

Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Defense Medical Research and Development Program

Joint Program Committee 6

Combat Casualty Care Research Program

Precision Trauma Care Research Award

Funding Opportunity Number: W81XWH-18-DMRDP-PTCRA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), March 17, 2017
- **Invitation to Submit an Application:** April 25, 2017
- **Application Submission Deadline:** 11:59 p.m. ET, June 15, 2017
- **End of Application Verification Period:** 5:00 p.m. ET, June 20, 2017
- **Peer Review:** August 2017
- **Programmatic Review:** September 2017

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.

TABLE OF CONTENTS

I. Funding Opportunity Description.....	3
A. Program Description	3
B. Award Information.....	3
C. FY18 DMRDP JPC-6/CCCRP PTCRA Focus Areas.....	4
D. Eligibility Information	10
E. Funding	10
II. Submission Information	12
A. Where to Obtain the Grants.gov Application Package	13
B. Pre-Application Submission Content.....	13
C. Full Application Submission Content.....	16
D. Applicant Verification of Grants.gov Submission in eBRAP	29
E. Submission Dates and Times	30
F. Other Submission Requirements.....	30
III. Application Review Information	30
A. Application Review and Selection Process.....	30
B. Application Review Process	31
C. Recipient Qualification	34
D. Application Review Dates	34
E. Notification of Application Review Results	34
IV. Administrative Actions.....	34
A. Rejection	34
B. Modification.....	35
C. Withdrawal.....	35
D. Withhold	36
V. Award Administration Information.....	36
A. Award Notice	36
B. Administrative Requirements	36
C. National Policy Requirements	36
D. Reporting.....	36
E. Award Transfers.....	36
VI. Version Codes and Agency Contacts.....	37
A. Program Announcement/Funding Opportunity and General Application Instructions Version.....	37
B. CDMRP Help Desk.....	37
C. Grants.gov Contact Center.....	37
VII. Application Submission Checklist.....	38

I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2018 (FY18) Joint Program Committee 6/Combat Casualty Care Research Program (JPC-6/CCCRP) are being solicited for the Defense Health Agency (DHA), Research and Development Directorate, by the US Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). The US Army Medical Research and Materiel Command (USAMRMC) CDMRP provides Defense Medical Research and Development Program (DMRDP) execution management support for DHP core research program areas, including the JPC-6/CCCRP. This Program Announcement/Funding Opportunity and subsequent awards will be managed and executed by CDMRP with strategic oversight from the JPC-6/CCCRP.

The JPC-6/CCCRP is one of six major research program areas within the DHP. The JPC-6/CCCRP is a committee of Department of Defense (DoD) and non-DoD medical and military technical experts in combat casualty care-related program areas. The JPC-6/CCCRP strives to optimize survival and recovery from combat-related or trauma-induced injury in current and future operational scenarios. This is being accomplished through the development of knowledge and materiel products for the acute and early management of combat-related or trauma-induced injury, including point-of-injury, en route, and forward surgical care. Innovations developed by JPC-6/CCCRP-supported research are applied in-theatre and within the clinical facilities of the Military Health System. These solutions not only minimize the morbidity and mortality of combat-related injuries in Service members, they also are often translatable to the civilian healthcare system.

B. Award Information

In support of the Precision Medicine Initiative¹, the OASD(HA) identified “precision medicine” as a top science and technical priority for the FY17 DHP RDT&E funds (this is also applicable to FY18 DHP RDT&E funds) and directed DHA to increase the use of “big data” and interdisciplinary approaches, establish a fundamental understanding of military disease and injury, and advance health status assessment, diagnosis, and treatment tailored to individual Service members and beneficiaries. For this Program Announcement/Funding Opportunity, precision medicine is defined as “an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person.”² Precision medicine pioneers a new model of patient-powered research that aims to accelerate biomedical discoveries and provide clinicians with new tools, knowledge, and approaches to select more accurate treatment and prevention strategies that will work best for individual patients.

¹<https://www.whitehouse.gov/precision-medicine>

²<https://ghr.nlm.nih.gov/primer/precisionmedicine/definition>

The intent of the Precision Trauma Care Research Award (PTCRA) is to support research applying precision medicine concepts to trauma care. In order to improve the care of combat casualties, the JPC-6/CCCRP requires capabilities to more accurately diagnose and treat injuries. In general, the field of trauma care progresses as empirical evidence accumulates. Accumulated evidence supports the reduction of unwarranted practice variability (e.g., protocol-driven care). Reduction in practice variability leads to refinement of protocols through improved diagnostic and prognostic indicators that account for patient-specific variables such as injury pattern, comorbidities, demographics, and morphometric data. These approaches are further refined by incorporation of near-term patient-specific variables such as injury progression, response to interventions, and theranostic indicators. The result is a precision medicine approach for trauma care that drives application of interventions to improve outcomes following trauma.

