

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

**Broad Agency Announcement for Combat Casualty Care Research Program (CCCRP)  
for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Defense Medical Research and Development Program (DMRDP)**

**Joint Program Committee-6 (JPC-6)/CCCRP**

**Multi-Domain Lifesaving Trauma Innovations (MuLTI) Award**

**Announcement Type: Modified**

**Funding Opportunity Number: W81XWH-19-S-CCC1**

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

### **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Proposal/Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), March 5, 2019
- **Invitation to Submit a Proposal/Application:** April 11, 2019
- **Proposal/Application Submission Deadline:** 11:59 p.m. ET, May 29, 2019
- **End of Proposal/Application Verification Period:** 5:00 p.m. ET, June 4, 2019
- **Peer Review:** August 2019
- **Programmatic Review:** October 2019

*This Broad Agency Announcement (BAA) must be read in conjunction with the General Submission Instructions, which are available for downloading from Grants.gov. The General Submission Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."*

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## II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

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

This Funding Opportunity Announcement is a Broad Agency Announcement (BAA) through the Fiscal Year 2019 (FY19) Defense Medical Research and Development Program (DMRDP) for the Joint Program Committee-6/Combat Casualty Care Research Program (JPC-6/CCCRP) Multi-Domain Lifesaving Trauma Innovations (MuLTI) Award. For the remainder of the announcement, this BAA will be referenced as MuLTI. Specific submission information and additional administrative requirements can be found in the document titled “General Submission Instructions,” available in Grants.gov along with this BAA.

This BAA for CCCRP is intended to solicit extramural research and development ideas using the authority provided by United States Code, Title 10, 2358. This BAA is issued under the provisions of the Competition in Contracting Act (CICA) of 1984 (Public Law 98-369), as implemented in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016 and in Department of Defense Grant and Agreement Regulations (DoDGARs) 22.315. In accordance with FAR 35.016, projects funded under this BAA must be for *applied and clinical research (including clinical trials)* not related to the development of a specific system or hardware procurement. Projects must be for scientific study and experimentation directed toward advancing the state of the art or increasing knowledge or understanding rather than focusing on a specific system or hardware solution. Research and development funded through this BAA is intended and expected to benefit and inform both military and civilian medical practice and knowledge.

**This BAA is intended for extramural applicants only. For definitions and additional information, see [Section II.C.1, Eligible Applicants](#).** (Intramural applicants applying through intramural organizations should use the separate Funding Opportunity Announcement that is available through the electronic Biomedical Research Application Portal (eBRAP) [<https://eBRAP.org/>] under the funding opportunity number W81XWH-19-DMRDP-MuLTI).

### II.A. PROGRAM DESCRIPTION

Proposals/Applications to the FY19 DMRDP JPC-6/CCCRP MuLTI Award are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) provides DMRDP management support aligned with specific DHA research program areas, including the JPC-6/CCCRP. This BAA 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 core research program areas within the DHP. JPC-6 is a committee of DoD and non-DoD medical and military technical experts in combat casualty care-related program areas. Per the program's mission statement, JPC-6/CCCRP seeks to drive medical innovation through development of knowledge and materiel solutions for the acute and early management of combat-related trauma on current and future battlefields, including point of injury, far forward, and prolonged, en route, and early facility-based care. Innovations developed by JPC-6/CCCRP-supported research are applied in-theater across the roles of care and within the prehospital and critical care clinical facilities within the Military Health System (MHS). These solutions not only help to minimize the morbidity and mortality of combat-related injuries sustained by the Warfighter; they are also often translatable to civilian care. An excerpt from the CCCRP Vision Statement ([Appendix II](#)) provides further illustration of the program's needs:

*“In responding to mid and long term guidance which is underscored by a predicted loss of air superiority, we must adapt our perspective and tactics with regard to casualty evacuation and the “golden hour” paradigm of OIF/OEF in order to continue to drive down case fatality and died of wound rates. There is a necessary paradigm shift away from transporting casualties to a damage control capability (ROC 2/3) to more efficiently bringing “golden hour” medical assets and intervention capabilities to the point of injury.”*

– Col Michael Davis, CCCRP Director (2017)

For additional information on JPC-6/CCCRP, the program's previous and current successes, and other documents related to the program's long-term planning efforts, please visit the JPC-6/CCCRP official website at <https://ccc.amedd.army.mil/Pages/default.aspx>.

### **II.A.1. FY19 JPC-6/CCCRP MuLTI Award Focus Areas**

The MuLTI Award will support the development of highly innovative materiel products and new ways, methods, or modifications to existing trauma practice (i.e., knowledge products) for future multi-domain operations (MDO) where evacuation capabilities may be significantly delayed or unavailable. Projects should consider the varied expertise levels of the medical providers and the possible diverse environmental conditions. A focus is on enhancing capabilities at the point of greatest need, including life-saving interventions to be rendered immediately post-injury, during periods of prolonged care in theater, and during transport/en route care within and from theater. Medical materiel solutions are encouraged to include characteristics relevant to military use in austere, combat environments. Characteristics and concepts to consider include but are not limited to:

- **Mobility:** The materiel product has a variety of transportation options and, when compared to existing products, few unique transportation requirements.

- Low-weight and low-cube: Compared to existing materiel products, the product is a smaller size and weight to aid in portability and storage.
- Low-power, longer shelf life: The product has reduced power usage requirements and longer shelf life than currently available products.
- Modularity and interoperability: The materiel product is compatible with and easily added to existing technologies, equipment, or platforms being used by the military.
- Ruggedization: The materiel product is able to withstand harsh and varied environments such as extreme temperature fluctuations, vibration, and high altitude while maintaining operability and stability.
- Low-complexity, decision-supported, closed or semi-closed loop feedback or automation: The product is simple to operate, provides decision support to user, or can be partially or fully autonomous. The product can be used by various level of medical providers with minimal training.
- Affordability: The materiel and knowledge products would result in cost-savings over what is currently available and considers the costs of maintaining and sustaining the product.

The proposed research must be relevant to Service members. It is also expected that outcomes of funded research will benefit Veterans, military beneficiaries, and the American public.

The JPC-6/CCCRP has identified three overarching Focus Areas for funding under the FY19 DMRDP JPC-6/CCCRP MuLTI Award. To meet the intent of the award mechanism, proposals/applications **MUST** specifically address at least one sub-Area within the three MuLTI Award Focus Areas. Research not aligned to at least one sub-Area will not be considered for funding. The MuLTI Award Focus Areas are:

### **Focus Area 1 –Prolonged and En Route Care:**

*The Prolonged and En Route Care portfolio seeks to provide materiel and knowledge solutions to enable increased levels of care closer to the point of injury, including care provided during evacuation, to provide patient care for longer time periods when delayed evacuation exceeds available capability and/or capacity, and to extend provider capabilities in order to care for larger numbers of casualties.*

- Real-time physiologic monitoring to improve triage capability, minimize over- and under-triage, assist in the initial assessment and continuous reassessment, and enable decision support during MASCAL<sup>1</sup> scenarios, austere conditions, or when resources (including medical providers and medical materiel) are limited.

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<sup>1</sup> MASCAL is the term given to a mass casualty event that overwhelms immediately available medical capabilities to include personnel, supplies, and/or equipment.

