

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Broad Agency Announcement

For Extramural Biomedical Research and Development

Department of Defense

United States Special Operations Command

Announcement Type: Initial

Funding Opportunity Number: W81XWH-17-R-SOC1

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Release/Posted Date: May 5, 2017**
- Pre-proposal submissions can be submitted throughout the open period of the BAA which is May 05, 2017 through May 04, 2018. The Government intends to review pre-proposals in three submission cycles. To be evaluated during one of these cycles, pre-proposals need to be submitted in accordance with the following:

Key Dates for First Cycle Submissions

- **Pre-proposal Submission for the first Program Review is due by 11:59 P.M. Eastern Time (ET), July 28, 2017**
 - Invitations to submit full proposals will occur on or about September 1, 2017
 - Full proposals will be due for the first Program Review by 11:59 P.M. Eastern Time (ET) on the 30th day after the invitation to submit letter has been sent.

Key Dates for Second Cycle Submissions

- **Pre-proposal Submission for the second Program Review is due by 11:59 P.M. Eastern Time (ET), November 3, 2017.**
 - Invitations to submit full proposals will occur on or about December 15, 2017

- Full proposals will be due for the second Program Review by 11:59 P.M. Eastern Time (ET) on the 30th day after the invitation to submit letter has been sent.

Key Dates for Third Cycle Submissions

- **Pre-proposal Submission for the third Program Review is due by 11:59 P.M. Eastern Time (ET), April 14, 2018**
 - Invitations to submit full proposals will occur on or about May 14, 2018
 - Full proposals will be due for the third Program Review by 11:59 P.M. Eastern Time (ET) on the 30th day after the invitation to submit letter has been sent.
- BAA Closes at 11:59 P.M. Eastern Time (ET) May 04, 2018
- **NOTE:** This BAA is an open and continuous announcement through May 04, 2018. Applicants invited to propose, but not selected, may be considered for subsequent cycles and awards for 24 months. Pre-proposal/pre-applications can be submitted through the closing dates listed for each programmatic review cycle. Three planned program reviews occur to assess pre-proposal/pre-application submissions. To have your pre-proposal/pre-application reviewed in a focused timeline, please submit by the dates listed above.
- Full proposal/full applications must be submitted according to the schedule as specified by the US Army Medical Research Acquisition Activity (USAMRAA) when you are notified to submit via an invitation letter from eBRAP.

This Broad Agency Announcement must be read in conjunction with the General Submission Instructions. 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

II.A. Program Description

Applications to the Fiscal Year 2017 (FY17) Broad Agency Announcement (BAA) for Extramural Biomedical Research and Development are being solicited for the United States Special Operations Command (USSOCOM), by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). The USSOCOM executes its extramural research program primarily through the award of contracts and assistance agreements (grants and cooperative agreements). The type of instrument used to reflect the business relationship between the organization and the government will be determined by the Contracting/Grants Office prior to negotiation of the award.

The USAMRAA will negotiate the award types for proposals/applications selected for funding. The Federal Grant and Cooperative Agreement Act of 1977, 31 USC 6301-6308, provides the legal criteria to select a procurement contract or an assistance agreement.

This BAA is intended to solicit extramural research and development ideas and is issued under the provisions of the Competition in Contracting Act of 1984 (Public Law 98-369), as implemented in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016 and in DoD Grant and Agreement Regulations (DoDGARS) 22.315. In accordance with FAR 35.016, projects funded under this BAA must be for basic and applied research to support scientific study and experimentation directed towards advancing the state of the art or increasing knowledge or understanding rather than focusing on development of a specific system or hardware solution. Research and development funded through this BAA are intended and expected to benefit and inform both military and civilian medical practice and knowledge.

The selection process is highly competitive and the quantity of meaningful proposal/applications (both pre-proposal/pre-applications and full proposal/full applications) typically received exceed the number of awards that available funding can support.

This BAA provides a general description of USSOCOM's research and development programs, including research areas of interest, evaluation and selection criteria, pre-proposal/pre-application and full proposal/application preparation instructions, and general administrative information. **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.**

The USSOCOM's supporting contracting office, USAMRAA will process proposals/applications selected for funding. The Grants/Contracting Officers at USAMRAA are the only individuals authorized to commit funds and bind the Government for awards to be funded under this Announcement.

II.A.1. FY17 SOCOM Research Areas of Interest

Special Operations Forces (SOF) medical personnel place a premium on medical equipment that is small, lightweight, ruggedized, modular, multi-use, and designed for operation in extreme environments. The equipment should be easy to use, require minimum maintenance, and have low power consumption. Drugs and biologics should not require refrigeration or other special handling. All materiel and related techniques should be simple and effective. Research projects may apply existing scientific and technical knowledge for which concept and/or patient care efficacy have already been demonstrated to meet SOF requirements. The following Research Areas of Interest (RAIs) are in no particular order.

1. Medical Simulation and Training Technologies:

The proposed project should research, apply and/or develop improved pre-hospital combat casualty training with an emphasis on the SOF pre-hospital providers. Medical simulations should replicate all phases of the pre-hospital combat environment, including care under fire, tactical field care and casualty evacuation. Human-like simulators should bleed, breath, void, have a physiologically relevant temperature, pulse, and response to medical care with little to no operator/controller input, should be all-weather capable and should evoke an emotional response from those with whom it interacts. Medical training simulations should capture and be capable of providing a report on the timing, appropriateness, and effectiveness of medical treatment. All simulators/simulations should meet Joint airworthiness standards. Proposals that result in a working prototype that can be field tested in cooperation with SOF training sites are encouraged.

2. Damage Control Resuscitation:

SOF medical personnel require capabilities for far-forward medical care to reduce the mortality and morbidity associated with major battlefield wounds and injuries. The primary emphasis is to research, apply and/or develop medical techniques and materiel (medical devices and biologics) for optimal triage and early intervention in life-threatening battle injuries when casualty evacuation is not possible. The project areas under “Damage Control Resuscitation” to which SOF will give highest consideration are:

a. Global Treatment Strategies and Next Generation Wound Management:

The proposed project should research, apply and/or develop effective treatment strategies that address the following elements: hypotensive resuscitation, optimal fluid(s), uncomplicated shock, non-compressible hemorrhaging, traumatic brain injuries, and austere damage control surgery. These strategies should be optimized for medics in austere, far-forward areas, with minimal logistical or specialty support, who should stabilize and treat patients for extended periods (days, not hours). Projects that research and develop an all-in-one traumatic wound care treatment that can achieve hemostasis, incorporate analgesia, deliver antibiotics, and start tissue regeneration are encouraged.