The JPC-6/CCCRP seeks to develop precision medicine approaches for trauma care in the most challenging of environments, including point-of-injury care on the battlefield, deployed healthcare facilities such as casualty collection points, forward surgical teams, and combat support hospitals. This challenge of diverse combat environments and medical capabilities also requires research to develop new solutions to include support for medical providers in the assessment, diagnosis, and treatment of military trauma in out-of-hospital settings (point of injury, austere environment, or en route care) with limited resources through Role 4.³ Proposed research should consider the entire continuum of trauma care and must be focused on enabling patient-specific interventions and improved outcomes rather than “one size fits all” population-based tools and techniques.

C. FY18 DMRDP JPC-6/CCCRP PTCRA Focus Areas

The JPC-6/CCCRP has identified four overarching Focus Areas for funding under this Program Announcement/Funding Opportunity. To meet the intent of the award mechanism, applications MUST propose research that specifically addresses at least one of the four FY18 JPC-6/CCCRP PTCRA Focus Areas. Research not aligned to at least one of these Focus Areas will not be considered for funding.

Neurotrauma

For studies proposing animal research, only proposals collecting data from gyrencephalic animal models of traumatic brain injury (TBI) will be considered for funding.

Focus Area 1: Improving the Characterization of TBI

- Identification and/or characterization of TBI biomarkers that are specific to TBI alone and/or TBI with concomitant injuries (e.g., burn, hemorrhage) and identification of biomarker profile specific to TBI pathology and treatment effectiveness
- Development of targeted therapies, devices, or clinical guidelines to improve diagnosis/stabilization/treatment of TBI casualties with and without concomitant polytrauma based upon the precise characterization and individualized assessment of affected domains

³See <http://www.cs.amedd.army.mil/FileDownloadpublic.aspx?docid=1a73495d-1176-4638-9011-9e7f3c6017d8> for a description of DoD roles of medical care.

- Improve TBI treatment decision capabilities based upon the precise characterization and individualized assessment of TBI pathology (e.g., contusion, diffuse axonal injury, subdural hematoma, epidural hematoma)
- Improve the understanding of risk factors and outcomes associated with specific brain pathology (e.g., contusions, diffuse axonal injury, hematomas) with the end state goal of improving prognosis and optimizing recovery
- Improve the understanding of the role of genetic factors and/or physiology status on short- and long-term consequences of combat-related TBI

Focus Area 2: Understanding the factors that influence and/or inform patient responsiveness to TBI therapeutic interventions

- Pharmacodynamic characterization of therapeutics with respect to patients responsive to treatment
- Targeting therapeutics to the blood-brain barrier in response to specific brain injuries (e.g., contusions, diffuse axonal injury, subdural hematoma, epidural hematoma)
- Understanding the impact of sex-associated differences on the efficacy of TBI treatments
- Understanding the potential role of genetics and sex-associated differences in TBI treatment decisions and TBI treatment response
- Identification of biomarkers of TBI that inform treatment effectiveness and stage of recovery
- Identify the impact of environmental factors (such as altitude, vibration, and/or temperature) that negatively affect TBI outcomes. Identify potential treatments and/or interventions to mitigate these effects

Forward Surgical, En Route, and Critical Care

Focus Area 3: Understanding the role of environmental and physiological factors impacting injury outcomes:

- Environmental, physiological, and physical factors that govern an individual's predisposition to various responses to trauma
- Physiological, genetic, or physical factors that govern the individual's response to blood loss (ability to compensate for blood loss)
- Impact of vascular disruption, repair, extremity ischemia and reperfusion, and its relationship to long-term limb recovery and function
- Determination of more effective and efficient ways to diagnose and manage vascular disruption (with or without hemorrhagic shock) in forward surgical and limited-resource critical care environments

Focus Area 4: Developing materiel and knowledge products to assist medical and non-medical care providers in administering individualized combat-related or trauma-induced injury care such as:

- Standardized, clinically relevant decision support model for severely mangled extremities (i.e., decisions regarding primary amputation vs. pursuit of limb salvage, optimal amputation level to support future treatment (i.e., transplant, prosthetic, etc.)
- Computational algorithms and predictive tools for physiological status monitoring that use available information and can predict necessary statuses in an expedient manner
- Evidence-based clinical decision support tools/protocols for the prehospital environment and throughout the continuum of care to include en route care (patient medical transport) and timing of transport (particularly for strategic air movement) for post-surgical patients
- Non-invasive physiological monitoring for compartment syndrome
- Innovative patient-centered technologies to maintain physiological equilibrium (homeostasis) such as dynamically responsive closed-loop technologies for oxygenation, core temperature maintenance, and medication delivery in the prehospital environment and throughout the continuum of care, to include en route care (patient medical transport)

For this Program Announcement/Funding Opportunity, a knowledge product is defined as a non-materiel product that addresses an identified need, research area, or capability gap in the continuum of trauma care. Knowledge products provide information, awareness, and procedures to support clinical practice, training recommendations, and the application of existing materiel products (e.g., drugs, medical devices, equipment).

This Program Announcement/Funding Opportunity may support preclinical research, clinical research, and early clinical trials/testing. 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 safety, effectiveness, efficacy, and/or exploratory information. This outcome represents a direct effect on the human subject of that intervention or interaction. For further definitions, categories, and resource information for human subject research, see the Human Subject Resource Document available on the eBRAP “Funding Opportunities and Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). ***Phase II and Phase III clinical trials for US Food and Drug Administration (FDA) licensure of drugs and definitive/pivotal testing for device clearance by the FDA will NOT be permitted under this Program Announcement/Funding Opportunity.***

Research Involving an FDA-Regulated Drug, Biologic, or Device: If the study proposed involves the use of a drug or biologic that has not been approved by the FDA for the proposed investigational use, evidence that an Investigational New Drug (IND) exemption application that meets all requirements under the Code of Federal Regulations, Title 21, Part 312 (21 CFR 312) ***has been submitted or will be submitted to the FDA within 60 days of award*** is required. If the investigational product is a device, evidence that an Investigational Device Exemption (IDE) application that meets all requirements under 21 CFR 812 has been reviewed and approved by

the FDA *has been submitted or will be submitted to the FDA within 60 days of award* is required. The Government reserves the right to withdraw funding if the IND or IDE application has not been submitted to the FDA within 60 days of the DoD award date or if the documented application status of the IND or IDE has not been obtained within 12 months of the award date.

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 USAMRMC Office of Research Protections (ORP), Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 6, 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.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. Principal Investigators (PIs) must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” ***Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 6, for additional information.

Rigor of Experimental Design: All projects should adhere to accepted standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. Core standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards were written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in research and should be applied consistently across basic and translational studies. Projects that include research on animal models are required to submit [Attachment 8, Animal Research Plan](#), as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at https://www.elsevier.com/_data/promis_misc/622936arrive_guidelines.pdf.

Military Relevance: Although the research outcomes are expected to benefit both the military and the general public, relevance to the healthcare needs of military Service members and other beneficiaries is a key requirement of this award. Investigators are encouraged to consider the following characteristics as examples of how a project may demonstrate relevance to the mission of the DHP, JPC-6/CCCRP, and the military:

- Explanation of how the project has direct relevance to DoD healthcare personnel, recipients, and other beneficiaries
- Use of military populations or data in the proposed research
- Collaboration with DoD investigators
- Involvement of military consultants (Army, Air Force) or specialty leaders (Navy, Marine Corps) to the Surgeons General in a relevant specialty area

Principal Investigators are encouraged to integrate and/or align their research projects with DoD and/or Department of Veterans Affairs (VA) research laboratories and programs. Collaboration with DoD or VA investigators is also encouraged. The following websites may be useful in identifying information about ongoing DoD and VA areas of research interest:

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

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

Center for Neuroscience and Regenerative
Medicine
<http://www.usuhs.mil/cnrm/>

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

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

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

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

Defense Medical Research and
Development Program
<http://cdmrp.army.mil/dmrdp/default>

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

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

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

National Center for Telehealth and
Technology
<http://t2health.org/>

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

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

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

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

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

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

US Army Medical Research and Materiel
Command

<https://mrmc.amedd.army.mil>

US Army Research Laboratory

<http://www.arl.army.mil>

US Department of Defense Blast Injury
Research Program

<https://blastinjuryresearch.amedd.army.mil/>

US Naval Research Laboratory

<https://www.nrl.navy.mil>

US Department of Veterans Affairs, Office
of Research and Development

<http://www.research.va.gov>

Walter Reed Army Institute of Research

<http://www.wrair.army.mil>

Use of Military and VA Populations or Resources: If the proposed research involves access to military and/or VA population(s) and/or resource(s), the PI is responsible for establishing access. 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.