- Novel capabilities for medical providers at Roles 1-3<sup>2</sup> to administer analgesia, sedation, and anesthesia, such as automated pain control or anesthesia delivery systems.
- Innovative capabilities to enable the provision of damage control interventions closer to point of need.
- Novel burn wound stabilization, non-surgical debridement, and coverage capabilities as well as more effective and efficient treatment protocols.
- Innovative organ support capabilities in a forward environment including field-appropriate markers of organ function/failure and therapeutics to prevent end organ failure/preserve function (e.g., extra-corporeal life support), particularly for the lungs, kidneys, liver, and gastrointestinal (GI) tract.
- Optimizing sustained (more than 12 hours) resuscitation for hemorrhagic shock and burn injuries.
- Increased understanding of the pathophysiology and development of strategies to mitigate the secondary effects of acute interventions, particularly mitigation of ischemia-reperfusion injury and acute respiratory distress syndrome (ARDS).
- Evidence-based safe transport and patient hand-off guidelines for medical transport of critically injured casualties during and following a prolonged care scenario. Considerations should include casualty injury characteristics (e.g., optimal altitude to prevent/reduce secondary trauma following hemorrhagic shock or traumatic brain injury (TBI), vibration (hertz) restrictions in post-operative patients) and documentation to improve outcomes.
- Development of capability to preserve tissue for autologous use to improve long-term outcomes (e.g., ex-vivo preservation of traumatically amputated extremity to enable autologous vascular repair).

## **Focus Area 2 – Battlefield Resuscitation for Immediate Stabilization of Combat Casualties:**

*Hemorrhage is the leading cause of preventable deaths among combat casualties occurring before a medical treatment facility is reached. The Battlefield Resuscitation for Immediate Stabilization of Combat Casualties portfolio seeks to provide materiel and knowledge solutions to enable the immediate stabilization at the point of injury. Current strategic objectives are to provide: (1) technologies to control bleeding in the prehospital environment, (2) safer, more effective, and more logistically supportable blood products, and (3) technologies and knowledge sets for improved damage control resuscitation.*

- Novel blood products and/or expanders with oxygen-carrying capacity that offer physiological, logistical, or cost advantages over current products with an intent to support large-scale MDO and high demand during peak conflicts. (**NOTE:** Proposals for using a

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<sup>2</sup> See references within section II.A.2 for a description of the DoD roles of care.

hemoglobin-based oxygen carrier (HBOC) must demonstrate how nitric oxide-scavenging will be addressed.)

- Adjunctive pharmacological solutions for hemorrhage, shock, coagulopathy, transfusion and/or stabilization of polytrauma, with attention to contra-indications and/or impact on TBI.
- Innovative technologies to enable better emergency airway management in austere pre-hospital environments.
- Automated capabilities to enable interventions at point of need (e.g., automated vascular access, automated airway access, intraosseous access, and decompressive thoracostomy).
- Innovative management of severely injured Warfighters with complex polytrauma conditions in the prehospital environments.
- Advanced innovative technologies in nanomedicine, precision medicine, stem cells and suspended animation specifically for trauma

### **Focus Area 3 – Neurotrauma:**

*The Neurotrauma Portfolio (NTP) is focused on closing military-relevant gaps across a broad range of research areas to improve the prevention, diagnosis, management, and treatment of TBI and related sequelae from point-of-injury through recovery. The NTP's goal is to decrease morbidity and mortality from neurotrauma, mitigate secondary brain injury across all TBI severities, and advance materiel and knowledge development to expand and develop new clinical practice guidelines, care algorithms, therapies, devices, and procedures that advance the decision-making capabilities of medical personnel, enabling earlier intervention and improved outcomes.*

**NOTE:** For studies proposing animal research, provide justification for the use of non-gyrencephalic (lissencephalic) models of TBI.

- Interventions to reduce the incidence and severity of secondary brain injury.
- Novel intervention and stabilization (e.g., maintain glucose levels, brain oxygenation, and cerebral blood flow) approaches to moderate and severe TBI.
- Simplified diagnostic capabilities (e.g., imaging) that do not require extensive interpretation by medical providers.
- Novel biofluid-based TBI biomarkers. The biomarker(s) can be prognostic or diagnostic and address mild or moderate TBI severities. Biomarkers that apply to multiple TBI severities (mild or moderate) are preferred.
- Development of field applicable treatments for post traumatic central nervous system (CNS) tissue preservation

## II.A.2. Award Background

For additional background information, please see the [references listed below](#).

As the Department of Defense (DoD) evolves and prepares for the future, the MDO concept has emerged. The MDO concept requires that the military be prepared to conduct operations in all potential contested domains (land, air, maritime, cyber, space, and electronic) with potential peer and near-peer adversaries that have the ability to limit or deter access to those domains. MDO includes the battlefield, but also encompasses military operations before and after high-intensity conflict and other operations such as humanitarian and disaster relief. The medical support to future MDO will require casualty care for dispersed forces and sometimes isolated forces under difficult conditions, such as dense urban, subterranean, maritime, high-altitude, dust storm, and extreme environments. MDO casualty care must address not only the scope of these challenges, but also the scale of casualties projected (e.g., prolonged MASCAL-like scenarios during peak conflict).

Given that MDO may be the most demanding environment the Warfighter has ever faced, the military must plan and act accordingly. The challenge of diverse globally dispersed combat environments requires medical research to develop new solutions to support medical providers in the assessment, diagnosis, and treatment of combat-related and trauma-induced injury at the point of injury, during prolonged care (minimum 72 hours) settings, and on en route platforms. The overall goal is to save the most lives with limited resources in austere conditions. Proposed research solutions submitted to this announcement must be focused on the development of innovations to support positive outcomes in challenging conditions and should consider the provision of highly effective care despite the formidable conditions.

The intent of the MuLTI Award is to fund research innovations that will provide cutting-edge medical solutions for the Service member injured in future MDO. The solutions will not be limited to military use. Technologies and techniques developed for prolonged prehospital life support have applications in civilian environments. Natural disasters, explosive events, accidents, and mass shootings can generate a surge of casualties and complex injuries that can mirror those seen on the battlefield. Additionally, civilians, particularly those in rural areas, face challenges with delayed access to hospital-based care. While only 20% of all Americans live in rural areas, they account for more than 50% of all trauma-related fatalities. The majority of these individuals do not live within an hour of a Level I or II trauma center and could benefit from improvements in prehospital care.

In support of the Warfighter and the public, the JPC-6/CCCRP expects the innovative approaches and technologies developed under the MuLTI Award to increase survivability from both combat-related and trauma-induced injuries.

References:

U.S. Army Training and Doctrine Command. 2018. The U.S. Army in Multi-Domain Operations 2028. Department of the Army. Retrieved from: [https://www.tradoc.army.mil/Portals/14/Documents/MDO/TP525-3-1\\_30Nov2018.pdf](https://www.tradoc.army.mil/Portals/14/Documents/MDO/TP525-3-1_30Nov2018.pdf)

For a description of the DoD roles of medical care go to:

<https://www.cs.amedd.army.mil/FileDownloadpublic.aspx?docid=6f9e0685-1290-4e92-8277-c1e7b0f2fef0>

McSwain N, Rotondo M, Meade P, and Duchesne J. 2012. A model for rural trauma care. *British Journal of Surgery* 99(3):309-314.

National Academies of Sciences, Engineering, and Medicine. 2016. *A national trauma care system: Integrating military and civilian trauma systems to achieve zero preventable deaths after injury*. Washington, DC: The National Academies Press. doi:10.17226/23511.

Riesberg J., et al. 2017. The loss of the golden hour. *Special Warfare* 30(1):49–51. Retrieved from: [https://www.soc.mil/swcs/SWmag/archive/SW3001/JAN\\_MAR\\_2017.pdf](https://www.soc.mil/swcs/SWmag/archive/SW3001/JAN_MAR_2017.pdf)

## **II.B. AWARD INFORMATION**

The JPC-6/CCCRP expects to allot approximately **\$10.7 million (M)** of the FY19, **\$9.9M** of the FY20, and **\$9.5M** of the FY21 DHP RDT&E appropriations to fund approximately 12 to 30 FY19 DMRDP JPC-6/CCCRP MuLTI Award proposals/applications, depending on the quality and number of proposals/applications received. Funding of applications received in response to this BAA is contingent upon the availability of Federal funds for this program. The funding estimated for this BAA is approximate and subject to realignment.

