specific aims/milestones of the project.
- **Project Design:** Briefly describe the project design.
- **Impact:** Provide a brief statement explaining the potential impact of the proposed work to advancing the standard of care for injured Service members and/or the general public.

- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. Abstracts of all funded proposals/applications may be posted online; *therefore, proprietary information should not be included in the abstracts.*

Lay abstracts should be written using the following outline.

- Describe the objectives and rationale for the proposal/application in a manner that will be readily understood by readers without a background in science or medicine.
  - Do not duplicate the technical abstract.
- Describe the ultimate applicability and potential impact of the research.
  - What types of patients will it 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 projected timeline it may take to achieve the expected patient-related outcome?
- Briefly describe how the proposed project will benefit Service members, Veterans, and/or their family members.

- **Attachment 5: Statement of Work (SOW) (two-page limit): Upload as “SOW.pdf.”** The SOW outlines and establishes the PI’s and an organization’s performance expectations for the work to be funded under this award. The SOW in an assistance agreement award establishes general objectives. The SOW in a contract sets rather specific goals and conditions for each year of the contracted project; the PI and contractor are expected to meet the provisions and milestones of the SOW. The SOW for all award types will be incorporated into the award document and, as such, is subject to release under the Freedom of Information Act.

A series of relatively short statements should be included that comprise the approach to each of the major goals or objectives of the proposed research. The statements should outline the specific tasks, systems, and materials that are reasonable estimates for testing the proposed hypotheses of the study. An outline should be included that shows the work statements to be accomplished in each year of the award. If this proposal/application is part of a larger study, present only tasks that this award would fund. Allow at least 2 to 3 months for the USAMRMC ORP’s regulatory review and approval processes for studies involving human subjects and 2 to 3 months for studies involving animal subjects.

- **Attachment 6: Outcomes and Impact Statement (one-page limit): Upload as “Impact.pdf.”** Explain in detail why the proposed research project is important, as follows:
  - **Short-Term Impact:** Describe the anticipated outcome(s)/results(s)/theoretical framework, design, and/or plan that will be directly attributed to the results of the proposed research.
  - **Long-Term Impact:** Describe the anticipated long-term clinical/ patient gains or commercial end product from the proposed project. What is the indication and will the project lead toward transforming the standard of care? Are there non-trauma-related indications that would expand the market for the proposed product?
  - **Military Relevance:** Clearly articulate how the proposed project or product meets the needs of injured Service members and either allow them to return to duty or resume a fully active lifestyle.
  - **Public Purpose:** If appropriate, provide a concise, detailed description on how this project will benefit the general public.
- **Attachment 7: Human Subject Recruitment and Safety Procedures (no page limit): Upload as “HumSubProc.pdf.”** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.
  - Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site (population from whom the sample will be recruited/drawn). Demonstrate that the research team has access to the proposed study population. 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. Include justification of any age, race, ethnicity, or sex limitations provided.

- b. 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 USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded from the clinical trial.

- c. Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care 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.
  - Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
  - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.
- d. 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/EC 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, please refer to the General Submission Instructions, Appendix 5, 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/EC to identify the conditions necessary for obtaining assent.
- e. 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. Please note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.
- f. Risks/Benefits Assessment**
- **Foreseeable risks:** Clearly identify all study risks. 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 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, to include 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.
- **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society. ***Note: Payment and/or other compensation for participation are not considered to be benefits and must be addressed in Attachment 7c.***
- **Attachment 8: Intervention (no page limit): Upload as “Intervention.pdf.”**  
The Intervention attachment should include the components listed below. Proposals/applications may be submitted without protocols and institutional approvals. However, protocols with required institutional approvals must be submitted no later than 60 days after award to demonstrate continued progress and ensure continuation of payment. The Contracting or Grants Officer may make exceptions in situations where human studies are not expected to begin until after the first year of the research project. In such cases, a timeframe for submission of the appropriate protocols and institutional approvals will be established prior to award.
  - a. **Description of the Intervention:** As applicable, the description of the intervention should include the following components: Complete name and composition, planned indication, storage and handling information, source, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed.  
  