Federal Interagency TBI Research (FITBIR) Informatics System: For studies that will enroll TBI subjects, the DoD requires that the awardees make data available to the TBI research community by depositing de-identified research data into the FITBIR Informatics System on a quarterly basis. The FITBIR Informatics System is a free resource to the TBI community designed to accelerate comparative effectiveness research on brain injury diagnosis and treatment. Data reporting to FITBIR is an opportunity for investigators to facilitate their own research and collaborate with others performing similar research. While use of the informatics system presents no direct cost to the user, a *project estimation tool* (<https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp>) is available to help estimate indirect cost and manpower needs associated with data submission.

- In order to facilitate FITBIR compliance, it is recommended that investigators contact the FITBIR Operations Center (FITBIR-ops@mail.nih.gov) during the application development phase to discuss submission requirements and potential IRB submission modifications.
- All reasonable efforts should be made to ensure that data elements are reported using the National Institute of Neurological Disorders and Stroke (NINDS) TBI Common Data Elements (CDEs), which are housed within the FITBIR data dictionary (<https://fitbir.nih.gov/content/data-dictionary>). Use of these TBI CDEs, as published, is required to facilitate data sharing and collaboration through the usage of standard definitions across studies. *If the proposed research data cannot be entered in CDE format, the investigators must supply a proposal for an alternative data submission or data sharing vehicle and justification for its use.* FITBIR Operations can provide

assistance in mapping study variables to specific CDEs. If necessary, FITBIR Operations will work with researchers to create new, unique data elements when suitable data elements are not available in the FITBIR data dictionary.

Additional information, including the advantages of FITBIR use to the researcher, is detailed at the FITBIR website (<http://fitbir.nih.gov/>).

The JPC-6/CCCRP and CDMRP intends 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 4, Section K.

D. Eligibility Information

This Program Announcement/Funding Opportunity is intended for extramural investigators only. Intramural investigators are required to apply to the FY18 JPC-6/CCCRP Precision Trauma Care Research Award Intramural Program Announcement/Funding Opportunity through eBRAP at <https://eBRAP.org/eBRAP/public/Program.htm>.

- 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 non-DoD Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- 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. ***If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement. Use Attachment 2 to provide this documentation (see [Section II.C., Full Application Submission Content, Attachment 2, Supporting Documentation](#)).***
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

Research supported under this Program Announcement/Funding Opportunity will be funded in three phases, Phase 1 Base, Phase 2 Option.I, and Phase 3 Option.II. Each Phase must be a distinct research effort with a non-overlapping period of performance, research outcomes/milestones, and budget. Research products from a previous Phase shall be leveraged in subsequent Phase(s) if planned. However, proposal of subsequent Option Phases is not required.

- Each Phase has a maximum period of performance of **12 months**. The maximum period of performance for all Phases is **36 months**.
- Transition from Phase 1 to subsequent Phase(s) will be based on the following criteria:
 - Completion of the research within the 12-month period of performance
 - Documented progress in making data available to the research community
 - Timely submission of quarterly and annual progress reports and quad charts
 - Availability of funds
 - Presentation of research at a minimum of one national research or military relevant conference (for Phase 2 to Phase 3 transition)
 - One or more documented publication submissions (for Phase 2 to Phase 3 transition)
- The anticipated total costs (direct and indirect) budgeted for each Phase will not exceed **\$1.5 million (M)**. The maximum anticipated total costs (direct and indirect) for all Phases are **\$4.5M**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding the total cost limitations or using an indirect rate exceeding the organization's negotiated rate.
- All direct and indirect costs of any subaward must be included in the total direct costs of the primary award.

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

- Travel costs for the PI(s) to disseminate project results at one DoD-related meeting to be determined at the discretion of the Government during the award performance period. Costs associated with travel to this meeting should be included in the budget. 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
- Research-related subject costs
- Clinical research costs
- Equipment
- Research supplies
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs for up to four investigators to travel to one scientific/technical meeting per year in addition to the required meeting described above

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Subawards to intramural (DoD) agencies and other Federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or DD Form 1144 Support Agreement. Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.***

The JPC-6/CCCRP expects to allot approximately \$9.5M of the FY18, \$9.5M of the FY19, and \$10.2M of the FY20 DHP RDT&E appropriations to fund approximately six (6) intramural and extramural FY18 JPC-6/CCCRP Precision Trauma Care Research 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. As of the release date of this Program Announcement/Funding Opportunity, the FY18, FY19, or FY20 Defense Appropriations Bills have not been passed and there is no guarantee that any funds will be made available to support this program. The funding estimated for this Program Announcement/Funding Opportunity is approximate and subject to realignment.

