
United States Special Operations Command

DEPARTMENT OF DEFENSE

# BROAD AGENCY ANNOUNCEMENT
For Extramural Biomedical Research and Development
W81XWH-16-R-SOC1
Release Date: April 15, 2016
Issued by:
**U.S. Army Medical Research Acquisition Activity**
Fort Detrick, Maryland

# Table of Contents

## NEW FOR FISCAL YEAR 2016

The Fiscal Year 2016 (FY16) United States Special Operations Command (USSOCOM) Broad Agency Announcement (BAA) for Extramural Biological Research and Development contains several changes from previous USSOCOM BAAs. Read each section carefully. Note the following:

- The "Program Description" that describes the "Research Areas of Interest" has been updated.
- **Submission of a pre-proposal/pre-application is required.** After review, if the USSOCOM is interested in receiving a full proposal/application, the Principal Investigator (PI) will be invited to submit. A full proposal/application will not be accepted if the PI has not submitted a pre-proposal/pre-application and received an invitation to submit a full proposal/application.
- A PI and the organization's business official must register in the electronic Biomedical Research Application Portal (eBRAP) before submitting a pre-proposal/pre-application.
- All pre-proposals/pre-applications must be submitted through eBRAP. Invited full proposals/applications (submitted through Grants.gov) will be available for viewing, modification, and verification in eBRAP, for a limited period.
- The Congressionally Directed Medical Research Program (CDMRP) office will be the execution management agent for 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. As such, the US Army Medical Research and Materiel Command (USAMRMC) General Submission Instructions (GSI) apply to this BAA.
- Safety, surety, and environmental requirements have been revised.
- This BAA consists of two documents containing instructions on how to prepare and submit pre- and full proposals/applications. The second document, titled "General Submission Instructions," is available along with this BAA for downloading from Grants.gov.
- The BAA submission total cost ceiling is $1,500,000 for proposals with outstanding scientific and technical merit that meet a critical need, however the total cost of submissions are generally anticipated to be at or under $700,000.

***NOTE:*** Any assistance agreement (grant or cooperative agreement) awarded under this BAA will be governed by the award terms and conditions that conform to the Department of Defense's (DoD) implementation of Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of awards made after December 26, 2014, may include

revisions to reflect DoD implementation of new OMB guidance in 2 CFR[1] part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

# I. OVERVIEW OF THE FUNDING OPPORTUNITY

## A. Administrative Overview

1. **Federal Agency Name: Department of Defense (United States Special Operations Command)**
2. **Funding Opportunity Title: U.S. Special Operations Command (USSOCOM) Broad Agency Announcement for Extramural Biomedical Research and Development**
3. **Announcement Type: Broad Agency Announcement**
4. **Funding Opportunity Number: W81XWH-16-R-SOC1**
5. **Catalog of Federal Domestic Assistance Number: 12.420**
6. **Key Dates:**

- **Release/Posted Date: April 15, 2016**
- **Opening Date: April 15, 2016**
- Pre-proposal submissions can be submitted throughout the open period of the BAA which is 15 April 2016 – 14 April 2017. 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 on August 1, 2016**
  - Invitations to submit full proposals will occur on or about August 31, 2016
  - Full proposals will be due for the first Program Review 30 days after the invitation to submit letter has been sent.

**Key Dates for Second Cycle Submissions**

[1] Code of Federal Regulations

- **Pre-proposal Submission for the second Program Review is due on November 15, 2016.**
    - Invitations to submit full proposals will occur on or about December 15, 2016
    - Full proposals will be due for the second Program Review 30 days 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 on April 14, 2017**
    - Invitations to submit full proposals will occur on or about May 14, 2017
    - Full proposals will be due for the third Program Review 30 Days after the invitation to submit letter has been sent.
- BAA Closes April 14, 2017

**NOTE:** This BAA will remain open through April 14, 2017. 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 BAA must be read in conjunction with the application guidelines in Grants.gov/Apply for Grants (hereafter called Grants.gov/Apply). It must also be read in conjunction with the document titled "General Submission Instructions" available with this BAA in Grants.gov.

