

Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Defense Medical Research and Development Program

Joint Program Committee 8/ Clinical and Rehabilitative Medicine Research Program

Extremity Regeneration Technology/Therapeutic Development Award

Funding Opportunity Number: W81XWH-15-DMRDP-CRMRP-ERTTDA

Catalog of Federal Domestic Assistance Number: 12.420

Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

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

The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.

This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2015 (FY15) Joint Program Committee 8/Clinical and Rehabilitative Medicine Research Program (JPC-8/CRM RP) 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 US 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. This Program Announcement and subsequent awards will be managed and executed by CDMRP with strategic oversight from JPC-8/CRM RP.

The JPC-8/CRM RP is one of six major DHP core research program areas within the DHP DHA RDA Directorate and is administered with oversight from JPC-8, which consists of Department of Defense (DoD) and non-DoD medical and military technical experts relevant to the program area. The JPC-8/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 JPC-8/CRM RP-supported research efforts are expected to improve restorative treatments and rehabilitative care to maximize function for return to duty (RTD) or civilian life. The 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.

B. FY15 JPC-8/CRM RP Extremity Regeneration Focus Areas

The area of interest for the FY15 JPC-8/CRM RP Extremity Regeneration Technology/Therapeutic Development Award (JPC-8/CRM RP ERTTDA) Program Announcement/Funding Opportunity is extremity regeneration to address complex blast and other traumatic injuries to Service members. The proposed research must have a military relevance but is expected to improve both public and military healthcare outcomes. Unprotected extremities are at greatest risk for significant tissue damage and loss and often sustain damage to muscle, nerve, blood vessels, bone, and connective tissues. To meet the intent of the FY15 JPC-8/CRM RP ERTTDA, applicants **must** specifically address one or both of the Focus Areas listed below.

- ***Treatments 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 denervated end organs distal to a nerve injury; (b) restore functional muscle tissue;

and (c) restore vascular perfusion. Both innovative definitive 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.

- ***Treatments for bone healing***, for example, technologies that create a wound environment more conducive to bone healing following injury to the extremities.

C. Award Information

The FY15 JPC-8/CRM RP ERTTDA is intended to support the translation of promising preclinical findings into products 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 products in development should be responsive to the health care needs of military Service members, Veterans, and other Military Health System beneficiaries, as well as the general public. All applications must specifically and clearly address the military relevance of the proposed research.

The product(s) to be developed may be a tangible item such as a pharmacologic agent (drugs or biologics) or device, or a knowledge-based product such as clinical guidance for standard of care. The Principal Investigator (PI) must provide a transition plan (including potential funding and resources) showing how the product will progress to the next level of development (e.g., clinical trials, delivery to the military or civilian market) after the completion of the award.

Proof-of-concept demonstrating the potential utility of the proposed product, or a prototype/preliminary version of the proposed product, should already be established.

Applicants must include relevant data that support the rationale for the proposed study. These data may be unpublished and/or from the published literature.

Examples of the types of research that may be supported include, but are not limited to:

- Developing and validating clinical guidance/guidelines for standard of care
- Testing new therapeutic modalities (agents, delivery systems, and chemical modification of lead compounds) using established or validated preclinical systems
- Designing and implementing pilot or full-scale Good Manufacturing Practice (GMP) production of therapeutics and/or delivery systems for use in advanced preclinical and initial clinical trials
- Developing pharmacologic agents through absorption, distribution, metabolism, excretion, and toxicity (ADMET) studies
- Developing pharmacologic agents to Investigational New Drug (IND) stage for initiation of Phase I clinical trials
- Developing prototype devices to Investigational Device Exemption (IDE) stage for initiation of clinical trials
- Optimizing diagnostic or treatment devices for field deployment

Research involving human subjects and human anatomical substances is permitted; however, ***this award mechanism may not be used to conduct clinical trials.*** A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to ***exploratory information, safety, effectiveness, and/or efficacy.*** This outcome represents a direct effect on the human subject of that intervention or interaction. For more information on how to distinguish clinical research from clinical trials, see the Human Subject Resource Document at <https://ebrap.org/eBRAP/public/Program> PIs seeking funding for a clinical trial should apply to the FY15 JPC-8/CRM RP Extremity Regeneration Intervention Broad Agency Announcement (<https://ebrap.org/eBRAP/public/Program.htm>).