b. Analgesia:

The proposed project should research, apply and/or develop novel, safe, efficacious, peripherally and centrally acting analgesia that provide easy administration in the field, tolerance of extreme

environments, and effectiveness at the point of injury for a prolonged period of field care (days, not hours) and does not sensitize the patient to topical analgesia. Maximum analgesia with minimal sedation is encouraged.

c. Far Forward Blood, Blood Components, Blood Substitute, & Injectable Hemostatic:

The proposed project should research novel strategies to increase the ease, efficacy, and safety of blood transfusion (i.e. person to person, pre-hospital blood banking, blood substitutes) forward of normal logistics support; (e.g., evaluating blood for type/cross matching and for the presence of pathogens to include point of injury AB antibody titer). Projects that will be considered also include other blood components such as freeze dried plasma and platelets, cryoprecipitate, fibrinogen, prothrombin complex concentrate and injectable medications to address the coagulopathy of trauma such as Tranexamic acid. Research focused on extending shelf life of whole blood beyond current limitations. A long term objective is a blood substitute that is comparable in size, weight of traditional blood products, and effectively functions like fresh whole blood without requiring refrigeration. Strategies to find the delivery of these prototypes individually or in concert will also be considered. Projects that are oriented towards solutions or prototypes that are shelf stable requiring minimal to no refrigeration as well as those that are capable of carrying oxygen are encouraged.

d. Austere Surgical Stabilization:

Future theatres where SOF personnel will operate are likely to be much less medically robust than the past decade of fighting in our current theatres. Rather than sitting at hardened structures waiting on patients, surgical personnel may be increasingly asked to go to the patient. Research should focus on mobility/portability of medical and surgical equipment, with emphasis on equipment with greater capabilities than currently fielded devices, smaller size and weight, low power demands, and flexibility in power supplies. Telehealth technologies linking forward surgical providers with higher medical authority consultation and effective, relevant, dynamic, surgical training capabilities. Research may also include a human systems approach to define limitations and mitigation strategies of surgical capability in austere environments (i.e. low light, temperature variability, surgery in-flight).

3. Prolonged Field Care (PFC):

SOF medical personnel require capabilities for far-forward medical care to reduce the mortality and morbidity associated with major battlefield wounds, injuries, diseases, and associated sepsis. Prolonged Field Care should focus on novel treatments that support the ability to manage 3-5 patients across the spectrum of illness to multi system injury for a minimum of 5-7 days. Significant consideration will be given to proposals focused on Prolonged Field Care that may also relate to Sections 2 (a-d) and 4(a-b) of this section.

a. Medical Devices:

The primary emphasis is to research, apply and/or develop medical techniques, pharmaceuticals, biologics and field sustainable, rapidly deployable medical devices for extended care beyond initial trauma resuscitation, to include austere/forward surgery while operating in disease endemic areas where casualty evacuation is delayed or unavailable.

b. Telehealth Technology:

PFC considerations should also focus on Telehealth capabilities for the far forward medic and sensor development as it relates to patient monitoring and transmission to COTS medical monitors. (Also referenced in Section 2d)

4. Portable Lab Assays and Diagnostics:

The proposed project should research, apply and/or develop novel concepts for portable and environmentally stable far forward laboratory assays and diagnostics. Equipment should be extremely portable, ruggedized, use limited or no external power and any reagents should be self-contained and stable in extreme environmental conditions. Proposals that are field oriented, rugged, low weight/cube space and have little to no refrigeration requirements are encouraged.

a. Biological:

The proposed project should research, apply and/or develop sensitive and specific methods of identifying and diagnosing antigens, antibodies, viruses, and bacteria in biological materials, including the development of sensitive and specific immunologic, chemical or biological assays suitable for use by first responders for rapid and reliable diagnostics of potential biological threats both from environmental or patient sample and identification of toxins in biological samples. In addition, there is interest in the research and development of therapeutic measures for treatment of infectious diseases of military relevance, including but not limited to Malaria, Dengue, Chikungunya, Zika, Leptospira, Crimean-Congo Hemorrhagic Fever, Ebola, Lassa, and Plague. Other focus areas include rapid, accurate identification and the ability to assess normal infectious processes (i.e. gram +/-, fungal, and viral infections) to include the ability to do blood panels to properly assess a multi system trauma in a long term field care setting (CBC, Chem 11, LFT, lactate, VBG/ABG, Coag Panel, CBRN lab assays and diagnostics). Technologies (ISTAT type testing capability, Lyophilize paper tests, mini microscopes and/or small/portable tech-leveraging android based products for lab) to rapidly identify the presence of diseases of military relevance within arthropods and vectors present to assist in determining health risk, personal protective measures and potential impacts to SOF forces.

b. Occupational and Environmental Health (OEH) Hazards:

The proposed project should focus on development of novel methods and devices for rapid identification and analysis of exposures to OEH hazards. Research should support the development and analysis of hand held field hardened and environmentally stable analytical devices, monitoring devices, dosimetry, assays for rapid on-site identification, and real-time analysis of OEH hazards in air, water, and soil that could pose an acute or chronic health hazard to SOF personnel. Such OEH hazards include toxic industrial chemicals/toxic industrial materials (TICs/TIMs), lead exposures, food and water borne pathogens, toxins, biological agents, and radiological material exposures. Research consideration should be given to development of small lightweight programmable submersible unmanned aerial vehicles (UAV) to conduct environmental analysis of OEH hazards in water, air and soil. UAVs should be capable of travel to designated locations, conduct point of collection analysis of OEH hazards, transmit data and return to originating base.

5. Force Health Protection and Environmental Medicine:

SOF personnel must often operate for extended periods of time in austere environments that expose them to extremes in altitude, temperature, humidity, wind, kinetosis, infectious diseases, toxic industrial chemicals, toxic industrial materials, and environmental hazards (including envenomation in marine environment). In addition, the environment may be compromised due to chemical, biological, and radiological contamination. The primary emphasis of this research area is to research, apply and develop techniques, therapeutic measures, and materiel (personal protective equipment (PPE), medical devices, drugs, and biologics) to ensure sustained human performance and effectiveness while operating in harsh environmental conditions and/or wearing appropriate PPE. Additional research opportunities include identification and characterization of specific risk profiles/threats associated with SOF unique mission sets.

a. Optimal Acclimatization Strategy:

The proposed project should research, apply and/or develop novel approaches that provide rapid and sustainable human acclimatization, to include fatigue counter actions, for extremes in temperature, altitude and time-zone change (circadian acclimatization).

b. Chemical, Biological, Radiological, Nuclear, and Explosive (CBRNE) Rapid Diagnostics, Treatment, and Prophylaxis:

The proposed projects should research and apply and/or develop novel approaches that will diagnose, treat and protect human exposure to chemical, biological, radiological, nuclear, and high yield explosives in near real time.

c. Prevention of Occupational Lead Exposure:

Lead is a potent neurotoxin, with no safe level for human exposure. Current regulation is outdated and allows for lead exposure beyond medically acceptable levels. The proposed project should research, apply or develop novel approaches to the elimination, substitution, engineering controls, administrative controls and personal protective equipment that can eliminate lead exposure while allowing optimum training. Focus on optimum design and retrofitting of training facilities should be emphasized. Eliminating respiratory absorption of lead should be the primary focus.