**Pre-Proposals/Pre-Applications:** To conserve both submitters' and federal government resources, organizations are ***required to submit preliminary proposals/applications (pre-proposals/pre-applications)*** so that the government can determine whether a proposed research idea meets the USSOCOM's mission and requirements described herein. Pre-proposal/pre-applications must be submitted by the due dates noted above. The pre-proposal shall include an attached quad chart following the example included in the "USSOCOM Biomedical Pre-proposal Template". The quad chart shall include: (1) description of the technology effort with drawing or schematic; (2) technical performance required to achieve and complete the effort; (3) costs by deliverable and schedule; and (4) technical resources and team members. All the quad chart along with pre-proposals/pre-applications must be submitted through eBRAP (https://eBRAP.org/). A

registration process through eBRAP (https://eBRAP.org) must be completed before a pre-proposal/pre-application can be submitted.

**Full Proposals/Applications:** To submit a full proposal/application, the PI must have received an invitation to submit from a Contracting or Grants Officer. An invited full proposal/application must be submitted electronically through Grants.gov (http://www.grants.gov/) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide.
***Proposals/Applications will not be accepted by mail or in person.***

Invited full proposals/applications can be submitted under the FY16 USSOCOM BAA by the dates listed. If an invited full proposal/application is not submitted by this date, it will have to be submitted under the FY17 USSOCOM BAA (aniticipated to be posted April 15, 2017).

An invited full proposal/application submitted under this FY16 USSOCOM BAA will be considered for funding for a period of 24 months from the date of submission to Grants.gov.

A compatible version of Adobe is required for download from Grants.gov. For assistance downloading this or any Grants.gov package, contact Grants.gov Customer Support at http://www.grants.gov/contactus/contactus.jsp.

## B. General Program Overview

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 6.102(d) (2) and 35.016. This announcement provides a general description of USSOCOM's research areas of interest, general information, evaluation and selection criteria, and proposal/application preparation instructions.

In accordance with FAR 6.102, projects funded under this announcement must be for basic and applied research and that part of development not related to the development of a specific system or hardware procurement. Projects must be for scientific study and experimentation directed toward advancing the state-of-the-art or increasing knowledge or understanding. **Projects that are for the development of a specific system or hardware procurement will not be considered.**

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. PROGRAM DESCRIPTION

### A. Research Areas of Interest

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 must 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 must 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.

1. Medical Simulation and Training Technologies: The proposed project must research, apply and/or develop improved pre-hospital combat casualty training with an emphasis on the SOF pre-hospital providers. Research involves technology based approaches, advanced generation trauma task trainers, and robotic training systems to include validation of system and training metrics/evaluation outcomes compared to currently used models. The effort includes research into best practices and new technologies for improved critical lifesaving skills and a cognitive behavioral approach to maximize training effectiveness. Priority will be given to proposals that result in a working prototype that can be field tested in cooperation with SOF training sites.

2. Prolonged Field Care: 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. 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. Significant consideration will be given to proposals focused on Prolonged Field Care that may also relate to Sections 3 (a-d) and 4(a-b) of this BAA.

3. 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 must 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 must be optimized for medics in austere, far-forward areas, with minimal logistical or specialty support, who must 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 preferred.

b. Analgesia: The proposed project must 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 preferred.

c. Far Forward Blood, Blood Components, Blood Substitute, & Injectable Hemostatics: The proposed project must 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. 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. Priority will be given towards projects that are oriented towards final solutions or prototypes that are shelf stable requiring minimal to no refrigeration as well as those that are capable of carrying oxygen.

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. 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).

4. Portable Lab Assays and Diagnostics: The proposed project must 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. Preference will be given to proposals that are field oriented, rugged, low weight/cube space and have little to no refrigeration requirements.

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 importance. Current focus areas include rapid and accurate identification of diseases of operational significance (Malaria, Typhoid, Dengue Fever, etc.) as well as 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).

b. Occupational and Environmental Health (OEH) Hazards: The proposed project must focus on development of novel methods and devices for rapid identification and analysis of exposures to OEH hazards. Research must 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 borne pathogens, toxins, biological agents, and radiological material exposures.

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 must 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 must 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. Chelation Strategy: The proposed project must research and provide viable protective solutions for acute lead exposure in training environments (Live Fire CQB/Breaching Training Environments and Shoothouses).