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB 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. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 5, and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

Military Relevance: Relevance to the health care needs of military Service members, Veterans, and other Military Health System beneficiaries is a key feature of this award. Investigators are encouraged to consider the following characteristics as examples of how a project may demonstrate military relevance:

- Addresses an aspect of extremity injuries that has direct relevance to military Service members, Veterans, or other Military Health System beneficiaries
- Use of military or Veteran populations or data in the proposed research
- Knowledge, information, products, or technologies gained from the proposed research could be implemented in a dual-use capacity to address a military need that also benefits the civilian population
- Collaboration with DoD or Department of Veterans Affairs (VA) investigators
- Involvement of military consultants (Army, Air Force) or specialty leaders (Navy, Marine Corps) to the Surgeons General in a relevant specialty area

DoD Collaboration and Alignment Encouraged: Relevance to the health care needs of military Service members, Veterans, and other Military Health System beneficiaries is a key feature of this award. Therefore, PIs are strongly encouraged to collaborate, integrate, and/or align their research projects with military and/or VA research laboratories and programs. The

following websites may be useful in identifying information about ongoing DoD areas of research interest:

Air Force Research Laboratory	http://www.wpafb.af.mil/	National Museum of Health and Medicine	http://www.medicalmuseum.mil/index.cfm
Armed Forces Institute of Regenerative Medicine	http://www.afirm.mil	Naval Health Research Center	http://www.med.navy.mil/sites/nhrc
Center for Neuroscience and Regenerative Medicine	http://www.usuhs.mil/cnrm/	Navy and Marine Corps Public Health Center	http://www.med.navy.mil/sites/nmcpbc
Clinical and Rehabilitative Medicine Research Program	https://crmrp.amedd.army.mil	Office of Naval Research	http://www.med.navy.mil
Combat Casualty Care Research Program	https://ccc.amedd.army.mil	Office of the Under Secretary of Defense for Acquisition, Technology and Logistics	http://www.darpa.mil/dmrd/
Congressionally Directed Medical Research Programs	http://cdmrp.army.mil	U.S. Army Medical Research Acquisition Activity	https://www.usamraa.army.mil/
Defense Advanced Research Projects Agency	http://www.darpa.mil/dmrd/	U.S. Army Medical Research and Materiel Command	https://mrmc.amedd.army.mil
Defense Medical Research and Development Programs	http://cdmrp.army.mil/dmrdp/default	U.S. Army Research Laboratory	http://t2health.org/
Defense Technical Information Center	http://www.dtic.mil	U.S. Department of Defense Blast Injury Research Program	https://blastinjuryresearch.amedd.army.mil/
Military Infectious Diseases Research Program	https://midrp.amedd.army.mil	U.S. Naval Research Laboratory	https://www.nrl.navy.mil
Military Operational Medicine Research Program	https://mormc.amedd.army.mil	U.S. Department of Veterans Affairs, Office of Research and Development	http://www.research.va.gov
National Center for Telehealth and Technology	http://www.araa.army.mil	Walter Reed Army Institute of Research	http://wrair-www.army.mil

Use of Military and VA Populations: If the proposed research involves access to military and/or VA population(s) and/or resource(s), the PI is responsible for establishing access. If possible, access to target military and/or VA patient population(s) should be confirmed at the time of application submission. A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving military Service members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases. Use Attachment 2 to provide this documentation (see [Section II.C., Full Application Submission Content, Attachment 2, Supporting Documentation](#)). If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until

the PI has demonstrated support for and access to the relevant population(s) and/or resources. Note that access to a Veteran population for clinical studies may only be obtained by (1) collaboration with a VA investigator where the VA investigator has a substantial role in the research or (2) advertising to the general public.