6. Canine Medicine:

SOF personnel rely on canines' exceptional capabilities as combat multipliers. This research area explores alternatives and/or new approaches to preserve and enhance SOF canine combat performance. SOF medical personnel place a premium on canine-specific approaches that are effective in extreme environments and do not require significant additional logistical support (i.e. maximize use of available SOF Medic materiel). The six "Canine Medicine" project areas, to which SOF will give consideration, are:

a. Environmental Extremes:

Project proposals should research and apply and/or develop novel strategies that address acclimatization to acute extremes in temperature, altitude, and/or time zone change (circadian acclimatization), and/or prolonged marine environmental exposure in SOF canines.

b. Sensory Optimization and Protection:

Research should be oriented toward innovative methods that enhance or conserve SOF canine olfactory, visual, and/or auditory performance during combat operations.

c. Trauma Resuscitation:

Research should support development of innovative techniques/strategies for canine trauma resuscitation (e.g. hypotensive resuscitation, whole blood/blood component replacement, non-compressible hemorrhaging), particularly to address ballistic projectile injuries, in diverse/austere environments that lack immediately available medical evacuation or restorative surgical capacity. Note: Research should minimize or refrain from utilizing canine specific equipment or devices; this will allow treatment from existing trauma kits fielded by SOF medics.

d. Non-Traditional Anesthesia Protocols:

Project proposals should seek to develop novel approaches for routine and emergency/post-traumatic canine field sedation and/or anesthesia in diverse environments and utilizing pharmaceuticals available to SOF Medics.

e. Optimizing Canine Performance and Nutrition:

Project proposals should research and apply and/or develop novel strategies that address optimization of canine performance through improved physical conditioning programs, enhanced nutrition, and genetics research.

f. Pre and Post Trauma Training / Behavioral Issues:

Research should address unique approaches to diagnosing and treating SOF-peculiar training and post-traumatic canine behavioral issues, in order to optimize pre-purchase selection and post-purchase training strategies across the enterprise and restore performance in canines with behavioral and/or post-trauma issues.

7. Human Operational Performance

a. Sleep Restoration:

The proposed project should research, apply and/or develop novel approaches to achieve the restorative effects of sleep through methods requiring less time (i.e. you get the effects of sleeping eight hours in four hours of time) or enabling the SOF operator to quickly reach the stages of sleep where highest restoration effects occur.

b. Enhanced Physiological & Mental Performance:

Develop technologies to maximize the physiological performance of operators, including greater mental acuity, increased endurance, enhanced senses, and tolerance to environmental extremes, in order to maintain operational posture/ability in high stress scenarios without noticeable augmentation and without hampering personnel mobility.

c. Diagnostics for Performance Sustainment:

The proposed project should research, apply and/or develop salivary diagnostic devices to provide genetic prediction of injury, response to training, and response to performance enhancement interventions.

d. Nutritional Status:

The proposed projects should research and/or apply methods to accurately measure nutritional status in SOF operators. The proposed project should focus on cost effectiveness, accuracy and end-user compatibility (user friendly) methods or devices for identifying an individual's nutrient status.

e. Pharmaceutical and Nutritional Supplement interactions:

The proposed project should research, apply and/or develop novel approaches to determining what, if any meaningful interactions occur between and among SOF-common medications (OTC or Rx) and commonly ingested and commercially available nutritional supplements.

f. Optimal Performance Strategy:

The proposed project should research, apply and/or develop novel approaches that provide rapid and sustainable human performance for austere environments and/or the SOF training calendar.

II.B. Award Information

It is estimated that approximately \$3million is available for this BAA, and the number of awards is indeterminate and contingent upon funding availability. Selection of research projects is a highly competitive process and is based on the evaluation of the proposal/application's technical merit, programmatic considerations, and **the availability of funds**. The quantity of meaningful submissions received (both pre-proposals/pre-applications and full proposals/applications) normally exceeds the number of awards that the available funding can support. Any funding that is received by the USSOCOM and is appropriate for a research area described within this BAA may be utilized to fund proposals/applications. Refer to Section II.D.5., Funding Restrictions, for detailed funding information.

A budget should be commensurate with the nature and complexity of the proposed research. Researchers should submit budgets that include the entire period of performance of the research project. Budgets should include all direct and indirect costs, based on supportable, verifiable estimates. The budget for the full proposal/application should not differ significantly from the Pre-Proposal/Pre-Application Budget Summary Form provided in the pre-proposal/pre-application submission.

Start dates will vary depending upon when proposals/applications were submitted and reviewed and the negotiation process. However, no proposal/application submitted under this BAA will be considered for funding after 24 months from the date of submission to Grants.gov.

PIs seeking additional or continuation funding must submit new pre-proposals/pre-applications and be invited to submit full proposals/applications.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All Department of Defense (DoD)-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application. Submission to HRPO of protocols covering more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol as DoD-supported research and may include extensive modifications to meet DoD human subjects protection requirements. Refer to the General Submission Instructions, Appendix 6, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

PIs 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, or laboratory animals until applicable regulatory documents are approved by the USAMRMC ORP to ensure that DoD regulations have been met.

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

The USSOCOM intends that information, data, and research resources generated under assistance agreements funded by this Broad Agency Announcement be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Submission Instructions, Appendix 4, Section K. Contracts awarded under this BAA will be governed by the Federal Acquisition Regulation (FAR) and Defense FAR Supplement (DFARS) provisions.

Awards will be made no later than May 04, 2018. For additional information refer to General Submission Instructions, Appendix 4.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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 USSOCOM is committed to supporting small businesses. Small business, veteran-owned small business, service-disabled veteran-owned small business, HUB Zone 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 applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

Subcontracting Plan: If the resultant award is a contract that exceeds \$700,000 and the offeror is a large business or an institution of higher education (other than Historically Black Colleges and Universities/Minority Institutions), the contractor will be required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.7. A mutually agreeable plan will be incorporated as part of the resultant contract.