Proposals/Applications received in response to both the FY19 DMRDP JPC-6/CCCRP MuLTI Award extramural BAA and intramural Funding Opportunity Announcement will be evaluated and considered for funding together. The Government reserves the right to fund any combination of extramural and/or intramural proposals/applications.

The anticipated total costs (direct and indirect) budgeted for the entire period of performance for an FY19 MuLTI Award will not exceed:

- **\$2.5M** total costs for studies involving prospective accrual of human subjects and clinical trials
- **\$1.0M** total costs for all other research

Refer to [Section II.D.6, Funding Restrictions](#), for detailed funding information.

The USAMRMC executes its extramural research program primarily through the awarding of contracts and assistance agreements (grants and cooperative agreements). The type of instrument used to reflect the business relationship between the organization and the Government is at the discretion of the Government, in accordance with the Federal Grant and Cooperative Agreement Act of 1977, as amended, Title 31 United States Code Sections 6301-6308 (31 USC 6301-6308), which provides the legal criteria to select a procurement contract or an assistance agreement.

An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a “thing of value” to a “state, local government,” or “other recipient” to carry out a public purpose of support or stimulation authorized by a law of the United States,

instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304).

Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305) and the award will identify the specific substantial involvement. Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award.

A contract is required when the principal purpose of the instrument is to acquire property or services for the direct benefit or use of the U.S. Government. The award type, along with the start date, will be determined during the negotiation process.

Please see Appendix 2, Section E of the General Submission Instructions for more information.

**Production and Testing of Prototypes (Contracts only):** USAMRAA may include an optional line item for the provision of advanced component development or for the delivery of initial or additional prototype units. However, such a contract addition shall be subject to the limitations contained in Section 819 of the National Defense Authorization Act (NDAA) for Fiscal Year 2010, as modified in Section 811 of the NDAA for Fiscal Year 2015.

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

**This BAA may support preclinical research, clinical research, and Phase 0 and Phase I 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 provided at <https://ebrap.org/eBRAP/public/Program.htm>. ***Phase II and Phase III clinical trials for U.S. Food and Drug Administration (FDA) licensure of drugs and definitive/pivotal testing for device clearance by the FDA will NOT be permitted under this BAA.***

**Recruitment Milestones:** For research involving human subject enrollment, the proposal/application must indicate the quarterly enrollment targets across all sites in [Attachment 5: Statement of Work](#). Successful applicants will work with USAMRAA to establish milestones for human subject recruitment. Continued support for the project will be based upon satisfactory progress in meeting the established milestones.

**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) 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.

**Multi-Institutional Clinical Trials:** If the proposed clinical trial is multi-institutional, plans for the multi-institutional structure governing the research protocol(s) should be outlined in [Attachment 14: Study Personnel and Organization](#). The lead organization responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements. A single Institutional Review Board (IRB) or Ethics Committee (EC) pathway is strongly recommended whenever possible. The master protocol and consent form must be reviewed by the USAMRMC Office of Research Protections (ORP) Human Research Protection Office (HRPO) prior to distribution to the additional sites for IRB/EC review. Communication and data transfer among the collaborating institutions, as well as how specimens and/or imaging products obtained during the study will be handled, should be included in the appropriate sections of the proposal/application. A separate intellectual and material property plan agreed upon by all participating institutions is also required for multi-institutional clinical trials.

**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 ORP HRPO, prior to research implementation. This administrative review requirement is in addition to the local IRB or 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 4 months for HRPO regulatory review and approval processes.* Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted proposal/application as a stand-alone study. Submission to HRPO of protocols involving more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Refer to the General Submission Instructions, Appendix 1, Section B, 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.

If the IRB determines that a trial presents greater than minimal risk to human subjects, the DoD requires an independent research monitor with expertise consistent with the nature of risk(s) identified within the research protocol. If applicable, refer to the General Submission

Instructions, Appendix 1, Section B, for more information on study reporting authorities and responsibilities of the research monitor.

**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 proposal/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 3 to 4 months for ACURO regulatory review and approval processes for animal studies.* Refer to the General Submission Instructions, Appendix 1, Section B, 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](http://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 proposal/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](https://www.elsevier.com/_data/promis_misc/622936arrive_guidelines.pdf).

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

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the VA Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief. If appropriate, the proposal/application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the proposal/application should include a letter from the

VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

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

**Federal Interagency Traumatic Brain Injury Research (FITBIR) Data Sharing:** The DoD requires that awardees make TBI research data generated by this award mechanism available to the research community through the FITBIR Informatics System. The FITBIR Informatics System is a free resource designed to accelerate research progress by allowing the storage, re-analysis, integration, and rigorous comparison of multiple datasets. Currently FITBIR eligible research include all studies generating prospectively collected human TBI subject data (e.g., clinical, demographic, phenotypic, imaging, and genomic).

Data reporting to FITBIR is an opportunity for investigators to facilitate their own research and to collaborate with others engaged in similar research. While there is no direct charge to users of the FITBIR Informatics System, a project estimation tool (<https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp>) is available to help estimate costs and manpower needs that may be associated with data submission. FITBIR guidance and policies, as well as the considerable advantages of FITBIR participation to the researcher, are detailed at <http://fitbir.nih.gov/>.

In order to share data with FITBIR, three elements must be included in the proposed research:

1. Updated informed consent language that includes FITBIR data sharing. Sample consent language is included in [Appendix III](#).
2. Global Unique Identifier (GUID): FITBIR encourages collaboration between laboratories, as well as interconnectivity with other informatics platforms. Such community-wide sharing requires common data definitions and standards. FITBIR allows for de-identification and storage of data (medical imaging clinical assessment, environmental and behavioral history, etc.) of various types (text, numeric, image, time series, etc.). Use of FITBIR's GUID system facilitates repeated and multi-user access to data without the need to personally identify data sources. In order to generate a GUID for a subject, the following personally identifiable information (PII) ***must be collected in the proposed research:***
  - Complete legal given (first) name of subject at birth
  - Complete legal additional name of subject at birth (if subject has a middle name)
  - Complete legal family (last) name of subject at birth

- Day of birth
- Month of birth
- Year of birth
- Name of city/municipality in which subject was born
- Country of birth

*Note that this PII is never sent to the FITBIR system. PII cannot be extracted from the GUID. Information on GUID compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations can be found at <https://fitbir.nih.gov/content/global-unique-identifier>.*

3. Common Data Elements (CDEs): Research data elements must be reported using the National Institute of Neurological Disorders and Stroke (NINDS) TBI CDEs or entered into the FITBIR data dictionary as new, unique data elements (UDEs). For the most current version of the NINDS TBI CDEs, go to <http://www.commondataelements.ninds.nih.gov>. Assistance will be available to help the researchers map their study variables to specific CDEs and ensure the formats of the CDEs collected are compatible with the FITBIR Informatics System. Use of the TBI CDEs is required wherever possible in an effort to create standardized definitions and guidelines about the kinds of data to collect and the data collection methods that should be used in clinical studies of TBI. *Use of UDEs is strongly discouraged and subject to program approval.*

*The CDMRP intends that information, data, and research resources generated under awards funded by this BAA 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 Submission Instructions, Appendix 2, Section L.*

## **II.C. ELIGIBILITY INFORMATION**

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

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

Awards are made to organizations only. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations. Refer to the General Submission Instructions, Appendix 3, for general eligibility information.

**NOTE:** In accordance with FAR 35.017, Federally Funded Research and Development Centers (FFRDCs) are not eligible to directly receive awards under this BAA. However, teaming arrangements between FFRDCs and eligible organizations are allowed so long as they are permitted under the sponsoring agreement between the Federal Government and the specific FFRDC.

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

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

Proposals/Applications for this BAA may only be submitted by extramural organizations. Applicants from an intramural organization should apply through eBRAP under the funding opportunity number W81XWH-19-DMRDP-MuLTI. These terms are defined below.

**Extramural Organization:** An eligible non-DoD organization. Examples of extramural organizations include academia, biotechnology companies, foundations, Government, and research institutes.