Summarize key preclinical pharmacological findings, dosage studies, and other clinical studies (if applicable) that examine the safety of the intervention. Description of devices should include detailed operational instructions, any potential risks to users, and intended benefits. Other types of interventions should be fully described.
  - b. **Study Procedures:** Describe the interaction with the human subject to include the study intervention that he/she will undergo. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will undergo. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures. Discuss how compliance with Good Clinical Practices (GCP), cGMP, and other regulatory considerations will be established, monitored, and maintained, as applicable.

- c. **Clinical Monitoring Plan:** Describe how the study will be conducted by and monitored for ICH E6 (International Conference on Harmonization 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.
  - d. **Clinical Practice Concept:** Describe how the successful intervention could be incorporated into current standard of care and what impact it would have on existing practices. The description may be a theoretical case study example of a patient with proposed intervention as compared to current standard of care. The description should include possible change in level of health care provider, reduced complexity, impact to cost, and likely accessibility and compliance of targeted patient population.
- **Attachment 9: Data Management (no page limit): Upload as “DataManage.pdf.”** The Data Management attachment should include the components listed below.
    - a. **Data Management:** Describe all methods used for data collection to include the following:
      - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
      - **Confidentiality:** Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
        - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRMC are eligible to review study records.
        - Address requirements for reporting sensitive information to state or local authorities.
      - **Disposition of data:** Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored. For FDA-regulated studies, compliance with 21 CFR 11 is required.
      - **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.

**b. Laboratory Evaluations**

- **Specimens to be collected, schedule, and amount:** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.
  - **Evaluations to be made:** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
  - **Storage:** Describe specimen storage, to include location of storage, how long specimens will be stored, any special conditions required, labeling, and disposition. Outline the plan to store specimens for future use to include considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.
  - **Labs performing evaluations and special precautions:** Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.
- **Attachment 10: IND/IDE Documentation: Upload as “IND-IDE.pdf.”** If submitting multiple documents, start each document on a new page. Combine and upload as a single file named “IND-IDE.pdf.”
    - a. Complete the IND/IDE Documentation Form, which is available for download on the Full Announcement page for this BAA on Grants.gov.
    - b. Provide evidence of one of the following:
      - That an IND or IDE application has been submitted and includes an explanation of the current status (e.g., past the critical 30-day review period, pending response to questions raised by the Agency, on clinical hold). Inclusion of copies of any Agency meeting minutes or other relevant correspondence (e.g., submission documents, email) is encouraged but not required to support this explanation.
      - That an IND or IDE application will be submitted and include a description of the submission plan. If applicable, indicate time required for submission and/or approval of IND or IDE applications to the FDA, or appropriate regional regulatory authority if the study will be conducted outside of the United States.
      - If the proposed study has been previously exempted by the FDA from IND or IDE regulation (or international equivalent thereof), provide evidence in the form of formal communication (e.g., letterhead correspondence) from the FDA or regional regulatory authority to that effect.