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

II.C.1.b. Principal Investigator: Includes individuals, regardless of ethnicity, nationality, or citizenship status, who are employed by, or affiliated with, an eligible organization.

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

II.D. Application and Submission Information

II.D.1. Addresses to Request an Application Package

The Congressionally Directed Medical Research Program (CDMRP) office is the management agent for administrative matters pertaining to this BAA; in general, this includes management of the new eBRAP system, receipt and processing of pre-proposals/pre-applications submitted through eBRAP, and retrieval and processing of full proposals/applications submitted to Grants.gov.

Submitting Organizations: Pre-application content and forms can be accessed at the electronic Biomedical Research Application Portal (eBRAP) <https://eBRAP.org>.

Submitting Organizations: Full proposal/application (submission) packages can be accessed at Grants.gov. Perform a basic search in Grants.gov for **W81XWH-17-R-SOC1**.

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

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

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

Pre-Application Submission: All pre-applications from organizations must be submitted through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>). The organization, Business Official, and PI must register in eBRAP before submitting a pre-proposal/pre-application. Upon completion of an organization's registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization's Business Officials and PIs as they register. The organization, Business Officials, and PIs must all be registered and affiliated in eBRAP. Additional information is included in Section II of the GSI.

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

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

Submitting Organizations: Full applications from organizations must be submitted through Grants.gov. 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.

For Submissions: A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Broad Agency Announcement requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Broad Agency Announcement.

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

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

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

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

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

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

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

- **Tab 1 – Application Information**

Enter the information as described in eBRAP before continuing the pre-proposal/pre-application.

- **Tab 2 – Application Contacts**

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

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

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

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

Enter the name, organization, and role of all collaborators and key personnel associated with the application (including co-investigators, mentors, collaborators, consultants, and subrecipients/subawardees).

FY17 Programmatic Panel members should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c., Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

The Initiating PI must enter the contact information for each Partnering PI in the Partnering PI section, if multiple PIs are applicable.

To enable the USSOCOM to avoid conflict of interest during the screening and review processes, list the name, organization, and role of all scientific participants in the proposed research project, including co-investigators, mentors, collaborators, consultants, and subrecipients/subawardees.

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

List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). All awards must be free of Conflicts of Interest (COIs) that could bias the research results. Prior to award, applicants will be required to disclose all potential or actual COIs along with a plan to manage them. An award may not be made if it is determined by the Contracting Officer or Grants Officer that a COI cannot be adequately managed. Refer to the General Submission Instructions, Appendix 1, for additional information.

Federal agency personnel involved in the review process and/or with making funding recommendations are prohibited from being involved in the conference or symposium support proposed or assisting in any pre-proposal, including, but not limited to, application development, budget preparation, and the development of any supporting documentation. *If formal collaboration with Military Facility personnel is planned (i.e., included in the proposal/application in performance of the research), this prohibition is not applicable. However, these Military Facility personnel cannot be involved in the review process and/or with making funding recommendations.*

All conflicts or potential conflicts of interest must be disclosed, along with a plan to mitigate the conflict, with the application submission. An assistance agreement or contract may not be awarded if it is determined by the respective Grants or Contracting Officer that a conflict of interest cannot be avoided or managed. Refer to the General Submission Instructions, Appendix 1, Section C, for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

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

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

The Pre-proposal Narrative should include the following:

- **Problem to Be Studied:** Describe the perceived issue(s) and the problems to be studied. This section should serve as an abstract of the proposed work.
- **Theoretical Rationale, Scientific Methods, and Design:** Describe how the research approach for accomplishing the specific aims is feasible, will accomplish the objectives, will provide information on proposed methods and analysis/ evaluation strategies, and is based on sound rationale. Describe how the proposed work and research will create and produce a demonstration and validation/proof of concept to meet the subject Topic Area.

- **Background/Rationale:** Clearly present the ideas and reasoning behind the proposed research. Include relevant military and civilian literature citations, preliminary and/or pilot data, and/or other evidence that led to the development of the proposed research. Any preliminary data should be from the laboratory of the PI or member(s) of the collaborating team.
 - **Hypothesis/Objective and Specific Aims:** State the proposed project's hypothesis and/or objectives and the specific aims/tasks of the proposed research.
 - **Approach/Methodology:** Describe the research approach. Include research design, methods, and analysis/evaluation strategies as well as materials anticipated to be used during the research. Include a description of human use in the proposed project. For studies involving human subjects, include a description of the size, characteristics, and partnering organizations of the subject population that will be employed.
- **Significance, Relevance, and Innovation of the Proposed Effort**
- **Significance and Relevance:** Clearly articulate how the proposed research is instrumental in addressing research gaps, meets military requirements, and has military relevance to improving theater/operational medicine.
 - **Innovation:** Explain how the proposed project is innovative and not an incremental advancement of previous work.
- **Proposed Study Design/Plan:** Provide the intended research methodology that will support the study. Provide preliminary information such as description and background of the technical solution, anticipated success criteria, research/test plan(s), and statistical protocols. Refer to Section II.A., Program Description, for additional information on the research areas of interest for this BAA.
- **Military Impact:** Describe the anticipated short- and/or long-term outcomes of the proposed project and their potential impact on improving technologies, data and/or processes. Refer to Section II.A., Program Description, for additional information on the anticipated outcomes sought by this BAA.
- **Personnel and Facilities:** Describe the role of the PI, co-PIs (if applicable), key personnel, sub-awards (if applicable), and consultants (if applicable) in the research team, including the expertise each brings to the proposed project. Explain how the team's expertise is appropriate and complementary for achieving the research goals. Also, briefly provide

information on the primary facility where the research is expected to be performed.

- **Open Source/License/Architecture:** Describe the intellectual property that is intended to be incorporated within the design/plan and identify any additional costs, such as licensing, which may be needed to ensure flexibility or adaption of the research project for Government use.

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 PDF documents* and are limited to:

- **References Cited (one-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).
- **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 (five-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 one-page Quad Chart Form (available for download in eBRAP) as instructed.