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, in priority order, are:

a. Environmental Extremes: Project proposals must 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 must be oriented toward innovative methods that enhance or conserve SOF canine olfactory, visual, and/or auditory performance during combat operations.

c. Trauma Resuscitation: Research must 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 must 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 must 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. Optimal Performance Strategy: The proposed project must research, apply and/or develop novel approaches that provide rapid and sustainable human performance for austere environments and/or the SOF training calendar.

b. Pharmaceutical and Nutritional Supplement interactions: The proposed project must 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.

c. Heart Rate Variability: The proposed projects must research, and/or apply heart rate variability's potential for measuring psychological and physical readiness and/or stress in SOF operators. Emphasis of research should validate (or repudiate) the use of HRV as an operational performance indicator and confirm use of HRV measurement as an accurate alternative to other accepted biomarkers and indicators. Additional research opportunities should identify unobtrusive means of measuring HRV on active service personnel without interfering with movement or physical activities.

d. Nutritional Status: The proposed projects must 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. Enhanced Physiological Performance: Develop technologies to maximize the physiological performance of operators, including greater mental acuity, increased endurance, enhanced senses, and tolerance to environmental extremes, without noticeable augmentation and without hampering personnel mobility.

## III. AWARD INFORMATION

### A. Funds Available and Anticipated Number of Awards

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.

### B. Award Amounts and Periods of Performance

The following limits on the duration and cost of research projects apply:

- Proposed projects longer than two (2) years will not be considered.
- Most projects are anticipated to have a total cost at or below $700,000. Projects that have a total cost higher than $700,000 with outstanding scientific merit that meet a critical need maybe accepted, however the total cost of these projects are not to exceed $1,500,000

- No budget will be approved by the Government exceeding $1,500,000 (including Indirect costs).

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.

See the General Submission Instructions, Section II.C, for additional information regarding the research and related budget.

### C. Mechanisms of Support

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[2] 6301-6308, provides the legal criteria to select a procurement contract or an assistance agreement. Refer to the General Submission Instructions, Appendix 3, for additional information.

## IV. ELIGIBILITY INFORMATION

### A. Eligible Applicants

Awards are made to organizations only. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations. Refer to the General Submission Instructions, Appendix 1, for general eligibility information.

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

[2] United States Code

**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.

### B. Eligible Investigators

Eligible investigators include all individuals, regardless of ethnicity, nationality, or citizenship status, who are employed by, or affiliated with, an eligible organization.

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

### C. Cost Sharing or Matching is not required under this announcement.

### D. Other Review Information

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

#### 1. "Exclusions" Identified in SAM

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

#### 2. Conflicts of Interest

**All awards must be free of Conflicts of Interest (COIs) that could bias the research results. Prior to award of an assistance agreement or contract, 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 Grants Officer or Contracting Officer that a COI cannot be adequately managed.** Refer to the General Submission Instructions, Appendix 1, for additional information.

### 3. Data Universal Number System (DUNS) Number

Applicant Organization and any Subawardee Must Have a Data Universal Number System (DUNS) Number. A DUNS number is a unique nine-digit identification number provided by the commercial company Dun & Bradstreet (D&B). If an organization does not have a DUNS number, an authorized official of the organization can request one by calling 866-705-5711 or online via web registration (http://fedgov.dnb.com/webform/displayHomePage.do). Organizations located outside of the United States can request and register for a DUNS number online via web registration.

### 4. Commercial and Government Entity (CAGE) Code

Applicant Organizations Must Have a Commercial and Government Entity (CAGE) Code. The Defense Logistics Information Service (DLIS) in Battle Creek, Michigan, is the only authorized source of CAGE Codes. CAGE Codes will be assigned to registrants as their SAM registration goes through the validation process. Foreign registrants in SAM must have a NATO CAGE Code (NCAGE) assigned. A NCAGE code can be obtained by contacting the National Codification Bureau of the country where the company is located or by connecting to Form AC135 (http://www.dlis.dla.mil/Forms/Form_AC135.asp). On average, CAGE Code or NGAGE Code validation in SAM occurs within 3 business days after the Tax Identification Number (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.

### 5. Review of Risk

The following areas may be reviewed in evaluating the risk posed by the an applicant: Financial stability; quality of management systems and operational controls; history of performance; reports and findings from audits; ability to effectively implement statutory, regulatory, or other requirements imposed on non-federal entities; degree of institutional support; integrity; adequacy of facilities; and conformance with safety and environmental statutes and regulations.

### 6. Subcontracting Plan

If the resultant award is a contract that exceeds $650,000 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.