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

Submissions from intramural applicants to this BAA will be rejected. *It is permissible, however, for an intramural investigator to be named as a collaborator on a proposal/application submitted through an extramural organization. In this case, the proposal/application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.* For more information, refer to the General Submission Instructions, Section II.C.

**Note:** Proposals/Applications from an intramural DoD organization or from an extramural non-DoD Federal organization may be submitted through a research foundation.

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

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

Independent investigators at all academic levels (or equivalent) are eligible to be named by the organization as the PI on the proposal/application.

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

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

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

Cost sharing/matching is not an eligibility requirement.

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

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

There are no limitations on the number of applications for which an investigator may be named as a PI.

For general information on required qualifications for award recipients, refer to the General Submission Instructions, Appendix 3.

**Subcontracting Plan:** If the resultant award is a contract that exceeds \$700,000 and the offeror is other than a small business, the contractor will be required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.704, Army Federal Acquisition Regulation Supplement, Subpart 5119.704 (AFARS 5119.704), and Defense Federal Acquisition Regulation Supplement, Subpart 219.704 (DFARS 219.704). A mutually agreeable plan will be developed during the award negotiation process and incorporated as part of the resultant contract.

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

Refer to [Section II.H.1, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-proposal/pre-application or proposal/application does not meet the administrative, eligibility, or ethical requirements defined in this BAA.

## **II.D. PROPOSAL/APPLICATION AND SUBMISSION INFORMATION**

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

*Intramural DoD Submission* is defined as an application submitted by a DoD organization to electronic Biomedical Research Application Portal (eBRAP).

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

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

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

**Intramural DoD Submissions:** Pre-proposal/Pre-application content and forms and full proposal/application packages for funding opportunity number W81XWH-19-DMRDP-MuLTI must be accessed and submitted at [eBRAP.org](http://eBRAP.org).

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

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

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

**Pre-Proposals/Pre-Application Submissions:** All pre-proposals/pre-applications must be submitted through eBRAP (<https://eBRAP.org/>).

**Full Proposal/Application Submissions:** Full proposals/applications must be submitted through the online portals as described below.

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

A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full proposal/application submissions associated with them. eBRAP will validate full proposal/application files against the specific BAA 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 proposal/application components for accuracy as well as ensure proper ordering as specified in this BAA.

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

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

**During the pre-proposal/pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the full proposal/application submission process.**

To begin the pre-proposal/pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel (*the selection chosen should be “extramural” as only extramural applicants are eligible to apply to this BAA*). **Incorrect selection of extramural or intramural submission type will delay processing.**

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

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

The applicant organization and associated PI identified in the pre-proposal/pre-application should be the same as those intended for the subsequent proposal/application submission. If any changes are necessary after submission of the pre-proposal/pre-application, the PI must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

A change in PI or organization after submission of the pre-proposal/pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

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

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

- **Tab 1 – Application Information**

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

- **Tab 2 – Application Contact**

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 Form). The Business Official must either be selected from the eBRAP list or invited for the pre-proposal/pre-application to be submitted.

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

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

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

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

[FY19 DMRDP JPC-6/CCCRP MuLTI Award Programmatic Panel members](#) should not be involved in any pre-proposal/pre-application or proposal/application. For questions related to panel members and pre-proposals/pre-applications or proposals/applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

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

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

- **Tab 5 – Pre-Application Files**

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

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

The Pre-Proposal/Pre-Application 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, specific aims, and briefly describe the experimental approach.
- **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the described research project.
- **Impact and Relevance:** State explicitly how the proposed work may improve trauma care. Describe the potential impact of this proposal/application to directly or indirectly benefit military Service members during MDO and the public.
- **Alignment with Focus Areas:** Identify and explain how the proposed work addresses at least one sub-Area within the three FY19 JPC-6/CCCRP MuLTI Award Focus Areas.
- **Pre-Proposal/Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-proposal/pre-application *must be uploaded as individual files* and are limited to the following:
  - References Cited (two-page limit): List the references cited (including URLs if available) in the Pre-Proposal/Pre-Application 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). Include both military and civilian research in the review of the literature, as applicable.
  - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Pre-Proposal/Pre-Application Narrative.
  - PI and Key Personnel Biographical Sketches (six-page limit per individual): Upload as “Biosketch\_LastName.pdf”. Bold or highlight publications relevant to the proposed project.
  - Budget Summary: Upload as “BudgetSummary.pdf”. Complete the two-page Pre-Application Budget Summary Form (available for download in eBRAP) as instructed.
  - Quad Chart: Upload as “QuadChart.pdf”. 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.

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

- **Tab 6 – Submit Pre-Application**

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

## Pre-Proposal/Pre-Application Screening Criteria

All pre-proposals/pre-application will be screened by the FY19 DMRDP JPC-6/CCCRP MuLTI Programmatic Panel members to determine technical merit and relevance to the mission of the DHP, DMRDP, and JPC-6/CCCRP. Pre-proposals/Pre-applications will be screened based on the following criteria:

- **Research Plan:** How well the rationale, hypotheses, objectives, specific aims, and experimental approach support the research idea(s).
- **Personnel:** To what extent the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed research project.
- **Impact and Relevance:** If successful, to what extent the study outcomes could improve trauma care. How well the proposed study will directly or indirectly benefit military Service members during MDO and the public.
- **Alignment with Focus Areas:** To what extent the proposed work addresses at least one sub-Area within the FY19 JPC-6/CCCRP MuLTI Award Focus Areas.

## Notification of Pre-Proposal/Pre-Application Screening Results

Following the pre-proposal/pre-application screening, applicants will be notified as to whether or not they are invited to submit proposals/applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-proposal/pre-application. The estimated timeframe for notification of invitation to submit a proposal/application is indicated on the [Section I, Overview of the Funding Opportunity](#) of this BAA.

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

**Proposals/Applications will not be accepted unless notification of invitation has been received.**

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

Each proposal/application submission must include the completed full proposal/application package for this BAA. The full proposal/application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://www.grants.gov/>) for extramural organizations. See Table 1 below for more specific guidelines.

### **II.D.2.b.i. Full Proposal/Application Guidelines**

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view,

complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the *same version* of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user’s computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Submission Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

**Table 1. Full Proposal/Application Submission Guidelines**

<b>Proposal/Application Package Location</b>
Download proposal/application package components for W81XWH-19-S-CCC1 from Grants.gov ( <a href="https://www.grants.gov/">https://www.grants.gov/</a> ) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.
<b>Full Proposal/Application Package Components</b>
<b>SF424 Research &amp; Related Application for Federal Assistance Form:</b> Refer to the General Submission Instructions, Section III.A.1, for detailed information.
Descriptions of each required file can be found under Full Proposal/Application Submission Components: <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">Research &amp; Related Subaward Budget Attachment(s) Form</a> (if applicable)</li> </ul>
<b>Proposal/Application Package Submission</b>
<p><b>Create a Grants.gov Workspace.</b> Add participants (investigators and Business Officials) to the Workspace, complete all required forms, and check for errors before submission.</p> <p><b>Submit a Grants.gov Workspace Package.</b> A proposal/application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the proposal/application package <b>at least 24-48 hours prior to the close date</b> to allow time to correct any potential technical issues that may disrupt the proposal/application submission.</p> <p><b>Note:</b> If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov proposal/application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the proposal/application submission deadline.</p>

<b>Proposal/Application Verification Period</b>
The full proposal/application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the proposal/application verification period. During the proposal/application verification period, the full proposal/application package may be modified, <i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i>
<b>Further Information</b>
<b>Tracking a Grants.gov Workspace Package.</b> After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission. Refer to the General Submission Instructions, Section III, for further information regarding Grants.gov requirements.

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

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

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

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

The Grants.gov submission package includes the following components (refer to the General Submission Instructions, Section III, for additional information on proposal/application submission).