- Proposals/applications that require an FDA IND/IDE application (or international equivalent thereof) must submit documentation of regulatory approval no later than 60 days after submission of the application to the regulatory authority to demonstrate continued progress and ensure continuation of payment.
- **Attachment 11: Post-Award Project Transition Plan (three-page limit). Upload as “Transition.pdf.”** Provide information on the methods and strategies proposed to move the product or knowledge outcomes to the next project phase of clinical trials, commercialization, and/or delivery to the civilian or military market after successful completion of the award. The transition plan should include the components listed below.
  - a. The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication.
  - b. The anticipated regulatory strategy (e.g., additional nonclinical or clinical studies anticipated/required, FDA or regulatory authority meetings desired, industry partnerships) for movement of the research into later phases of development and to support a potential marketing application [e.g., New Drug Application, Biologics License Application, Premarket Approval Application, 510(k)].
  - c. Details of the funding strategy that will be used to bring the outcomes to the next level of development and/or commercialization (e.g., specific potential industry partners, specific funding opportunities to be applied for).
  - d. For knowledge products, a description of how the knowledge will be further developed, disseminated, and incorporated into clinical care.
  - e. A description of collaborations and other resources that will be used to provide continuity of development.
  - f. A brief schedule and milestones for bringing the outcome(s) to the next phase of clinical trials, commercialization, and/or delivery to the military or civilian market, including when it can be anticipated to be transitioned to an industry partner or approved by the FDA, if applicable.
  - g. A risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 12: Conflicts of Interest, if applicable: Upload as “COI.pdf.”** Provide details with the proposal/application submission of all organizational or individual investigator COIs, or potential COIs, along with a plan to resolve them. A contract or assistance agreement will not be awarded if it is determined by the respective Contracting or Grants Officer that a COI cannot be resolved.  
  
Federal agency personnel involved in the review process and/or with making funding recommendations are prohibited from assisting in any proposal/application, including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *If formal collaboration with Military Facility personnel is planned (i.e., included in the*

*proposal/application in performance of the research), this prohibition is not applicable. However, these individuals may not be involved in the review process and/or with making funding recommendations.*

Questions related to this topic should be directed to the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507. Refer to the General Submission Instructions, Appendix 1, for additional information.

- **Attachment 13: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility will be a collaborator in performance of the project complete the Collaborating DoD Military Facility Budget Form (available for download on eBRAP “Funding Opportunities and Forms” web page), including a budget justification for each year. If more than one Military Facility is proposed, submit a separate budget form for each site. Refer to the General Submission Instructions, Section II.C.8., for detailed information.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Submission Instructions, Section II.C.4., 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 five-page National Institutes of Health Biographical Sketch may also be used.
  - **PI Previous/Current/Pending Support (three-page limit 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 (three -page limit each):** Upload as “Support\_LastName.pdf.”
- 4. Research & Related Budget:** Refer to the General Submission Instructions, Section II.C.5., 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.

***NOTE: For all Federal agencies or organizations collaborating with Military Facilities, special restrictions apply to the budget and are described below.***

- **For Federal Agencies:** Proposals/Applications from **Federal agencies** must include in their budget justifications a **Federal Financial Plan (Plan)**. The Plan must address how all funds will be obligated before their period for obligation expires, and how funds will be available to cover research costs over the entire award period. The Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.

- **For Collaborating Military Facilities:** Proposals/Applications from organizations that include **collaborations with DoD Military Facilities** (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) must submit Collaborating DoD Military Facility Budget Form(s) as instructed in Attachment 13.

**5. Project/Performance Site Location(s) Form:** Refer to the General Submission Instructions, Section II.C.6., for detailed information.

**6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Submission Instructions, Section II.C.7., for detailed information.

#### **D. Applicant Verification of Grants.gov Proposal/Application in eBRAP**

Prior to the end of the proposal/application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of a proposal/application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific BAA 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 proposal/application components and ensure proper ordering as specified in the BAA. *If either the Project Narrative or the budget fails eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the proposal/application submission deadline.* The Project Narrative and Budget Form cannot be changed after the proposal/application submission deadline.

Refer to the General Submission Instructions, Section II.A.2., for additional information.

#### **E. Data Universal Number System Numbers, Commercial and Government Entity Code, and System for Award Management**

All proposals/applications must be submitted through Grants.gov. An applicant organization and any subaward organization must have Data Universal Number System (DUNS) numbers (issued by Dun and Bradstreet) before submitting a proposal/application to Grants.gov. In addition, an applicant organization must have a CAGE (Commercial and Government Entity) Code. Also, the organization must be registered as an Entity with the SAM and have an "Active" status before submitting a proposal/application through Grants.gov or receiving an award from the Federal Government.