- **Tab 6 – Submit Pre-Application**

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

Pre-Application Screening

- **Pre-Application Screening Criteria**

- The USSOCOM scientists or outside experts will screen pre-proposals/pre-applications for technical merit and programmatic considerations. Based on the screening of the pre-proposal/pre-application, a PI may be invited to submit a full proposal/application. Pre-proposals/pre-applications will be screened based on the following criteria, listed in descending order of importance:

To determine the technical merits of the pre-application and the relevance to the mission of the USSOCOM, pre-applications will be screened based on the following criteria:

1. **Theoretical Rationale, Scientific Methods, and Research:** To what degree the research approach for accomplishing the specific aims is feasible, will accomplish the objectives, will provide information on proposed methods and analysis/ evaluation strategies, and is based on sound rationale. To what degree the proposed work and research will create and produce a demonstration and validation/proof of concept to address the Topic Area.
2. **Significance, Relevance, and Innovation:** To what degree the proposed research is relevant and innovative, including whether the proposed research is duplicative of existing research.
3. **Study Design/Plan:** To what degree the proposed demonstration and validation study methodologies, anticipated sample and sample size, test plan(s), anticipated success criteria, evaluation criteria/metrics, and statistical protocols will justify and support the intended outcomes of the proposed research.
4. **Military Impact:** To what degree the project's anticipated short- and/or long-term outcomes will impact the military and provide advancement in theater/operational medicine in the military health system in a way that is consistent with the intent of the award mechanism.
5. **Personnel, Facilities, Timelines, and Budget:** To what degree the expertise, experience, and knowledge of the key research personnel (including co-PIs if applicable), sub-awards (if applicable), and consultants (if applicable) are appropriate and complementary for achieving the research goals. To what degree the prime facility will be able to perform the proposed research.

Notification of Pre-Application Screening Results

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-proposals/pre-applications. The estimated time frame for notification of invitation to submit an application is indicated in Section I, Overview of the Funding Opportunity, of this Broad Agency Announcement. Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above. A recommended for funding notification is NOT an authorization to begin performance or a guarantee of an award.

The organization and PI will have registered in eBRAP during the pre-proposal/pre-application stage. This will permit an organization's representatives and PIs to be able to view and modify Grants.gov proposal/application submissions associated with them, but only if the organization, Business Officials, and PIs are registered and affiliated in eBRAP.

Proposal/Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. Modification of proposal/application components is permitted at any time *within 5 calendar days of proposal/application submission to Grants.gov, i.e., the verification period*. If modification and/or verification are not completed by the end the verification period, the proposal/application will be reviewed as submitted through Grants.gov, provided there is no cause for administrative rejection of the proposal/application.

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

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

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

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

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

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

Table 1. Full Application Submission Guidelines

Download application package components for W81XWH-17-R-SOC1 from Grants.gov (http://www.grants.gov)
SF424 (R&R) Application for Federal Assistance Form: Refer to the General Submission Instructions for detailed information.
Descriptions of each required file can be found under Full Application Submission Components: <ul style="list-style-type: none"> • Attachments • Research & Related Senior/Key Person Profile • Research & Related Budget • Project/Performance Site Location(s) Form • R&R Subaward Budget Attachment(s) Form (if applicable)
Submit package components to Grants.gov (http://www.grants.gov).

If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application submission deadline.

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

Refer to Section II of the General Submission Instructions for further information regarding Grants.gov requirements.

The organization’s Business Official or Authorized Organization Representative (or Resource Manager/Comptroller) should approve/verify the full application submission prior to the application verification deadline.

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

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

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

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

SF424 (R&R) Application for Federal Assistance Form: Refer to the General Submission Instructions, Section II, for detailed information.

Attachments: 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 incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply

in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire full application package may not exceed 200 MB.

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in Appendix 2 of the General Submission Instructions.

- **Attachment 1: Project Narrative (20-page limit).** Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the information below.

- **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations or preliminary data on the proposed technical solution(s) and how they may have been utilized in similar environment(s). Describe previous experience most pertinent to this project. Any preliminary data should be from the laboratory of the PI or member(s) of the collaborating team.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims. If this research project is part of a larger study, present only the tasks that this award would fund.
- **Project Design:** Describe and define the research design, methods, and analyses/evaluations in sufficient detail for analysis.
 - Clearly support the choice of study variables/metrics and explain the basis for the research questions and/or study hypotheses. Establish the relevance of the study and explain the applicability of the proposed findings.
 - Provide a detailed protocol, including but not limited to, proposed methodologies, research/test plan(s) and criteria, intended medical domain(s) or discipline(s), control groups, and defined statistical models.
 - Define the study variables (independent/dependent) and define how they will be measured. Include a description of appropriate controls and the endpoints to be tested. Describe how data will be collected and analyzed in a manner that is consistent with the study objectives. Describe a plan for data access and outcome dissemination.
 - For development of devices and technologies, discuss the engineering/technical design that will be used to achieve the project goals,

demonstrating the feasibility of the proposed product development. Discuss the perceived engineering/design strengths and flaws and recommendations for overcoming/preventing them.

- Address all potential barriers and provide plans for addressing potential delays, unexpected events, changes in key personnel, and ongoing adaptation of the application. Provide a risk management plan to address barriers to plans. As relevant, describe plans for addressing potential issues unique to working within the military health system.
- Document the availability and accessibility of the study materials (including data) needed as applicable.

- **Project Milestones:** Identify timelines for critical events that must be accomplished in order for the project to be successful in terms of cost, schedule, and performance. For development of devices and technologies, discuss the timelines and provide a commercial strategy plan for the technology being developed.

Note: *Impact and innovation should not be addressed in the Project Narrative (Attachment 1) but instead should be articulated in Attachments 6 and 7, respectively (see below).*

- o **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. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application.

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

- **References Cited:** List the references cited (including URLs, if available) in the order they appear 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). Do not send or attach copies of articles in print. There is no form for this information. The attachments should be in PDF in accordance with the formatting guidelines specified for full proposal/application preparation.
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.

- Facilities, 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.

Note: For researchers who will require access to the Defense Healthcare Management Systems Modernization (DHMSM) Cerner Electronic Health Record (EHR) solution for testing related to research workflows and/or interfaces: Access will be provided through a research environment within the Program Executive Office (PEO) Defense Healthcare Management Systems (DHMS) Testing Infrastructure at Allegheny Ballistics Laboratory (ABL). This research enclave will be established, third quarter, FY17 and users will follow the PEO DHMS Testing Infrastructure Onboarding Guide to access the environment. Direct support from the DHMSM vendor will not be provided through the DHMSM contract. No one is authorized to engage the DHMSM contractor for this purpose. Research must remain in these stated bounds.

- Publications and/or Patents (five-document limit): Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Broad Agency Announcement, such as those from Members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.
- Provide letter(s) supporting stated collaborative efforts necessary for the project's success, even if provided at no cost. ***If the project involves collaboration with a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center), special requirements apply.*** A collaborating DoD researcher must obtain a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the research project. This letter must be included with the proposal/application.