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

#### **Attachments:**

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

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or if they have incorrect file

names, i.e., containing characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire full submission package may not exceed 200 MB.

- **Attachment 1: Project Narrative (15-page limit): Upload as “ProjectNarrative.pdf”.** There is no form for this information. The attachments must be PDF files in accordance with the formatting guidelines specified for full proposal/application preparation. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the proposal/application.

Describe the proposed project in detail using the outline below.

- **Background:** 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 address at least one sub-Area within the FY19 JPC-6/CCCRP MuLTI Award Focus Areas.
- **Objectives/Specific Aims/Hypothesis:** Provide a description of the purpose and objectives of the study with detailed specific aims and hypotheses.
- **Research Design and Methods:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for evaluation. Describe the statistical plan as appropriate for the proposed research. 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. Proposals/Applications that include research on animal models are also required to submit [Attachment 8, Animal Research Plan](#).

***For 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 proposals/applications including a clinical trial:***

- Define each arm/study group of the proposed trial.
  - Outline whether subjects, clinicians, data analysts, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias.
  - 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 current Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Good Manufacturing Practice (GMP) guidelines 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.
- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community.

- Refer to General Submission Instructions, Appendix 2, Section L, for more information about the CDMRP expectations for making data and research resources publicly available.
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

- References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patent Abstracts: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support (2-page limit per letter): 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 BAA, such as those from members of Congress, do not impact proposal/application review or funding decisions.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on a proposal/application submitted through an extramural organization, the proposal/application must include

a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- Joint Sponsorship (if applicable): Describe present or prospective joint sponsorship of any portion of the program outlined in the proposal/application. In the absence of agreements among sponsors for joint support, the proposal/application should be structured so that the research can be carried out without the resources of any other sponsor. If, however, it is desirable to request partial support from another agency, the proposed plan should be stated and the reasons documented. If the plan cannot be formulated at the time the proposal/application is submitted, information should be sent later as an addendum to the proposal/application. Prior approval from both agencies must be secured for research to be undertaken under joint sponsorship. Provide letters of support related to recruitment, subject access, and data access plans.
- Current Quad Chart: Provide a current Quad Chart in the same format as in the pre-proposal/pre-application. If no changes have been made to the project, the same Quad Chart submitted with the pre-proposal/pre-application may be used.
- Intellectual Property: Information can be found in 2 CFR 200.315, "Intangible 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 the proposed research 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; and
    - ❖ Identify the cost to the Federal Government for use or license of such property, if applicable;
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations. Describe existing Cooperative Research and Development Agreements (CRADAs), Material Transfer Agreements (MTAs), and Memorandum of Understanding (MOU) agreements. CRADAs, MTAs, and MOU agreements must be in place within 90 days of the award start date.
- Use of DoD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military patient populations and/or DoD resources or databases.
- Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the ACOS/R&D or Clinical Service Chief confirming access to VA patients, resources, and/or VA research space. For VA applicants, if the VA NPC is not identified as the applicant institution for administering the funds, include a letter from the VA

ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

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

The structured technical abstract should be clear and concise and, at a minimum, provide the following information:

- **Background:** Present the ideas and reasoning behind the proposed work.
  - **Objective/Hypothesis:** State the objective to be reached/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
  - **Specific Aims:** State the specific aims of the study.
  - **Study Design:** Briefly describe the study design including appropriate controls. For studies enrolling human subjects, describe the population and enrollment targets. For animal studies, include a description of the animal model.
  - **Impact:** Identify the FY19 JPC-6/CCCRP MuLTI Award sub-Area(s) to be addressed and briefly describe how the proposed research will impact 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.

Lay abstracts should be written using the outline below. Do not duplicate the technical abstract.

- 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 FY19 JPC-6/CCCRP MuLTI sub-Area(s) to be addressed.
  - 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 and/or the public.
- **Attachment 5: Statement of Work (SOW) (five-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 FY19 DMRDP JPC-6/CCCRP MuLTI Award mechanism, use the SOW format example titled “SOW for Advanced Tech Development Research” or “SOW for Clinical Research” as appropriate. The SOW must be in PDF format prior to attaching. Refer to the General Submission Instructions, Section III.A.2, for detailed guidance on creating the SOW.

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

- Include the name(s) of the key personnel and contact information for each study site/subaward site.
- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Submission Instructions, Appendix 2, for additional information regarding regulatory requirements.
- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets across all enrollment sites.
- Identify cell line(s) and commercial or organizational source(s) to be used, if applicable.
- If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the FDA or other Government agency.
- For FITBIR, eligible research should include:
  - FITBIR investigator and study registration within the first 30 days of the award
  - Sharing of draft data collection forms with FITBIR
  - Annual FITBIR data submissions
- **Attachment 6: Impact and Military Benefit Statement (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.
  - **Long-Term Impact:** Describe the anticipated long-term vision for implementation of the proposed materiel 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 materiel 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 during future MDO that feature delayed evacuation, delayed damage control surgery, and austere environments.
  - **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 and strategies that may be employed to overcome those issues.
- **Attachment 7: Transition Plan (three-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. Applicants are encouraged to work with their organization’s Technology Transfer Office (or equivalent) to develop the transition plan. PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development. The post-award transition plan should include the components listed below.
    - Details of the funding strategy 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.
    - For Knowledge Products, a description of collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. A “Knowledge Product” is a non-materiel product that addresses an identified need, topic area, or capability gap, is based on current evidence and research, aims to transition into medical practice, training, tools, or to support materiel solutions (systems to develop, acquire, provide, and sustain medical solutions and capabilities), and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.
    - A brief schedule and milestones for transitioning the intervention to the next phase of development (i.e., next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by the FDA).

- Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the Government’s ability to access such products or technologies in the future.
- A risk analysis for cost, schedule, manufacturability, and sustainability, if applicable.
- **Attachment 8: Animal Research Plan (if applicable; required for all studies utilizing animals; five-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. For studies using non-gyrencephalic (lissencephalic) animal models of TBI, include justification for their use.
- 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: Regulatory Strategy (if applicable; required for clinical trials; no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named “Regulatory.pdf”.** Answer the following questions and provide supporting documentation as applicable.
  - State the product/intervention name.

***For products/interventions that do not require regulation by the FDA:***

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

***For products that require regulation by the FDA:***

- State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the U.S.
- If the product is marketed in the U.S., state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).
- If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification. Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.
- For the FY19 DMRDP JPC-6/CCCRP MuLTI Award, ***if an IND or IDE is required, the application must be submitted to the FDA prior to or within 60 days of award.*** The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed clinical trial. Provide the date of submission, the application number, and a copy of the FDA letter acknowledging the submission. If there are any existing cross-references in place, provide the application number(s) and associated sponsor(s). Provide an explanation of the status of the application (e.g., past the critical 30-day period, pending response to questions raised by the FDA, on clinical hold, on partial clinical hold, etc.). If the IND or IDE application has been placed on clinical hold or partial hold, explain the conditions that must be met for release of the hold. Provide a summary of any previous meetings with the FDA on development of this product. A copy of the Agency meeting minutes should be included if available. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application.
- If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.
- If an active IND or IDE for the investigational product is in effect, but an amendment is needed to include the proposed trial, describe the type and nature of the

- amendment(s) and the timeline for submission. Indicate whether the amendment increases the risk of the intervention.
- If the clinical trial will be conducted at international sites, provide equivalent information and supporting documentation relevant to the product indication/label and regulatory approval and/or filings in the host country(ies).
  - Provide the current status for manufacturing development (e.g., manufacturer’s name, GMP-compliant lots available, status of stability testing, etc.), non-clinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support Phase I testing, etc.), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).
  - Describe the overall regulatory strategy and product development plan that will support the planned product indication. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy. Include considerations for compliance with current GMP, GLP, and GCP guidelines.
- **Attachment 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.