#### **F. Submission Dates and Times**

All submission dates and times are indicated on the [title page](#) of this BAA. Pre-proposal/pre-application and proposal/application submissions are required. Failure to meet either of these deadlines will result in proposal/application rejection.

#### **G. Intergovernmental Review**

This BAA is not subject to Executive Order (EO) 12372.

## **H. Funding Restrictions**

Refer to the General Submission Instructions, Section II.C.5., “Research & Related Budget,” for discussion of allowable costs, including pre-award costs and collaborations with Military Facilities.

## **I. Other Submission Requirements**

Proposals/applications must be submitted electronically to Grants.gov. Refer to the General Submission Instructions, Appendix 2, for detailed formatting guidelines.

## **III. PROPOSAL/APPLICATION REVIEW AND SELECTION INFORMATION**

### **A. Proposal/Application Review and Selection Process**

All applicants are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of proposals/applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the OASD(HA), based on (a) technical merit and (b) the relevance to the mission of the DHP and JPC-8/CRM RP and to the specific intent of the award mechanism. The highest-scoring proposals/applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign agreements to protect the confidentiality of the information that proposal/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 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 proposal/application. Violations by panel members or applicants that compromise the confidentiality of the review 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 by military personnel or employee of the Federal Government is a crime in accordance with 18 USC 1905.

### **B. Peer and Programmatic Review**

- 1. Peer Review:** To determine technical merit and feasibility, all proposals/applications will be evaluated according to the following scored criteria, which are listed in descending order of importance:

- **Project Strategy**

- How well the scientific rationale for 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 or objectives, experimental design, methods, 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.
  - Appropriateness of the data collection instruments (e.g., surveys, questionnaires), if applicable, to the proposed study.
  - How well the manufacturing and testing support the clinical trial phase and ultimate submission for an FDA marketing application.
- **Clinical Impact**
    - 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.
    - To what degree the intervention represents an improvement upon what is currently available.
    - How well the intended indication will impact and transform the standard of care provided to injured Service members and the public.
    - How well the proposed clinical trial assesses one or more of the FY15 JPC-8/CRM RP ECI Focus Areas.
  - **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.
    - To what degree the preclinical and/or clinical evidence to support the safety of the intervention.
    - The maturity of the project development plan along the FDA regulatory pathway.
    - For investigator-sponsored IND/IDEs, whether there is evidence of appropriate institutional support, including capabilities to ensure clinical monitoring as required by the FDA, and support required to prepare, submit, and maintain an IND/IDE.

- Whether plans to comply with cGMP (for investigational drug, biological, and device interventions), and GCP guidelines are appropriate.
- Whether measures are described to ensure the consistency of dosing of active ingredients for nutritional supplements (if applicable).
- **Statistical Plan**
  - The suitability of the statistical model and data analysis plan 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.
- **Personnel**
  - To what degree the composition and balance of the research team (including other organization personnel, sub-awards, and consultants, as applicable) are appropriate.
  - To what degree the PI's and research team's backgrounds and expertise are appropriate and complementary to accomplish the proposed work.
  - Appropriateness of the levels of effort by the PI and other key personnel to ensure the success of proposed research.
  - 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.
- **Recruitment, Accrual, and Feasibility**
  - How well the proposal addresses the availability of human subjects for the clinical trial and the prospect of their participation.
  - Whether the proposal 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 proposal/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?)
- **Ethical Considerations**
  - 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.

- 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 issues are appropriately considered.
- Appropriateness of the process for seeking informed consent and whether safeguards are in place for vulnerable populations.
- **Post-Award Project Transition Plan**
  - Whether the funding strategy described to bring the outcome(s) to the next level of development (e.g., higher phase clinical trial, transition to industry, delivery to the market, incorporation into standard practice) is appropriate.
  - How the development plan to support a product label change, if applicable, is appropriate and well described.
  - Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.
  - How the schedule and milestones for bringing the outcome(s) to the next level of development (e.g., higher phase clinical trial, transition to industry, delivery to the market, incorporation into standard practice) are appropriate.
  - How well developed the potential risk analysis is for cost, schedule, manufacturability, and sustainability.
  - How well the proposal/application identifies intellectual property ownership, describes any 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 BAA.
  - For knowledge products, to what degree the plan for further developing, disseminating, and incorporating into clinical care is presented.
- **Environment**
  - To what degree the research environment and the accessibility of institutional resources support the proposed study (including collaborative arrangements).
  - Whether there is evidence for appropriate institutional commitment.
  - Whether there is evidence of appropriate industrial interest and/or commitment.
  - If applicable, appropriateness of the intellectual property plan.