Reporting Guidelines: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical/animal studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies and should be applied to those projects as well.

Research Involving Animals: Projects that include research on animal models are required to submit Attachment 8, Animal Research Plan, as part of the application package. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at http://www.elsevier.com/_data/promis_misc/622936arrive_guidelines.pdf.

All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. The ACURO must review and approve all animal use prior to the start of working with animals. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” ***Allow at least 3 to 4 months for regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 5, for additional information.

The CRM RP and CDMRP intend that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 3, Section L.

D. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, nonprofit, public, and private organizations.

- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **3** years.
- The anticipated total costs (direct plus indirect) budgeted for the entire period of performance will not exceed **\$2,100,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$2,100,000** total costs or using an indirect rate exceeding the organization's negotiated rate.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

Refer to the General Application 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 Application Instructions.***

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

- Travel costs for the PI(s) to disseminate project results at one DoD JPC-8/CRM RP In Progress Review meeting. For planning purposes, it should be assumed that the 2-day meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary of non-Governmental personnel (includes contract research personnel at Government facilities)
- Research supplies
- Equipment
- Research-related subject costs (clinical trials are NOT allowed)
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs to attend scientific/technical meetings in addition to the required meeting described above

Shall not be requested for:

- Clinical trial costs

Intramural (DoD), other Federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. 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. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. ***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.***

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from Federal agencies submit applications, they must submit through Grants.gov. Therefore, Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Section II.A. of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards 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 Application Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

The JPC-8/CRM RP expects to allot approximately \$6.3M of the FY15/16 DHP RDT&E appropriation to fund approximately three Extremity Regeneration Technology/Therapeutic Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities in different programs or funding agencies is allowed, however, it must be noted in the application under PI Previous/Current/Pending Support (see [Section II.C.3, Research & Related Senior/Key Person Profile](#)). Failure to provide notification will result in administrative withdrawal of the duplicative application. NOTE: Funding can only be accepted from one funding source for the same proposal.

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>). Refer to the General Application Instructions, Section II.A. for registration and submission requirements for eBRAP and Grants.gov.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the full application submitted to Grants.gov must match those named in the pre-application in eBRAP.

A. Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-15-DMRDP-CRMRP-ERTTDA in Grants.gov (<http://www.grants.gov/>).

B. Pre-Application Submission Content

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>).

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

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

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
 - Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF-424 Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
 - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Collaborators and Key Personnel – Tab 3**
 - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
 - [FY15 JPC-8 Regenerative Medicine Working Group](#) members should not be involved in any pre-application or application. For questions related to the [JPC-8 Regenerative Medicine Working Group](#) members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.
- **Conflicts of Interest (COIs) – Tab 4**
 - List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship).
- **Pre-Application Files – Tab 5**
 - **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the FY15 JPC-8/CRM RP Extremity Regeneration Focus Area 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 sessions.
- **Submit Pre-Application – Tab 6**
 - This tab must be completed for the pre-application to be accepted and processed.

C. Full Application Submission Content

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

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

Note: The Project Narrative and Budget Form cannot be changed after the 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*.