*Applicants and collaborating organizations may not use, employ, or subcontract for the use of any human participants, including the use of human anatomical substances, human data, and/or human cadavers until applicable regulatory documents are reviewed and approved by the USAMRMC ORP to ensure that DoD regulations have been met.*

- **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). Provide a table of anticipated enrollment counts at each study site. Demonstrate that the research team has access to the proposed study population at each site. 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, including a mitigation plan for slow or low enrollment. Identify ongoing clinical trials that may compete for the same patient population and how they may impact enrollment progress. Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender. *For clinical studies proposing to include military personnel, refer to the regulatory requirements in General Submission Instructions, Appendix 1, for additional information.*

- **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.

- **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.
- **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. FITBIR eligible proposals/applications should include FITBIR consent language (see [Appendix III](#) for sample consent language).***
  - 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:* In compliance with 10 USC 980 (<https://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf>), 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. If applicable, refer to the General Submission Instructions, Appendix 1, for more information.
  - *Assent.* If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.
- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.
  - **Risks/Benefits Assessment:**
    - **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Study risks include any risks that the human subject is exposed to as a result of participation in the clinical trial. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
    - **Risk management and emergency response:**
      - ❖ Describe how safety surveillance and reporting to the IRB and FDA (if applicable) will be managed and conducted.
      - ❖ Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include

safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.

- ❖ Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the cost of such care.
  - ❖ Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).
  - ❖ Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
  - ❖ If the IRB determines that a trial presents greater than minimal risk to human subjects, the DoD requires an independent research monitor with expertise consistent with the nature of risk(s) identified within the research protocol. If applicable, refer to the General Submission Instructions, Appendix 1, Section B (Research Monitor Requirement), for more information on study reporting authorities and responsibilities of the research monitor.
- **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.
- **Attachment 11: Data Management (if applicable; required for all studies recruiting human subjects; no page limit): Upload as “Data\_Manage.pdf”.** The Data Management attachment should include the components listed below.

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.
  - If applicable, address collection and management of data collected to generate FITBIR GUIDs.
- **Confidentiality:**
  - Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality

of study records, particularly those containing identifying information, should be addressed.

- Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of the DoD are eligible to review study records.
- Address requirements for reporting sensitive information to state or local authorities.
- **Data capture, verification, and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, the process for locking the database at study completion, and the length of time data will be stored. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. Describe the database lock process. For FDA-regulated studies, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) are required.
- **Data reporting:** Describe how data, other than that submitted to FITBIR, will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- **Sharing Study Results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.
- **Common and Unique Data Elements (*For FITBIR eligible proposals/applications only*):**
  - Identify and describe the planned CDEs, any UDEs, and alignment to FITBIR data elements and forms. If the proposed research cannot be entered in CDE format, explain why an existing CDE does not apply or is not appropriate.
  - For any UDEs, provide a justification for alternative data submission or data sharing vehicles. Refer to the General Submission Instructions, Appendix 2, Section L, for more information about the CDMRP expectations for making data and research resources publicly available.
- **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: Representations: Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Submission Instructions, Appendix 5, Section B, Representations.
  - **Attachment 13: DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf”.** If a Military Facility (MHS facility, research laboratory, medical treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the DoD Military 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 Submission Instructions, Section III.A.8, for detailed information.
  - **Attachment 14: Study Personnel and Organization (if applicable; required for multi-institutional studies; no page limit): Start each document on a new page. Combine into one document and upload as “Personnel.pdf”.** The Study Personnel and Organization attachment should include the components listed below.
    - **Organizational Chart:** Provide an organizational chart that identifies key members of the study team and provides an outline of the governing structure for multi-institutional studies. Identify collaborating organizations, centers, and/or departments and name each person’s position on the project. Include any separate laboratory or testing centers. Identify the data and clinical coordinating center(s) and note any involvement from Contract Research Organizations, as appropriate. Identify and provide justification for the inclusion of international sites, as appropriate. If applicable, identify the FDA regulatory sponsor and any external consultants or other

experts who will assist with FDA applications. While there is no specified format for this information, a table(s) or diagram is recommended.

- **Study Personnel Description:** Briefly describe the roles of the individuals listed in the organizational chart on the project. Describe relevant experience and qualifications that demonstrate appropriate expertise for the given role, including previous interactions with the FDA, if applicable. An external research monitor (if applicable) and study coordinator(s) should be included.
- **Study Management Plan:** Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial is multi-institutional, clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. Provide a regulatory submission plan for the master protocol and master consent form by the lead organization; include a single IRB/EC pathway whenever possible. If applicable, describe how communication and data transfer between the collaborating institutions will occur, as well as how data, specimens, and/or imaging products obtained during the study will be handled and shared.

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A1681 et seq.), the DoD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in proposals/applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each proposal/application must include the following forms completed as indicated.

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

**Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Submission Instructions, Section III.A.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 PDF format that is not editable.
- **PI Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.
- **Key Personnel Biographical Sketches (six-page limit each):** Upload as “Biosketch\_LastName.pdf”.
- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.

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

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

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

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

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Submission Instructions, Section III.A, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the proposal/application verification period. If these components are missing, upload them to eBRAP before the end of the proposal/application verification period.
- **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 13. (Refer to the General Submission Instructions, Section III.A, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

**Note:** Proposals/Applications from **Federal agencies** must include a **Federal Financial Plan** in their budget justifications. Proposals/Applications from organizations that include **collaborations with DoD Military Facilities** must comply with special requirements. Refer to the General Submission Instructions, Section III.A.5, Research & Related Budget, for detailed information.

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

Applicant organizations and all subrecipient organizations must have a DUNS number to submit proposals/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 proposals/applications through the Grants.gov portal. Verify the status of the applicant organization’s Entity registration in SAM well in advance of the proposal/application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Submission Instructions, Section III, for further information regarding Grants.gov requirements.

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

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

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

#### **Applicant Verification of Full Proposal/Application Submission in eBRAP**

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

The full proposal/application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the proposal/application verification period. During the proposal/application verification period, the full proposal/application package, ***with the exception of the Project Narrative and Budget Form***, may be modified.

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

#### **II.D.5. Intergovernmental Review**

This BAA is not subject to Executive Order (EO) 12372, “Intergovernmental Review of Federal Programs.” The EO provides for state and local government coordination and review of proposed Federal financial assistance and direct Federal development. The EO allows each state to designate an entity to perform this function. This coordination and review is not required under this BAA.

#### **II.D.6. Funding Restrictions**

The requested budget level should be appropriate for the scope of research proposed.

- The maximum period of performance is **3 years (36 months)**.
- **For research proposals/applications with prospective accrual of human subjects and clinical trials:**

The anticipated total costs budgeted for the entire period of performance will not exceed **\$2.5M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the Government exceeding **\$2.5M** total costs or using an indirect cost rate exceeding the organization’s negotiated rate.

- **For all other research proposals/applications:**

The anticipated total costs budgeted for the entire period of performance will not exceed **\$1.0M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the Government exceeding **\$1.0M** total costs or using an indirect cost rate exceeding the organization’s negotiated rate. ]

- All direct and indirect costs of any subaward, contract, or subcontract must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3 years (36 months)**.

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

- Travel costs for the PI to present project outcomes or disseminate project results at one DoD-designated meeting during the period of performance. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

- Travel costs for the PI to present project information or disseminate project results at one DoD-sponsored scientific meeting (e.g., Military Health System Research Symposium) during the period of performance. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Preparation and submission of data to FITBIR (FITBIR budget estimation tool can be found at <https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp>)
- Salary
- Research supplies
- Research-related subject costs
- Clinical research costs
- Support for multidisciplinary collaborations, including travel
- Travel costs for up to two investigators to attend one scientific/technical meeting per year in addition to the required meetings described above. The intent of travel costs to scientific/technical meeting is to present project information or disseminate project results.