- **Joint Sponsorship (if applicable):** Describe present or prospective joint sponsorship of any portion of the program outlined in the proposal/application. In the absence of agreements among sponsors for joint support, the proposal/application should be structured so that the research can be carried out without the resources of any other sponsor. If, however, it is desirable to request partial support from another agency, the proposed plan should be stated and the reasons documented. If the plan cannot be formulated at the time the proposal/application is submitted, information should be sent later as an addendum to the proposal/application. Prior approval from both agencies must be secured for research to be undertaken under joint sponsorship. Provide letters of support related to recruitment, subject access, and data access plans.

- Intellectual Property:
 - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license. A term of the award requires the recipient to grant the Government all necessary and appropriate licenses, which could include licenses to background and proprietary information that have been developed at private expense.
Therefore, it is important to disclose/list any intellectual property (software, data, patents, etc.) that will be used in performance of the project or provide a statement that none will be used. If applicable, all proprietary information to be provided to the Government should be stated and identified; the applicant should indicate whether a waiver of the Federal purpose license will be required.
 - Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), “Intangible Property.”
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
 - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

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

The technical abstract should address the following elements:

- **Background:** Provide a brief statement of the ideas and theoretical reasoning behind the proposed work.
 - **Objective/Hypothesis:** State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
 - **Specific Aims/Milestones:** State concisely the specific aims/milestones of the project.
 - **Project Design:** Briefly describe the project design.
 - **Impact:** Provide a brief statement explaining the potential impact of the proposed work to advancing the standard of care for injured Service members and/or the general public.
 - **Relevance:** Provide a brief statement explaining the potential relevance of the proposed work to the specific topic area being addressed and its impact on health outcomes.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”**

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

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

- Describe the objectives and rationale for the proposal/application in a manner that will be readily understood by readers without a background in science or medicine.
- Describe the ultimate applicability and potential impact of the research.
 - What types of patients will it help, and how will it help them? Include the current available statistics to the related injury/condition.
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected timeline it may take to achieve the expected

- patient- related outcome?
 - Briefly describe how the proposed project will benefit Service members, Veterans, and/or their family members.
- **Attachment 5: Statement of Work (SOW) (two-page limit).** Upload as “SOW.pdf.” The 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 Idea Development Award mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching.
 - The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:
 - Include the name(s) of the key personnel and contact information for each study site/subaward site.
 - Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to Appendix 6 of the General Submission Instructions for additional information regarding regulatory requirements.
 - Briefly state the methods to be used.
 - The SOW outlines and establishes the PI’s and an organization’s performance expectations for the work to be funded under this award. The SOW in an assistance agreement award establishes general objectives. The SOW in a contract sets rather specific goals and conditions for each year of the contracted project; the PI and contractor are expected to meet the provisions and milestones of the SOW. The SOW for all award types will be incorporated into the award document and, as such, is subject to release under the Freedom of Information Act.
 - A series of relatively short statements should be included that comprise the approach to each of the major goals or objectives of the proposed research. The statements should outline the specific tasks, systems, and materials that are reasonable estimates for testing the proposed hypotheses of the study. An outline should be included that shows the work statements to be accomplished in each year of the award. If this proposal/application is part of a larger study, present only tasks that this award would fund. Allow at least 2 to 3 months for the USAMRMC ORP’s regulatory review and approval processes for studies involving human subjects and 2 to 3 months for studies involving animal subjects.
 - For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

- Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.
- 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 U.S. Food and Drug Administration or other Government agency.
- **Attachment 6: Impact Statement (one-page limit).** Upload as “Impact.pdf.” Explain in detail why the proposed research project is important, as follows:
 - **Short-Term Impact:** Describe the anticipated outcome(s)/results(s)/theoretical framework, design, and/or plan that will be directly attributed to the results of the proposed research.
 - **Long-Term Impact:** Describe the anticipated long-term clinical/ patient gains or commercial end product from the proposed project. What is the indication and will the project lead toward transforming the standard of care? Are there non-trauma-related indications that would expand the market for the proposed product?
 - **Military Relevance:** Clearly articulate how the proposed project or product meets the needs of military medical providers and injured Service members.
 - **Public Purpose:** If appropriate, provide a concise, detailed description on how this project will benefit the general public.
- **Attachment 7: Innovation Statement (two-page limit).** Upload as “Innovation.pdf”
 - Summarize how the proposed work is innovative.
 - Describe how the proposed research project introduces a new paradigm, challenges existing paradigms, or looks at existing problems or issues from a new perspective.
 - Describe how the research represents more than an incremental advance on published data or current work in the applicant’s laboratory. Investigating the next logical step or incremental advancement on published data is not considered innovative.
 - If the proposed research project is high-risk, explain the potential gain from accomplishing the work and finding the outcomes.
 - Identify which potential components will be open source/open architecture vs. proprietary.
- **Attachment 8 Data and Research Resource-Sharing Plan (one-page limit):** Upload as “Sharing.pdf.”

Describe how data and resources generated during the performance of the project will be shared with the research community, along with any resulting research resources. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the proposed project. If there are limitations associated with a pre-existing agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data- and/or research resource-sharing plan. For projects involving clinical trials, PIs may be required to register their clinical trials on Clinicaltrials.gov (<https://clinicaltrials.gov/>). For projects involving TBI, PIs may be required to report data to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system (<http://fitbir.nih.gov/>). If the project includes systems biology- related research, the PI may be required to make the systems biology data, generated via an award, available to the research community by depositing research data into the SysBioCube system (<https://sysbiocube-abcc.ncifcrf.gov/>). Refer to the General Submission Instructions, Appendix 4, Section K, for more information about the USSOCOM expectations for making data and research resources publicly available.

- **Attachment 9: Conflicts of Interest (if applicable): Upload as COI.pdf.”**
 - Provide details with the proposal/application submission of all potential or actual COIs, along with a plan to resolve them. A contract or assistance agreement will not be awarded if it is determined by the respective Contracting or Grants Officer that a COI cannot be managed.
 - Personnel involved in the review process and/or with making funding recommendations are prohibited from assisting in any proposal/application, including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation.
 - Questions related to this topic should be directed to the CDMRP Help Desk at help@eBRAP.org or 301-682-5507. Refer to the General Submission Instructions, Appendix 1, for additional information.
- **Attachment 10: Data Management (no page limit): Upload as “DataManage.pdf.”**

The Data Management attachment should include the components listed below.