Grants.gov application package components: For the FY15 JPC-8/CRM RP ERTTDA , the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF-424 (R&R) Application for Federal Assistance Form:** Refer to the General Application 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 Application 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 (15-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 may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background:** Describe the product (materiel or knowledge-based) to be developed and its proposed indication. State the relevance of the proposed product development plan to at least one of the FY15 JPC-8/CRM RP ERTTDA Focus Areas and explain the applicability of the proposed findings to improving clinical outcomes for individuals recovering from extremity injury. Present the ideas and scientific rationale behind the proposed research project, and clearly demonstrate that there is sufficient evidence to support the proposed stage of research. Cite relevant literature. Describe previous experience most pertinent to this project. Include relevant preliminary data that support proof-of-concept of the product or a prototype/preliminary version of the project (these data may be unpublished or from the published literature).
- **Hypothesis/Objective:** State the hypothesis to be tested and/or the objective(s) to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims. These aims should agree with the primary aims and associated tasks described in the Statement of Work. If the proposed research project is part of a larger study, present only aims that would be funded under the FY15 JPC-8/CRM RP ERTTDA.
- **Research Strategy:**
 - Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis of appropriateness and feasibility.
 - Provide a well-developed, well-integrated research strategy that supports the translational feasibility and promise of the approach.

- Define the specific study outcomes and how they will be measured. Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis, if applicable.
- Address potential problem areas and present alternative methods and approaches.
- If animal studies are proposed, briefly describe the key elements of the study/studies as they relate to the overall project; detailed information is required in Attachment 8, Animal Research Plan.
- If human subjects or human anatomical substances will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Specify the approximate number of human subjects to be enrolled. If multiple study sites are to be involved, state the approximate number to be enrolled at each site. Demonstrate that the sample size is appropriate and sufficient to meet the objectives of the study. Describe the availability of the proposed study population and past successes in recruiting similar populations. ***Clinical trials are not allowed under the FY15 JPC-8/CRM RP ERTTDA.***
- **Military Benefit:** Describe how the proposed work would impact the health care needs of military Service members, Veterans, and other Military Health System beneficiaries recovering from traumatic extremity injury.
- **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; inclusion of items not requested will result in the removal of those items or may result in administrative withdrawal of the application.***
 - **References Cited:** List the references cited (including URLs if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
 - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
 - **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
 - **Publications and/or Patent Abstracts:** Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then

copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration: Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Letters of Commitment (if applicable): If the proposed study involves use of a commercially produced investigational drug, device, or biologic, provide a letter of commitment from the commercial entity indicating the availability of the project for the duration of the study, support for the proposed phase of research, and support for the indication being tested.
- Letters Confirming Access to Military or VA Patient Populations or Resources (if applicable): If the proposed research plan involves access to active duty military and/or VA patient populations or resources, include a letter of support, signed by the lowest ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.
- Intellectual Property
 - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license. 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.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 3, Section L for more information about the CDMRP expectations for making data and research resources publicly available.
- **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.

Technical abstracts should be written using the outline below. *Abstracts of all funded applications may be posted online; therefore, proprietary information should not be included in the abstracts.*

- **Background:** Describe the product to be developed and its proposed indication. Present the ideas and scientific rationale behind the proposed research project, including sufficient scientific evidence to support the proposed stage of research.
- **Hypothesis/Objective:** State the hypothesis/objective to be tested. Provide evidence or rationale that supports the hypothesis/objective.
- **Specific Aims/Study Design:** State the specific aims of the proposed research project, and briefly describe the study design, including appropriate controls.
- **Impact:** State the short-term and long-term impact of the proposed product development plan on individuals recovering from extremity injury, including the impact on at least one of the FY15 JPC-8/CRM RP ERTTDA Focus Areas.
- **Military Relevance:** Briefly explain how the proposed project will have an immediate or potential long-term benefit for the health care needs of military Service members, Veterans, and other Military Health System beneficiaries recovering from traumatic extremity injury.
- **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.

Lay abstracts should be written using the outline below. *Abstracts of all funded applications may be posted online; therefore, proprietary information should not be included in the abstracts.*

- Describe the objectives and rationale for the application in a manner that will be readily understood by readers without a background in science or medicine.
 - Do not duplicate the technical abstract.
- 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) (three-page limit): Upload as “SOW.pdf.”** The suggested SOW format and examples specific to different types

of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the ERTTDA mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.3., for detailed guidance on creating the SOW.