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

Funds to be obligated on any award resulting from this BAA will be available for use for a limited time period based on the fiscal year of the funds. The time is considered when establishing the award's period of performance. It is anticipated that awards made from this funding opportunity will be funded with FY19 through FY21 appropriations. FY19 funds will expire for use on September 30, 2025; FY20 funds will expire for use on September 30, 2026; and FY21 funds will expire for use on September 30, 2027.

#### **II.D.7. Other Submission Requirements**

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

### **II.E. PROPOSAL/APPLICATION REVIEW INFORMATION**

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

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

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

- **Research Strategy and Feasibility**

- How well the preliminary data and/or scientific rationale support the research project.
- How relevant and applicable the proposed research and findings are to at least one sub-Area within the FY19 JPC-6/CCCRP MuLTI Award 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 proposal/application acknowledges potential problems and addresses alternative approaches.
- Whether the research can be completed within the proposed period of performance.
- How well the proposal/application 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 proposal/application 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 or will hold the IND/IDE and whether the timeline proposed for IND/IDE application is appropriate (if applicable).
- For FITBIR eligible proposals/applications:
  - How well the study utilizes TBI CDEs and describes processes and timelines for integrating data to the FITBIR Informatics System.
  - If UDEs are utilized, how well the application justifies the rationale for UDE collection.

- **Impact**
  - To what extent the outcomes of the proposed research has the potential to optimize survival and recovery from combat-related or trauma-induced injury in austere environments and when access to definitive medical care is delayed.
  - To what extent the anticipated research outcomes or long-term vision of the proposed research may impact the development of medical solutions for Service members and the public.
  - If applicable, to what degree the proposed materiel or knowledge product represents an improvement to currently available pharmacologic agents, devices, or clinical guidance.
- **Personnel**
  - How 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 the proposed research.
  - How the study team's background, expertise, and record(s) of accomplishment demonstrate their ability to accomplish the proposed work.
- **Ethical Considerations (for studies recruiting human subjects)**
  - 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/power analysis, blinding, randomization, 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.

- **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 BAA.

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

- **Budget**

- Whether the total maximum costs are equal to or less than the allowable total maximum costs as published in the BAA.
- Whether the budget is appropriate for the proposed research.

- **Proposal/Application Presentation**

- To what extent the writing, clarity, and presentation of the proposal/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.

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

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and JPC-6/CCCRP as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Relative impact and innovation
  - Relative military benefit

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

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

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

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

Prior to making an award where the Federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

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

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when determining an organization's qualification prior to award, according to the qualification standards of the DoDGARs or the FAR.

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

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

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

#### **II.F. FEDERAL AWARD ADMINISTRATIVE INFORMATION**

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

Awards will be made no later than September 30, 2020. Refer to the General Submission Instructions, Appendix 2, for additional award administration information.

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

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

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

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

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

An organizational transfer of an award is discouraged and will be evaluated on a case-by-case basis and only allowed at the discretion of the Contracting/Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or

any extension. Refer to the General Submission Instructions, Appendix 2, for general information on changes to applicants and organizational transfers.

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

***Should the PI of a funded project leave the award organization, both the PI and organization must contact the USAMRAA as soon as possible to discuss options for continued support of the research project. Every effort should be made to notify the USAMRAA prior to the PI leaving the organization.***

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

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

Applicable requirements in the FAR, found in 48 CFR, Chapter 1, the DFARS, found in 48 CFR Chapter 2, and the AFARS (Army Federal Acquisition Regulation Supplement), found in 48 CFR Chapter 51, apply to contracts resulting from this BAA.

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

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

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

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

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

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

Quarterly technical progress reports and quad charts will be required.

In addition to written progress reports, in-person presentations may be requested.

**Award Expiration Transition Plan:** An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template titled “Award Expiration Transition Plan,” available on the eBRAP “Funding Opportunities & Forms” web page

(<https://ebrap.org/eBRAP/public/Program.htm>) under the “Progress Report Formats” section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

Awards resulting from this BAA will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Terms and Conditions (see General Submission Instructions, Appendix III, Section A).

## **II.G. FEDERAL AWARDING AGENCY CONTACTS**

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

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

Phone: 301-682-5507

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

### **II.G.2. Grants.gov Contact Center**

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

Phone: 800-518-4726 (International: 1-606-545-5035)

Email: [support@grants.gov](mailto:support@grants.gov)

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

## **II.H. OTHER INFORMATION**

### **II.H.1. Administrative Actions**

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

#### **II.H.1.a. Rejection**

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

- Pre-Proposal/Pre-Application Narrative exceeds the page limit.
- Pre-Proposal/Pre-Application Narrative is missing.

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

- Submissions from intramural applicants to this BAA will be rejected.
- Submission of a proposal/application for which a letter of invitation was not received.
- Project Narrative exceeds the page limit.
- Project Narrative is missing.
- Budget is missing.

*For proposals/applications involving animal research:*

- Attachment 8, Animal Research Plan, is missing.

*For proposals/applications recruiting human subjects:*

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

*For proposals/applications proposing a clinical trial:*

- Attachment 9, Regulatory Strategy, is missing. |

#### **II.H.1.b. Modification**

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

### **II.H.1.c. Withdrawal**

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

- An FY19 DMRDP JPC-6/CCCRP MuLTI Award Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-proposal/pre-application or proposal/application processes including, but not limited to, concept design, proposal/application development, budget preparation, and the development of any supporting documentation. *A list of the FY19 DMRDP JPC-6/CCCRP MuLTI Award Programmatic Panel members can be found at: [https://cdmrp.army.mil/dmrp/panels/19jpc\\_6](https://cdmrp.army.mil/dmrp/panels/19jpc_6).*
- The proposal/application fails to conform to this BAA description.
- An investigator at an intramural organization is named as a collaborator on a proposal/application submitted through an extramural organization, but the proposal/application does not include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.
- 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 proposals/applications. For FY19, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). The programmatic review is performed by the FY19 DMRDP JPC-6/CCCRP MuLTI Award Programmatic Panel. Proposals/Applications that include names of personnel from either of these companies or programmatic panel will be administratively withdrawn.
- 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.

### **II.H.1.d. Withhold**

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

### III.I. PROPOSAL/APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance	Complete form as instructed.	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Impact and Military Benefit: Upload as Attachment 6 with file name "Impact.pdf"	
	Transition Plan: Upload as Attachment 7 with file name "Transition.pdf"	
	Animal Research Plan: Upload as Attachment 8 with file name "AnimRschPln.pdf" (if applicable; required for all studies utilizing animals)	
	Regulatory Strategy: Upload as Attachment 9 with file name "Regulatory.pdf" (if applicable; required for all clinical trials)	
	Human Subjects Recruitment and Safety Procedures: Upload as Attachment 10 with file name "HumSubProc.pdf" (if applicable; required for all studies recruiting human subjects)	
	Data Management: Upload as Attachment 11 with file name "Data_Manage.pdf" (if applicable; required for all studies recruiting human subjects)	
	Representations: Upload as Attachment 12 with file name "RequiredReps.pdf"	
	DoD Military Facility Budget Form(s): Upload as Attachment 13 with file name "MFBudget.pdf" (if applicable)	
Study Personnel and Organization: Upload as Attachment 14 with file name "Personnel.pdf" (if applicable, required for multi-institutional studies)		

<b>Grants.gov Application Components</b>	<b>Action</b>	<b>Completed</b>
Research & Related Personal Data	Complete form as instructed	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed.	