Data Management: Describe all methods used for data collection to include the following:

- **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
- **Confidentiality:** Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.

- Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRMC are eligible to review study records.
- Address requirements for reporting sensitive information to state or local authorities.
- **Disposition of data:** Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored. For FDA-regulated studies, compliance with 21 CFR 11 is required.
- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.
- **Attachment 11: Post-Award Project Transition Plan (three-page limit). Upload as “Transition.pdf.”** Provide information on the methods and strategies proposed to move the project or knowledge outcomes to the next project phase of studies, commercialization, and/or delivery to the civilian or military market after successful completion of the award. The transition plan should include the components listed below.
 - The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication.
 - The anticipated regulatory strategy (e.g., additional nonclinical or clinical studies anticipated/required, FDA or regulatory authority meetings desired, industry partnerships) for movement of the research into later phases of development and to support a potential marketing application [e.g., New Drug Application, Biologics License Application, Premarket Approval Application, 510(k)].
 - Details of the funding strategy that will be used to bring the outcomes to the next level of development and/or commercialization (e.g., specific potential industry partners, specific funding opportunities to be applied for).
 - For knowledge products, a description of how the knowledge will be further developed, disseminated, and incorporated into clinical care.
 - A description of collaborations and other resources that will be used to provide continuity of development.
 - A brief schedule and milestones for bringing the outcome(s) to the next phase of studies, commercialization, and/or delivery to the military or civilian market, including when it can be anticipated to be transitioned to an industry partner or approved by the FDA, if applicable.
 - A risk analysis for cost, schedule, manufacturability, and sustainability.

- **Attachment 12: DoD Military Budget Form(s), if applicable.** Upload as “MFBudget.pdf.” If a military facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the DoD Military Budget Form, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Submission Instructions, Section II.D.5., for detailed information.

Research & Related Senior/Key Person Profile (Expanded): For submissions (via Grants.gov), refer to the General Submission Instructions, Section II.D.4. for detailed information.

- PI Biographical Sketch (five-page limit): Upload as “Biosketch_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.
- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch_LastName.pdf.”
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”

Research & Related Budget: For submissions (via Grants.gov), refer to the General Submission Instructions, Section II.D.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): For detailed information regarding submissions (via Grants.gov), refer to the General Submission Instructions, Section II.D.7.

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

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

Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity

Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Verify the status of the applicant’s organization’s Entity registration in SAM well in advance of the 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 by 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. To protect the public interest, the federal government ensures the integrity of federal programs by striving to conduct business only with responsible organizations. USSOCOM uses the “Exclusions” within the Performance Information functional area of the System for Award Management (SAM); data from the Federal Awardee Performance and Integrity Information System, a component within SAM, is used to verify that an organization is eligible to receive federal awards. [More](#) information about the “Exclusions” reported in SAM is available at <https://www.sam.gov/>. Refer the General Submission Instructions for further information regarding Grants.gov requirements.

The applicant organization must have a Commercial and Government Entity (CAGE) Code. The Defense Logistics Information Service in Battle Creek, Michigan, is the only authorized source of CAGE Codes. CAGE Codes will be assigned to registrants as their SAM registration advances through the validation process. Foreign registrants in SAM must be assigned a NATO CAGE Code (NCAGE). An NCAGE code can be obtained by contacting the National Codification Bureau of the country where the organization is located or by connecting to Form AC135 (<http://www.nato.int/structur/AC/135/welcome.htm>). On average, CAGE Code or NCAGE Code validation in SAM occurs within 3 business days after the TIN is validated.

Collecting the information for registration (Employer Identification Number [EIN] or Tax Identification Number [TIN], etc.) can take 1-3 days. Once you have collected/obtained the necessary information, online registration will take about 1 hour to complete, depending upon the size and complexity of your organization. If your organization does not have either an EIN or TIN, allow at least 2 weeks to obtain the information from the Internal Revenue Service (IRS). **Allow a minimum of 10 business days for your SAM status to become “Active” after submitting an error free registration.** Foreign entities have encountered difficulties with SAM registration and are advised to begin the registration process 3 to 4 weeks in advance of their anticipated Grants.gov application submittals.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in Section I, under “Overview of the Funding Opportunity,” of this Broad Agency Announcement. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of a submitted application. Following

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

II.D.5. Funding Restrictions

The maximum period of performance is two (2) years. Proposed projects longer than two (2) years will not be considered.

Most projects are anticipated to have a total cost at or under \$700,000 (Including Indirect Costs). Projects that have a total cost higher than \$700,000 with outstanding scientific merit that meet a critical need maybe accepted, however these projects should not exceed \$1,500,000 (Including Indirect Costs).

All direct and indirect costs of any subaward 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 2 years.

For this award mechanism, direct costs may be requested for (not all inclusive):

- Salary
- Research supplies
- Support for multidisciplinary collaborations, including travel
- Travel costs

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances.

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

It is estimated that approximately \$3M is available for this BAA, and the number of awards is indeterminate and contingent upon funding availability. Selection of research projects is a highly

competitive process and is based on the evaluation of the proposal/application's technical merit, programmatic considerations, and the availability of funds. The quantity of meaningful submissions received (both pre-proposals/pre-applications and full proposals/applications) normally exceeds the number of awards that the available funding can support. Any funding that is received by the USSOCOM and is appropriate for a research area described within this BAA may be utilized to fund proposals/applications.

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Research Objectives:** The degree to which the stated objectives are clear, valid, and logical. For development of devices and technologies, the degree to which the performance objectives are plausible; the proposed effort demonstrates familiarity with the historical background of the problem and previous/current solutions; and the awareness of similar projects previously undertaken and related activities. The extent that the proposed research projects demonstrate an innovative approach and relate to the Research Areas of Interest identified in Section II.A.
- **Scientific Design Excellence:** The degree to which proposed plans, methods, techniques and procedures are feasible, clear, valid, adequately referenced, and state-of-the-art. The merit of the statistical features of the study. The extent to which literature searches were used to document the strengths of the proposed project. For development of devices and technologies, the feasibility of the proposed prototype/technology development plan; how well the engineering/technical design is likely to achieve the goals indicated; adequacy of the engineering/design solutions; and how well the perceived engineering/design strengths and flaws are addressed.
- **Impact/Outcomes:** The potential impact of the research in the field, the significance of this impact, and when it can be anticipated. For development of devices and technologies, the potential translation, implementation, and/or commercial use for the prototype/technology being developed.
- **Budget:** The degree to which the budget reflects the actual needs of the proposed work, is thoroughly detailed and fully justified so that the government can evaluate and determine the cost commensurate with the complexity and nature of the research

proposed.