NOTE: Applications received under this mechanism will compete with applications received under the FY18 JPC-6/CCCRP Precision Trauma Care Research Award Intramural Program Announcement/Funding Opportunity found at <https://ebrap.org/eBRAP/public/Program.htm>.

II. SUBMISSION INFORMATION

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.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. 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 Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

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.

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

Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the [application verification period](#). After the end of the application verification period, the full application cannot be modified.

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-18-DMRDP-PTCRA in Grants.gov (<http://www.grants.gov/>).

B. Pre-Application Submission Content

The pre-application process should be started early to avoid missing deadlines. There are no grace periods. During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the application process on Grants.gov.

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

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

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

- **Tab 1 – Application Information**
- **Tab 2 – Application Contacts**
 - Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
 - Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on “*Add Organizations to this Pre-application.*” The organization(s) must either be selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.
- **Tab 3 – Collaborators and Key Personnel**
 - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
 - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
 - FY18 JPC-6/CCCRP Precision Trauma Care Research Award Programmatic Panel 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 FY18 JPC-6/CCCRP Precision Trauma Care Research Award Programmatic Panel members can be found at http://cdmrp.army.mil/dmrdp/panels/18jpc_6. For questions related to Panel 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.
 - To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in application preparation, research, or other duties for submitted applications. The identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.
- **Tab 4 – Conflicts of Interest**
 - List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or

professional relationship). Refer to Appendix 1, Section C, of the General Application Instructions for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

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

Preproposal Narrative (2-page limit): The Preproposal Narrative page limit 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 Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should include the following:

- **Research Plan:** Concisely state the ideas and reasoning on which the proposed work is based. State the project’s hypotheses, objectives, and specific aims, and briefly describe the experimental approach. Organize the research plan according to the Phase 1 Base, Phase 2 Option.I, and Phase 3 Option.II periods, as applicable. Each Phase should be a distinct research effort with a non-overlapping period of performance and research outcomes/milestones.
- **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the described research project.
- **Impact and Military Benefit:** State explicitly how the proposed work will impact the development of precision medicine approaches for trauma care. Describe how the proposed work will directly or indirectly benefit military Service members and other beneficiaries.
- **Alignment with Focus Areas:** Identify and explain how the proposed work aligns with the intent of the PTCRA and addresses at least one of the [FY18 JPC-6/CCCRP PTCRA Focus Areas](#).

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* and are limited to:

- **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, 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 used in the Preproposal Narrative.
- **Key Personnel Biographical Sketches (six-page limit per individual).** *All biographical sketches should be uploaded as a single combined file.* Biographical

sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- Quad Chart: Complete the Quad Chart template, a one-page PowerPoint file that must be downloaded from the CDMRP eBRAP System at <https://ebrap.org/eBRAP/public/Program.htm>, and save, using Adobe Acrobat Reader, as a PDF file.

- **Tab 6 – Submit Pre-Application**

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

Pre-Application Screening

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the JPC-6/CCCRP, pre-applications will be screened based on the following criteria:

- **Research Plan:** How well the rationale, hypotheses, objectives, specific aims, experimental design, and proposed research Phase(s) support the research idea.
- **Personnel:** To what extent the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed research project.
- **Impact and Military Benefit:** If successful, to what extent the study could impact the development of precision medicine approaches and improve trauma patient care. How well the proposed study will directly or indirectly benefit military Service members and other beneficiaries.
- **Alignment with Focus Areas:** How well the projects address at least one of the [FY18 JPC-6/CCCRP PTCRA Focus Areas](#).

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

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

C. Full Application Submission Content

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of the applicant's organization's Entity registration in the SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the General Application Instructions, Section II, for additional information.

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

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. See Section II.C. of the General Application Instructions for details on compatible Adobe software.

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 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*.

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

Grants.gov application package components: For the FY18 JPC-6/CCCRP Precision Trauma Care Research Award, 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. SF424 (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 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 project. The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or study hypotheses. Establish the relevance and applicability of the proposed study and findings to the intent of the mechanism and at least one of the FY18 JPC-6/CCCRP PTCRA Focus Areas.
- **Objectives/Specific Aims/Hypothesis:** Provide a description of the purpose and objectives of the study with detailed specific aims and hypotheses. Clearly communicate the objectives/specific aims of the Phase 1 Base and each Option and their performance periods, as applicable. Each Phase should reflect a distinct research effort with a non-overlapping period of performance and research outcomes/milestones.
- **Research Design and Methods:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Applications that include research on animal models are also required to submit [Attachment 8, Animal Research Plan](#).