## **APPENDIX I: ACRONYMS AND ABBREVIATIONS**

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
AFARS	Army Federal Acquisition Regulation Supplement
ARDS	Acute Respiratory Distress Syndrome
BAA	Broad Agency Announcement
CCCRP	Combat Casualty Care Research Program
CDE	Common Data Element
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CICA	Competition in Contracting Act
COI	Conflict of Interest
CRADA	Cooperative Research and Development Agreement
DFARS	Defense Federal Acquisition Regulation Supplement
DHA	Defense Health Agency
DHP	Defense Health Program
DMRDP	Defense Medical Research and Development Program
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
EO	Executive Order
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FAQs	Frequently Asked Questions
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
FFRDC	Federally Funded Research and Development Center
FISMA	Federal Information Security Management Act
FITBIR	Federal Interagency Traumatic Brain Injury Research Informatics System
FSD	Federal Service Desk
FY	Fiscal Year
GI	Gastrointestinal

GSA	General Services Administration
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GSI	General Submission Instructions
GUID	Global Unique Identifier
HBOC	Hemoglobin-Based Oxygen Carrier
HIPAA	Health Insurance Portability and Accountability Act
HRPO	Human Research Protection Office
HUBZone	Historically Underutilized Business Zone
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IRB	Institutional Review Board
JPC-6	Joint Program Committee-6
LAR	Legally Authorized Representative
M	Million
MASCAL	Mass Casualty
MDO	Multi-Domain Operations
MHS	Military Health System
MIPR	Military Interdepartmental Purchase Request
MTA	Material Transfer Agreement
MuLTI	Multi-Domain Lifesaving Trauma Innovations
NINDS	National Institute of Neurological Disorders and Stroke
NTP	Neurotrauma Portfolio
NPC	Non-Profit Corporation
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OIF/OEF	Operation Iraqi Freedom/Operation Enduring Freedom
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
PII	Personally Identifiable Information
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SB	Systems Biology
SOW	Statement of Work

STEM	Science, Technology, Engineering, and/or Mathematics
TBI	Traumatic Brain Injury
UDE	Unique Data Element
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
VA	Department of Veterans Affairs

## **APPENDIX II: CCCRP VISION STATEMENT**







## **APPENDIX III: SAMPLE FITBIR CONSENT LANGUAGE**

Data from this study may be submitted to the Federal Interagency Traumatic Brain Injury (FITBIR) informatics system. FITBIR is a computer system run by the National Institutes of Health that allows researchers studying traumatic brain injury to collect and share information with each other. With an easier way to share, researchers hope to learn new and important things about traumatic brain injury more quickly than before.

During and after the study, the researchers will send information about you or your child's health and behavior and in some cases, you or your child's genetic information, to FITBIR. However, before they send it to FITBIR, they will remove information such as name, date of birth, and city of birth, and replace that information with a code number. Other researchers nationwide can then file an application to obtain access to your study data for research purposes. Experts who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You or your child may not benefit directly from allowing your information to be shared with FITBIR. The information provided to FITBIR might help researchers around the world treat future children and adults with traumatic brain injury so that they have better outcomes. FITBIR will report on its website about the different studies that researchers are conducting using FITBIR data; however, FITBIR will not be able to contact you or your child individually about specific studies.

You may decide now or later that you do not want to share you or your child's information using FITBIR. If so, contact the researchers who conducted this study, and they will tell FITBIR, which can stop sharing the research information. However, FITBIR cannot take back information that was shared before you changed your mind. If you would like more information about FITBIR, this is available on-line at <http://fitbir.nih.gov>

### **Language to be used to describe certificates of confidentiality (3 versions):**

#### **1. Language for new studies that will be consenting subjects for the first time or for ongoing studies that will be re-consenting subjects because they are applying for a Certificate of Confidentiality (COC) for the study**

To help protect you and/or your child's privacy the investigators of this study [have applied for]/[have obtained] a Certificate of Confidentiality from the National Institutes of Health, part of the U.S. Department of Health and Human Services (DHHS), an agency of the U.S. Government.

With this Certificate, we, the investigators, cannot be forced (e.g., by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Be aware that disclosure of you and/or your child's identity may be found necessary, however, upon request of DHHS for the purpose of audit or evaluation.

You should also understand that a Confidentiality Certificate does not prevent you or a member of your family from **voluntarily** releasing information about your child, yourself, or your involvement in this research. Note however, that if an insurer or employer learns about you

and/or your child's participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

We are also asking your consent to provide research data and related findings to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system. FITBIR is a biomedical informatics system and data repository, created by the Department of Defense and the National Institutes of Health to assist biomedical researchers working to develop a better understanding of traumatic brain injury and/or to develop more effective methods to diagnose, treat and prevent traumatic brain injuries.

Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by qualified researchers only. Data provided to FITBIR as part of you and/or your child's participation in this research study will be de-identified—i.e., you and/or your child's name will be separated from the data. However, since this institution and others submitting data to FITBIR will retain individually identifying information related to the data they provide, NIH has issued a legislatively authorized "Certificate of Confidentiality" that will help FITBIR and participating institutions avoid being forced to disclose information that may identify you as a FITBIR participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Finally, you should understand that we, the investigators, are not prevented from taking steps, including reporting to authorities, to prevent serious harm to you, your child, or others. With respect to you and/or your child's participation in FITBIR, we do not plan to make voluntary disclosures except if there were severe threats to the public health or safety.

## **2. Language for studies that already have a Certificate and will be re-consenting subjects about FITBIR**

With your consent, this study will collect and provide research data and related findings to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system. FITBIR is a biomedical informatics system and data repository created by the Department of Defense and National Institutes of Health—part of the U.S. Department of Health and Human Services (DHHS), an agency of the U.S. Government—to assist biomedical researchers working to develop a better understanding of traumatic brain injury and/or to develop more effective methods to diagnose, treat and prevent traumatic brain injury.

Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by researchers only. Data provided to FITBIR as part of you and/or your child's participation in this research study will be de-identified—i.e., you and/or your child's name will be separated from the data. However, since this institution and others submitting data to FITBIR will retain individually identifying information related to the data they provide, NIH has issued a legislatively authorized "Certificate of Confidentiality" to help FITBIR and participating institutions avoid being forced (e.g., by court subpoena) to disclose information that may identify you as an FITBIR participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Be aware that disclosure of you and/or your child's identity may be found necessary, however, upon request of DHHS for the purpose of audit or evaluation.

As you know, we have obtained a Certificate of Confidentiality from NIH that enables us to keep the individually identifiable information that you provide as a research subject private. With this Certificate, we, the investigators cannot be forced to disclose research information collected in this study that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. This protection will continue to protect you and/or your child's privacy even though we are providing de-identified data to FITBIR.

You should also understand that a Confidentiality Certificate does not prevent you or a member of your family from **voluntarily** releasing information about your child, yourself, or your involvement in this research. Note however, that if an insurer or employer learns about you and/or your child's participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Finally, as we explained when we told you about this privacy protection before, we, the investigators, are not prevented from taking steps, including reporting to authorities, to prevent serious harm to you and/or your child or others based on information they learn during this study. With respect to you and/or your child's participation in FITBIR, we do not plan to make voluntary disclosures except if there were severe threats to the public health or safety.

### **3. Language for studies without a Certificate of their own**

With your consent, this study will collect and provide research data and related findings to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system. FITBIR is a biomedical informatics system and data repository created by the Department of Defense and the National Institutes of Health—part of the U.S. Department of Health and Human Services (DHHS), an agency of the U.S. Government—to assist biomedical researchers working to develop a better understanding of traumatic brain injury and/or to develop more effective methods to diagnose, treat and prevent traumatic brain injury.

Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by researchers only. Data provided to FITBIR as part of you or your child's participation in this research study will be de-identified—i.e., you and/or your child's name will be separated from the data. However, since this institution and others submitting data to FITBIR will still retain individually identifying information related to the data provided, the NIH has issued a legislatively authorized "Certificate of Confidentiality" to help FITBIR and participating institutions avoid being forced (e.g., by court subpoena) to disclose information that may identify you as an FITBIR participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Finally, you should understand that we, the investigators, are also permitted to make voluntary disclosures with respect to information that is submitted to FITBIR, but do not plan to do so except in the event of severe threats to public health or safety. If, as part of your participation in this research study itself, we learn about serious harm to you, your child or someone else, we would take steps to prevent that harm including notifying appropriate authorities like the police or child welfare.