- **PI and Key Personnel Qualifications:** The qualifications, capabilities, and experience of the proposed PI and other key personnel to demonstrate that the proposed staff has the knowledge, technical expertise, and management skills to achieve the proposed objectives as well as the time available for the percentage of efforts indicated for the project.
- **Facilities:** The proposed facilities and equipment, or unique combinations of these, to demonstrate that the organization has the necessary facilities required for the accomplishing the proposed objectives.

II.E.1.b. Programmatic Review

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

- Scientific peer review results
- Military relevance (mission, health, medicine, and beneficiaries)
- Portfolio balance
- Programmatic priorities
- **NOTE:** Military-relevant research must be responsive to the health care needs of the Armed Forces, family members of the Armed Forces, and the U.S. Veteran population. Proposals/applications must address a military-relevant health problem responsive to one of the Research Areas of Interest identified in Section II.A.1.

II.E.2. Application Review and Selection Process

All invited proposals/applications are evaluated by USSOCOM scientists, other federal agency representatives, outside scientists with diverse expertise, clinicians, consumers, or combinations thereof, using a two-tier review process. The first tier is peer review of proposals/applications against established criteria for determining technical merit. The second tier is programmatic review based on established criteria for determining relevance to the mission of the USSOCOM and its programs.

The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b., Programmatic Review.

All USSOCOM review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the

dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905 (18 USC 1905).

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement or contract award where the Federal share is expected to exceed the simplified acquisition threshold (currently \$150,000) 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 a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGAR), section 22.415 and Federal Acquisition Regulation (FAR) Part 9.104.

An organization must meet certain minimum standards pertaining to institutional support, financial resources, record of performance, integrity, experience, operational controls, facilities and conformance with safety and environmental statutes and regulations.

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

All application review dates and times are indicated in Section I, under "Overview of the Funding Opportunity," of this Broad Agency Announcement.

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards are made to organizations, not to individual PIs. The types of awards made under the Broad Agency Announcement will be contracts or assistance agreements (grants or cooperative

agreements). The level of involvement on the part of DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement. A recommended for funding notification is NOT an authorization to begin performance or a guarantee of an award.

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). Authority comes from 10 USC 2358 for DoD to conduct research, and also to use grants and cooperative agreements in support of research. Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. DoD staff may become directly involved in performing the research, managing the effort, and/or reviewing and providing approval before work can proceed. The award type, along with the start date, will be determined during the negotiation process.

Any assistance instrument awarded under this Broad Agency Announcement will be governed by the award terms and conditions, which conform to DoD’s implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the 2 CFR 200, “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.”

After email notification of application review results through the 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 Officer or 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 Officer or Grants Officer is the official authorizing documents.

II.F.1.a. Award Transfers

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

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

II.F.2. Administrative and National Policy Requirements

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

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

II.F.3. Reporting

Refer to the General Submission Instructions, Appendix 4, for general information on reporting requirements.

Awards resulting from this Broad Agency Announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose semiannually information about criminal, civil, and administrative proceedings as specified in the applicable term and condition. The applicable term and condition for institutions of higher education, hospitals, and nonprofit organizations is available in OAR Article I, Section B, in the July 2016 R&D General Terms and Conditions. The applicable term and condition for for-profit organizations is available in Section 34 of the February 2017 USAMRAA General Research Terms and Conditions with For-Profit Organizations.

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

- **Contractor Manpower Reporting (CMR)**
 - CMR is a requirement of all DoD contracts. Offerors are allowed to include a nominal fee in their cost/price proposal for providing these data. A “nominal fee” is defined as a computation of an administrative assistant equivalent labor category providing approximately 6-8 hours to complete data input. Offerors may opt to not separately price this required annual data input. CMR costs/price will not be evaluated as part of the total evaluated proposal cost/price.
 - The contractor shall report ALL contractor labor hours (including subcontractor labor hours) required for performance of services provided under each contract via a secure data collection site. The contractor is required to completely fill in all required data fields using the following web address: <http://www.ecmra.mil/>.
 - Reporting inputs will be for the labor executed during the period of performance during each Government fiscal year (FY), which runs October 1 through September 30. While inputs may be reported any time during the FY, all data shall be reported no later than October 31 of each calendar year, beginning with 2017. Contractors may direct questions to the help desk at: contractormanpower@hqda.army.mil or via phone at 703-377-6199.

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

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

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

Email: support@grants.gov

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

II.H. Other Information

II.H.1. Administrative Actions

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

II.H.1.a. Rejection

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

- Pre-proposal Narrative exceeds page limit.
- Pre-proposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

II.H.1.b. Modification

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

II.H.1.c. Withdrawal

- The following may result in administrative withdrawal of the pre-proposal/pre-application or proposal/application:
 - A Federal agency personnel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation.
 - The application fails to conform to this Broad Agency Announcement description to the extent that appropriate review cannot be conducted.
 - Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
 - Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
 - Inclusion of any employee of USSOCOM review contractors in pre-proposals/pre-applications or full proposals/applications for funding without adequate plans to resolve conflicts of interest. Refer to General Submission Instructions, Appendix 1, for detailed information.
 - Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
 - The full proposal/application does not propose the same research project as described in the pre-proposal/pre-application.
 - The full proposal/application budget differs significantly from the budget included in the pre-proposal/pre-application.
 - An application submitted by a PI who does not meet the eligibility criteria will be withdrawn.

II.H.1.d. Withhold

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

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 (R&R) 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 Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf."	
	Data and Research Resource-Sharing Plan: Upload as Attachment 8 with file name "Sharing.pdf."	
	Conflicts of Interest: Upload as Attachment 9 with file name "COI.pdf."	
	Data Management: Upload as Attachment 10 with file name "DataManage.pdf," as applicable.	
	Post-Award Project Transition Plan: Upload as Attachment 11 with file name "Transition.pdf."	
	DoD Military Budget Form(s): Upload as Attachment 12 with file name "MFBudget.pdf," as applicable.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Budget	Complete the DoD Military Budget Form and justification.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed.	

APPENDIX 1: ACRONYM LIST

ACURO	Animal Care and Use Review Office
CAGE	Commercial and Government Entity (CAGE)
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DoD	Department of Defense
DoDGAR	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
OMB	Office of Management and Budget
ORP	Office of Research Protections
PI	Principal Investigator
RAI	Research Areas of Interest
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOF	Special Operations Forces
SOW	Statement of Work
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
USSOCOM	United States Special Operations Command