For clinical trials and research involving human subjects:

- 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 laboratory analyses to be conducted and how they relate to the objectives of the study and the anticipated research outcomes.
- 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).
- 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 to meet the objectives of the study. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study.

For clinical trials:

As appropriate, identify and describe the intervention to be tested and describe the projected outcomes.

- Summarize key preclinical 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 as applicable.
- Describe the interaction with the human subject to include the study intervention that he/she will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will experience.
- Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures.
- Discuss how compliance with Good Laboratory Practices, Good Manufacturing Practices, and other regulatory considerations will be established, monitored, and maintained, as applicable. Demonstrate that the research team has access to the proposed intervention, from its source for the proposed indication, for the duration of the proposed study.
- **Technical Risks:** Identify and describe potential problem areas in the proposed approach and alternative methods and approaches that will be employed to mitigate any risks that are identified.
- **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.
 - If applicable, describe the plan to make data available to the TBI research community through the FITBIR Informatics System. If an alternative data sharing vehicle will be employed, provide a justification for its use.
 - Refer to the General Application Instructions, Appendix 4, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
- **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 Patents:** Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- **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 (if applicable):** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work, to include:
 - Availability of and access to research resources (to include proprietary material for the purpose/duration of the proposed research), and/or
 - Availability of and access to appropriate populations (and/or access to available samples/data or databases), if applicable
 - For applications that include an intramural (DoD) collaborator, include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement in the proposed research.
- **Letter(s) of Support for Use of Military and VA 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(s) 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.
- **Joint Sponsorship (if applicable):** Describe present or prospective joint sponsorship of any portion of the program outlined in the application. In the

absence of agreements among sponsors for joint support, the 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 application is submitted, information should be sent later as an addendum to the 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**

- Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
 - Clearly identify all such property;
 - Identify the cost to the Federal Government for use or license of such property, if applicable; or
 - Provide a statement that no property meeting this definition will be used on this project.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

- **Current Quad Chart:** Provide a current Quad Chart in the same format as in the pre-application. If no changes have been made to the project, the same Quad Chart submitted with the pre-application may be used.

- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The technical abstract is used by all reviewers and should be clear and concise and written using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed work.
- **Objective/Hypothesis:** State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- **Specific Aims:** State the specific aims of the study. Denote which aims will be accomplished during each performance phase of the project.

- **Study Design:** Briefly describe the study design including appropriate controls. For studies enrolling human subjects, describe the population and enrollment targets. For animal studies, include a description of the animal model.
- **Impact:** Identify the FY18 JPC-6/CCCRP PTCRA Focus Area(s) to be addressed and briefly describe how the proposed research will impact the field of precision medicine research for trauma care.

- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. **Do not include proprietary or confidential information.** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The lay abstract should not duplicate the technical abstract. The lay abstract should be written using the outline below:

- Describe the objectives and rationale for the research in a manner that will be readily understood by readers without a science or medical background.
 - Identify the FY18 JPC-6/CCCRP PTCRA Focus Area(s) to be addressed.
 - Describe the types of patients that will be helped by the research and how it will help them. Include currently available statistics to the related injury/condition, if applicable.
 - Describe the potential clinical applications, benefits, and risks.
 - Describe the projected timeline to achieve the expected patient-related outcome.
 - 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 FY18 JPC-6/CCCRP PTCRA mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW should clearly delineate the tasks that will be performed during each performance phase. The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.
 - **Attachment 6: Impact and Military Benefit (two-page limit): Upload as “Impact.pdf.”** Explain the proposed research project’s potential impact and military benefit as follows:
 - **Short-Term Impact:** Describe the anticipated short-term outcome(s) that will be directly attributed to the results of the proposed research. Describe how the proposed work will impact the development of precision medicine for trauma care.