- **Attachment 6: Impact and Military Relevance Statement (two-page limit): Upload as “ImpactMilRel.pdf.”** Address the impact of the proposed research on one or more of the FY15 JPC-8/CRM RP ERTTDA Focus Areas.

Describe the short-term impact: Describe the anticipated outcome(s)/product(s) (intellectual and/or material) that will be directly attributed to the results of the proposed research.

Describe the long-term impact: Describe the anticipated long-term clinical/patient gains or commercial end product from the proposed project. Compare to the information known/products currently available, if applicable. Describe the indication and discuss whether the project will lead toward transforming the standard of care. Describe any non-trauma-related indications that would expand the market for the proposed product.

Military Relevance: Describe how the proposed study is responsive to the health care needs of military Service members, Veterans, and other Military Health System beneficiaries recovering from traumatic extremity injury. Provide information about the incidence and/or prevalence of extremity injuries in military Service members, Veterans, and other Military Health System beneficiaries. If active duty military, military families, and/or Veteran population(s) or datasets will be used in the proposed research project, describe the population(s)/dataset(s), the appropriateness of the population(s)/dataset(s) for the proposed study, and the feasibility of accessing the population(s)/dataset(s). If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., military Service members, Veterans, and/or beneficiaries).

- **Attachment 7: Transition Plan (one-page limit): Upload as “Transition.pdf.”**

Provide information on the methods and strategies proposed to move the product or knowledge outcomes to the next phase of development (e.g., clinical trials, commercialization, and/or delivery to the military or civilian market) after successful completion of the award. Applicants are encouraged to work with their organization’s Technology Transfer Officer to develop the transition plan. The transition plan should include the components listed below.

- The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication.
- The anticipated regulatory strategy (e.g., additional nonclinical or clinical studies anticipated/required, U.S. Food and Drug Administration (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).

- 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).
- For knowledge outcomes a description of how the knowledge will be further developed, disseminated, and incorporated into clinical care.
- A description of collaborations and other resources that will be used to provide continuity of development.
- A brief schedule and milestones for bringing the outcome(s) to the next phase of development, 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.
- A risk analysis for cost, schedule, manufacturability, and sustainability.
- If applicable, ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the Government's ability to access such products or technologies in the future.
- Commercialization strategy
 - Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team.
 - Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- **Attachment 8: Animal Research Plan (if applicable; required if the proposed research involves animals, five-page limit): Upload as "AnimalPlan.pdf."**

When the study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the Institutional Animal Care and Use Committee (IACUC) as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:

- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.
- Summarize the procedures to be conducted. Describe how the study will be controlled.

- Describe the randomization and blinding procedures for the study and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
 - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
 - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
- **Attachment 9: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility (Military Health System facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form (available for download on the eBRAP “Funding Opportunities & Forms” web page), including a budget justification, for each Military Facility as instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application 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 (no page limit): Upload as “Support_LastName.pdf.”
 - Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch_LastName.pdf.”
 - Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- 4. Research & Related Budget:** Refer to the General Application 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.
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.6., for detailed information.

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

D. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an 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 Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. *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 application submission deadline.* The Project Narrative and Budget Form cannot be changed after the application submission deadline.

E. Submission Dates and Times

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

F. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of 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 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 a nondisclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review Process

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

- **Research Strategy and Feasibility**

- How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, supporting data, and logical reasoning.
- To what extent the outcomes will support the translation of promising preclinical findings into a product for clinical application.
- How well the hypothesis or objective(s) and specific aims are developed.
- How well the experimental design, methods, data collection procedures, and analyses are developed and support completion of the aims.
- The degree to which the expected outcomes are specific and measurable.
- If applicable, to what degree the statistical plan and power analysis are appropriate for the proposed project.
- How well the application acknowledges potential problems and addresses alternative approaches.
- If applicable, the degree to which the plan to study patient populations is appropriate and feasible and whether the application provides evidence of availability of and access to the necessary study population(s) and/or resource(s).
- Whether the research can be completed within the proposed period of performance.