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

- **Budget**
  - Whether the budget is appropriate for the proposed intervention and product development and within the limitations of this BAA.

- Whether the proposed timeline is appropriate and tasks outlined in the proposal/application are logical in their progression.
  - **Proposal/Application Presentation:** To what extent the writing, clarity, and presentation of the proposal/application components influence the review.
2. **Programmatic Review:** To make funding recommendations, the following criteria will be used by programmatic reviewers:
- a. **Ratings and evaluations of the peer reviewers**
  - b. **Relevance to the mission of the DHP and JPC-8/CRM RP as evidenced by the following:**
    - Adherence to the intent of the award mechanism
    - Proposed project timeliness towards clinical implementation
    - Relative impact
    - Program portfolio balance

### C. Submission Review Dates

All submission review dates and times are indicated on the [title page](#) of this BAA.

### D. Notification of Submission Review Results

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 proposal/application.

## IV. ADMINISTRATIVE ACTIONS

After receipt of proposals/applications from Grants.gov, the following administrative actions may occur:

### A. Rejection

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

- The pre-proposal/pre-application is submitted by an intramural organization or FFRDC.
- Narrative (Letter of Intent) is missing.

The following will result in administrative rejection of the proposal/application:

- Submission of a proposal/application for which a letter of invitation was not received.
- Project Narrative exceeds the page limit.
- Project Narrative is missing.
- Budget is missing.

- Attachment 7, Human Subject Recruitment and Safety Procedures, is missing.
- Attachment 8, Intervention, is missing.
- Attachment 9, Data Management, is missing.

## **B. Modification**

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

## **C. Withdrawal**

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

- An FY15/16 JPC-8 Extremity Regeneration Steering Committee (ERSC) member is named as being involved in the research proposed or is found to have assisted in the pre-proposal/pre-application or proposal/application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. A list of the FY15 JPC-8 ERSC members can be found at <http://cdmrp.army.mil/dmrdp/panels/ERpanel15>.
- Inclusion of any employee of CDMRP review contractors in pre-proposals/pre-applications or full proposals/applications for funding without adequate plans to resolve conflicts of interest. Refer to General Submission Instructions, Appendix 1, for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The full proposal/application does not propose the same research project as described in the pre-proposal/pre-application.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections

## **D. Withhold**

Proposals/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 Contracting or Grants Officer for a determination of the final disposition of the proposal/application.

## **V. AWARD ADMINISTRATION INFORMATION**

### **A. Award Notice**

The awarding agency will be the USAMRAA. The USAMRAA Contracting and Grants Officers are the only individuals authorized to obligate funds and bind the Federal Government. Authorization to begin performance will be received via an award document (contract, grant, or cooperative agreement, as applicable) signed by the USAMRAA Contracting or Grants Officer. No commitment on the part of the Government should be inferred from discussions with any other individual.

A recommended for funding notification is NOT an authorization to begin performance nor a guarantee of an award. Awards will be made no later than September 30, 2016. Refer to the General Submission Instructions, Appendix 3, for additional information.

### **B. Administrative Requirements**

Refer to the General Submission Instructions, Appendix 3, for general information regarding administrative requirements.

### **C. National Policy Requirements**

Refer to the General Submission Instructions, Appendix 4, for general information regarding national policy requirements.

### **D. Reporting Requirements**

Refer to the General Submission Instructions, Appendix 3, for general information on reporting requirements.