- **Long-Term Impact:** Describe the anticipated long-term vision for implementation of the proposed material or knowledge product in trauma care. Describe how the research will contribute to the development or validation of evidence-based policy or guidelines for patient evaluation and care. Compare the proposed material or knowledge product to currently available pharmacologic agents, devices, or clinical guidance, if applicable.
- **Military Benefit:** Clearly articulate how the proposed research can optimize survival and recovery from combat-related or trauma-induced injury.
- **Public Purpose:** Concisely describe how this research can benefit the general public.
- **Challenges:** Describe potential issues that might limit the impact of the proposed research.
- **Attachment 7: Transition Plan (one-page limit): Upload as “Transition.pdf.”**
Provide information on the methods and strategies proposed to move the anticipated research outcomes to the next phase of research or delivery to the military or civilian market/clinical practice after successful completion of the award. The transition plan should include the components listed below.
 - Details of the funding strategy that will be used to bring the outcomes to the next level (e.g., specific potential industry partners, specific funding opportunities to be pursued).
 - 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 level of research and development. Include identification of the FDA regulatory strategy (if appropriate).
 - The involvement of appropriate intellectual property, licensing, and/or business professionals.
 - A risk analysis for cost, schedule, manufacturability, and sustainability, if applicable.
- **Attachment 8: Animal Research Plan (if applicable; required for all studies utilizing animals; three-page limit per animal study): Upload as “AnimRschPln.pdf.”**
When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:
 - Briefly describe the research objective(s) of the animal study. Explain how and why the 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).
- Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- **Attachment 9: IND/IDE Documentation (if applicable): 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.”
 - **Complete the IND/IDE Documentation Form**, which is available for download on the Full Announcement page for this Program Announcement/Funding Opportunity on Grants.gov, and provide one of the following:
 - Evidence 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.
 - Evidence 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.
 - The Government reserves the right to withdraw funding if the IND/IDE application has not been submitted **within 60 days of the DoD award date** or if the documented application status of the IND/IDE has not been obtained within **12 months of the award date**.

- **Attachment 10: Human Subject Recruitment and Safety Procedures (if applicable; required for all studies recruiting human subjects; no page limit): Upload as “HumSubProc.pdf.”** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.
 - a. **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 studies (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. *For clinical studies proposing to include military personnel, refer to the regulatory requirements in General Application Instructions, Appendix 6 for additional information.*
 - b. **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical study. 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 study.
 - c. **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, healthcare provider identification).
 - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
 - 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 study.
 - 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 brain injury, stress/life situations, or human subject age or administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia), if applicable.
 - Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
 - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
 - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial to be in compliance with Title 10 United States Code Section 980 (10 USC 980) (<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf>). If applicable, refer to the General Application Instructions, Appendix 6, for more information.
 - ***Assent for minors or other populations that cannot provide informed consent:*** If these populations are included in the proposed clinical trial, describe a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.
- 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. 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 proposed research. Consider psychological, legal, social, and economic

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

- **Risk management and emergency response:**
 - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. 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.
- **Attachment 11: Data Management (required for all studies recruiting human subjects; no page limit): Upload as “Data_Manage.pdf.”** The Data Management attachment should include the components listed below.
 - 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 human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
 - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of the DoD are eligible to review study records.
 - Address requirements for reporting sensitive information to state or local authorities.
 - **Data capture, verification, and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, the

process for locking the database at study completion, and the length of time data will be stored. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. 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 specimen 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 12: 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 (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., 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 (six-page limit):** Upload as “Biosketch_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.

Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.
 - **PI Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf.”
 - **Key Personnel Biographical Sketches (six-page limit each):** Upload as “Biosketch_LastName.pdf.”
 - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf.”
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4., for detailed information.
- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6., for detailed information.
- Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. *However, do not complete the Grants.gov R & R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 12, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs.* The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section 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 or 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.*** 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 submission rejection.

F. Other Submission Requirements

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

All extramural 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 consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the DHA and the Commanding General, USAMRMC, based on technical merit, the relevance to the mission of the DHP and JPC-6/CCCRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section III.B.2., Programmatic Review](#).*** Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess.shtml>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement that application and evaluation

information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review 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.

Extramural and Intramural applications will be reviewed by the same panels and evaluated with the same criteria.

B. Application Review Process

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

- **Research Strategy and Feasibility**
 - How well the preliminary data and scientific rationale supports the research project.
 - How relevant and applicable the proposed research and findings are to at least one of the FY18 JPC-6/CCCRP PTCRA Focus Areas.
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
 - How consistent the methods and procedures are with a sound research design.
 - How well the study is designed to achieve the research objectives, including the choice of model (if applicable) and endpoints/outcome measures to be used, and generate reproducible and rigorous results.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
 - Whether the research can be completed within the proposed period of performance (including Base and Option Phases, as applicable).
 - How well the PI has outlined a plan for management and sharing of research data as appropriate for the type of study.
 - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
 - For clinical trials and research involving human subjects:
 - How well the PI describes the population(s) of interest, demonstrates access to these populations, and has a viable plan for recruitment, consent, screening, and retention of appropriate subjects.