For applications involving animal research:

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

- How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.
- **Impact/Military Benefit**
 - To what extent the project impacts a central critical problem or question in at least one of the FY15 JPC-8/CRM RP ERTTDA Focus Areas.
 - How the proposed research project, if successful, will make important scientific advances in traumatic extremity regeneration research.
 - To what degree the proposed project could, if successful, make a significant impact on the lives of individuals recovering from traumatic extremity injury in the short term or long term.
 - How relevant the anticipated outcomes of the proposed research are to military Service members, Veterans, and other Military Health System beneficiaries, as well as the general public, recovering from traumatic extremity injury.
- **Transition Plan**
 - Whether the funding strategy described to bring the outcome(s) to the next level of development (e.g., clinical trial, transition to industry, delivery to the market, progression toward incorporation into standard practice) is appropriate.
 - How well the development plan to support a product label change, if applicable, is appropriate and well described.
 - To what extent the collaborations and other resources (established or planned) described are appropriate and will provide continuity of development.
 - How the schedule and milestones for bringing the outcome(s) to the next level of development (e.g., clinical trial, transition to industry, delivery to the market, progression toward incorporation into standard practice) are appropriate and feasible.
 - How well the potential risk analysis for cost, schedule, manufacturability, and sustainability is developed.
 - How well the application identifies intellectual property plan ownership, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent Government access to products supported by this Program Announcement/ Funding Opportunity.
- **Statistical Plan**
 - If applicable, to what degree the statistical plan and power analysis are appropriate for the proposed project.
 - How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.

- **Personnel**

- How the background and expertise of the PI and other key personnel demonstrate their ability to perform the proposed work.
- How the levels of effort by the PI and other key personnel are appropriate to ensure the successful conduct of the project.

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

- **Environment**

- How the scientific environment is appropriate for the proposed research.
- How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
- How the quality and extent of organizational support are appropriate for the proposed research.

- **Budget**

- Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- **Application Presentation**

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

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

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
- Relative impact and military relevance
- Program portfolio balance

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D. Application Review Dates

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

E. Notification of Application 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 application.

IV. ADMINISTRATIVE ACTIONS

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

A. Rejection

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

- Letter of Intent exceeds page limit.
- Letter of Intent is missing.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.

B. Modification

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

C. Withdrawal

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

- A [FY15 JPC-8 Regenerative Medicine Working Group](#) member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. **A list of the FY15 JPC-8 Regenerative Medicine Working Group members can be found at <http://cdmrp.army.mil/dmrpd/panels/RMpanel15>.**
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., 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.
- Preliminary data are not included.
- If a clinical trial is proposed, the application will be withdrawn.
- An application submitted by a PI who does not meet the eligibility criteria will be withdrawn.
- If the application does not address at least one of the ERTTDA focus areas, the application will be withdrawn.

D. Withhold

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

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2016. Refer to the General Application Instructions, Appendix 3, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

B. Administrative Requirements

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

C. National Policy Requirements

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

D. Reporting

Refer to the General Application Instructions, Appendix 3, Section I, 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.

E. Award Transfers

Refer to the General Application Instructions, Appendix 3, Section M, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the 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. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

B. Grants.gov Contact Center

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

Phone: 800-518-4726

Email: support@grants.gov

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

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Completed
SF-424 (R&R) Application for Federal Assistance		Complete form 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	Impact and Military Benefit Statement: Upload as Attachment 6 with file name "ImpactMilBen.pdf."	
	7	Transition Plan: Upload as Attachment 7 with file name "Transition.pdf."	
	8	Animal Research Plan: Upload as Attachment 8 with file name "AnimalPlan.pdf."	
	9	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 9 with 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		Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form		Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.	