Quarterly technical progress reports and quad charts will be required. In addition to written progress reports, in-person presentations may be requested. Reporting of contractor manpower is required for all contracts.

- Contractor Manpower Reporting (CMR)
  - CMR is now a requirement of all DoD contracts. Offerors are allowed to include a nominal fee in their cost/price proposal for providing these data. A “nominal fee” is defined as a computation of an administrative assistant equivalent labor category providing approximately 6-8 hours to complete data input. Offerors may opt to not separately price this required annual data input. CMR costs/price will not be evaluated as part of the total evaluated proposal cost/price.

- The contractor shall report ALL contractor labor hours (including subcontractor labor hours) required for performance of services provided under each contract via a secure data collection site. The contractor is required to completely fill in all required data fields using the following web address: <http://www.ecmra.mil/>.
- Reporting inputs will be for the labor executed during the period of performance during each Government fiscal year (FY), which runs October 1 through September 30. While inputs may be reported any time during the FY, all data shall be reported no later than October 31 of each calendar year, beginning with 2013. Contractors may direct questions to the help desk at: [contractormanpower@hqda.army.mil](mailto:contractormanpower@hqda.army.mil) or via phone at 703-377-6199.

## **E. Changes of Principal Investigator and Organization**

Refer to the General Submission Instructions, Appendix 3, for general information on changes to PIs and organizational transfers.

The institution 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 Contracting or Grants Officer.

## **VI. AGENCY CONTACTS**

### **A. CDMRP Help Desk**

Questions related to BAA content or submission requirements as well as questions related to the submission of the pre-proposal/pre-application 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. Eastern Time. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

### **B. Grants.gov Contact Center**

Questions related to full proposal/application submission through the 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 BAA or by responding to the prompt provided by Grants.gov when first downloading the application package. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.***

### C. Common Submission Problems

- Failure to enter an email address for change notifications under the BAA Funding Opportunity Announcement in Grants.gov for notifications on any modification made to the initial posting.
- Attachments are uploaded into the incorrect form on Grants.gov forms. (See [Section VII., Proposal/Application Submission Checklist.](#))
- Failure to contact the Grants.gov Help Desk when needed.
- Failure to send attachments.
- Inability to locate attachment forms. (Select “Search Grants” at <http://www.grants.gov> and enter W81XWH-16-R-CRM1 in the “Funding Opp #” block. When the Funding Opportunity appears, select the Funding Opportunity #. When you reach the “View Grant Opportunity” screen, select “Full Announcement.” The forms will be listed on the following screen.)
- Use of “illegal” characters (i.e., characters not available on a standard QWERTY keyboard, e.g., Greek letters) in attachment titles.
- Attachments exceed size limits.
- Upload attempts of unacceptable attachments: bitmap, TIFF, etc.
- Duplicate upload of documents.

## VII. PROPOSAL/APPLICATION SUBMISSION CHECKLIST

Grants.gov Submission Package Components	Upload Order	Action	Completed
SF-424 (R&R) Application for Federal Assistance		Complete as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Outcomes and Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	7	Human Subject Recruitment and Safety Procedures: Upload as Attachment 7 with file name "HumSubProc.pdf."	
	8	Intervention: Upload as Attachment 8 with the file name "Intervention.pdf."	
	9	Data Management: Upload as Attachment 9 with the file name "DataManage.pdf."	
	10	IND/IDE Documentation: Upload as Attachment 10 with the file name "IND-IDE.pdf."	
	11	Post-Award Project Transition Plan: Upload as Attachment 11 with the file name "Transition.pdf."	
	12	Conflicts of Interest: Upload as Attachment 12 with file name "COL.pdf," if applicable.	
	13	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 13 with the file name "MFBudget.pdf," if applicable.	
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		Attach Budget Justification (BudgetJustification.pdf) to the appropriate field. Complete form as instructed.	
Project/Performance Site Location(s) Form		Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form (if applicable)		Complete form as instructed.	