- If applicable, whether there is evidence demonstrating availability of the device/intervention from its source for the duration of the proposed study.
 - Whether a member of the study team holds the IND/IDE and whether the timeline proposed for IND/IDE application is appropriate (if applicable).
- **Ethical Considerations (if applicable)**
 - 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.
 - To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
 - **Statistical Plan**
 - To what degree the statistical plan, including sample size projections and power analysis, and data analysis plan are adequate for the study and all proposed correlative studies.
 - If applicable, 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.
 - **Impact**
 - To what extent the anticipated research outcomes or long-term vision of the proposed research may impact the development of precision medicine approaches for trauma care.
 - To what extent the proposed research has the potential to optimize survival and recovery from combat-related or trauma-induced injury.
 - To what extent the proposed research can benefit the general public.
 - If applicable, to what degree the proposed materiel or knowledge product represents an improvement to currently available pharmacologic agents, devices, or clinical guidance.
 - **Transition Plan**
 - Whether the funding strategy described to bring the anticipated research outcome(s) to the next level of development and/or delivery to the military or civilian market is appropriate.
 - 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 are appropriate.

- If applicable, how well the potential risk analysis for cost, schedule, manufacturability, and sustainability is developed.
- How well the 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 Program Announcement/Funding Opportunity.
- **Personnel**
 - Whether the composition of the research or study team (e.g., study coordinator, statistician) is appropriate.
 - How the levels of effort by the PI and other key personnel are appropriate to ensure success of this project.
 - Whether the levels of effort by the PI and other key personnel are appropriate to ensure success of this project.
 - Whether the investigator(s) record(s) of accomplishment demonstrates his/her ability to accomplish the proposed work.

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

- **Budget**
 - Whether the budget is appropriate for the proposed research.
 - Whether the total maximum costs are equal to or less than the allowable total maximum costs as published in the Program Announcement/Funding Opportunity.
- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influence the review.
- **Environment**
 - To what degree the scientific environment and the accessibility of institutional/organizational resources support the proposed research requirements (including collaborative arrangements).
 - How the quality and extent of institutional/organizational support are appropriate for the proposed project.

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-6/CCCRP, as evidenced by the following:**
 - Adherence to the intent of the award mechanism
 - Programmatic relevance
 - Program portfolio composition
 - Relative impact and military benefit

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 pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

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

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

The following will result in administrative rejection of the application:

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

For applications including animal studies:

- Attachment 8, Animal Research Plan, is missing.

For applications recruiting human subjects:

- Attachment 10, Human Subject Recruitment and Safety Procedures, is missing.
- Attachment 11, Data Management, is missing.

For clinical trial applications:

- Attachment 9, IND/IDE Documentation, is missing.

B. Modification

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

C. Withdrawal

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

- An FY18 JPC-6/CCCRP PTCRA Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the FY18 JPC-6/CCCRP PTCRA Programmatic Panel members can be found at http://cdmrp.army.mil/dmrtp/panels/18jpc_6.*
- 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).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. The identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Application 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.
- Proposed research includes a Phase II or Phase III clinical trial.

D. Withhold

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

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2019. Refer to the General Application Instructions, Appendix 4, 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 4, for general information regarding administrative requirements.

C. National Policy Requirements

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

D. Reporting

Refer to the General Application Instructions, Appendix 4, Section H, for general information on reporting requirements.

Quarterly technical progress reports, quad charts, and in-person presentations will be required.

E. Award Transfers

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

Refer to the General Application Instructions, Appendix 4, Section L, for general information on organization or PI changes.

VI. VERSION CODES AND AGENCY CONTACTS

A. Program Announcement/Funding Opportunity and General Application Instructions Version

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code [20160210k]. The Program Announcement/Funding Opportunity numeric version code will match the General Applications Instructions version code [20160210].

B. 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

C. 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 US Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

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

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/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
SF424 (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: Upload as Attachment 6 with file name "Impact.pdf."	
	7	Transition Plan: Upload as Attachment 7 with file name "Transition.pdf."	
	8	Animal Research Plan: Upload as Attachment 8 with file name "AnimRschPln.pdf."	
	9	IND/IDE Documentation: Upload as Attachment 9 with file name "IND_IDE.pdf" (required for clinical trials).	
	10	Human Subject Recruitment and Safety Procedures: Upload as Attachment 10 with file name "HumSubProc.pdf" (required for all studies recruiting human subjects).	
	11	Data Management: Upload as Attachment 11 with file name "Data_Manage.pdf" (required for all studies recruiting human subjects).	
	12	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 12 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.	