### 7. Contractor Manpower Reporting

CMR is now a requirement of DOD contracts. Offerors are allowed to include a nominal fee in their cost/price proposal for providing this 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 this contract for the U.S. Special Operations command via a secure data collection site. The contractor is required to completely fill in all required data fields using the following web address: http://www.ecmra.mil/

Reporting inputs will be for the labor executed during the period of performance during each Government fiscal year (FY), which runs October 1 through September 30. While inputs may be reported any time during the FY, all data shall be reported no later than October 31 of each calendar year, beginning with 2013. Contractors may direct questions to the help desk at help desk at: http://www.ecmra.mill.

### 8. Other Eligibility Information

a. To protect the public interest, the Federal Government ensures the integrity of Federal programs by striving to conduct business only with responsible recipients/contractors. USSOCOM uses the Exclusions within the Performance Information functional area of the System for Award Management (SAM), formerly the Federal Awardee Performance and Integrity Information System (FAPIIS), to verify that a recipient/contractor is not ineligible to receive Federal awards. More information about the Exclusions reported in SAM is available at https://www.sam.gov.

b. 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.

c. In accordance with FAR 6.102, projects funded under this announcement must be for basic and applied research and that part of development not related to the development of a specific system or hardware procurement. Projects should be for scientific study and experimentation directed toward advancing the state-of-the-art or increasing knowledge or understanding rather than focusing on a specific system or hardware solution.

d. All conflicts of interest on the part of an organization or individual investigators must be resolved prior to the award of an assistance agreement or contract under this BAA. All awards must be free of any conflicts of interest that could bias the research projects.

e. Contracts awarded under this BAA must comply with the requirements found in Federal Acquisition Regulation (FAR) Part 9.5 Organizational and Consultant Conflicts of Interest. An organizational conflict of interest may result when factors create an actual or potential conflict of interest on a contract, or when the nature of the work to be performed creates an actual or potential conflict of interest on future acquisitions and some restrictions on future activities of the contractor may be required. FAR Part 9.5 will also be used as a guide in analyzing and resolving organizational conflicts of interest relating to assistance agreements.

f. All conflicts or potential conflicts of interest must be disclosed, along with a plan to mitigate the conflict, with the application submission. (See Section II.D.2, R&R Other Project Information Form, Block 11, for submission instructions.) 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.

## V. PROPOSAL/APPLICATION SUBMISSION INFORMATION

### A. Where to Obtain the Submission Package

To obtain the complete Grants.gov proposal/application package (hereinafter, submission package), including all required forms, perform a Grants.gov (http://www.grants.gov/) basic search using the Funding Opportunity Number **W81XWH-16-R-SOC1**.
Submission is a two-step process requiring both: (1) Pre-proposal/pre-application submission through eBRAP (https://eBRAP.org/); and (2) full proposal/application submission through Grants.gov (http://www.grants.gov/).

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

Submission of a pre-proposal/pre-application is required and must be submitted through eBRAP (https://eBRAP.org/). If the USSOCOM is interested in receiving a full proposal/application, the PI will be sent an invitation to submit via eBRAP.

Because the invitation to submit a proposal/application is based on the contents of the pre-proposal/pre-application, a PI should not change the title or research objectives after the pre-proposal/pre-application is submitted. A PI and organization identified in the pre-proposal/pre-application should be the same as those intended for the full proposal/application submission. If any changes are necessary after submission of the pre-proposal/pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507. A change in PI or organization

after submission of the pre-proposal/pre-application will be allowed only at the discretion of the USAMRAA Contracting or Grants Officer.

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

Pre-proposals/pre-applications may be submitted at any time prior to the BAA closing date. Pre-proposals/pre-applications should describe specific ideas or projects that pertain to any of the areas described under "Program Description" in this BAA. A pre-proposal/pre-application must include a brief description of the scientific methods and design to address the problem as described below. Brochures or other descriptions of general organizational or individual capabilities will not be accepted as a pre-proposal/pre-application. ***DO NOT include any proprietary information in the pre-proposal/pre-application.***

The pre-proposal/pre-application consists of the following components, which are organized in eBRAP by separate tabs. Refer to the General Submission Instructions, Section II., for additional information on pre-proposal/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 and the organization's Business Official responsible for sponsored program administration (or equivalent). This is the individual listed as "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 form. The Business Official must either be named or invited in order for the pre-proposal/pre-application to be submitted. If the organization's Business Official is not in eBRAP, an invitation to the Business Official to register in eBRAP must be sent. In addition, it is recommended that the PI identify an Alternate Submitter in the event that assistance with pre-proposal/pre-application submission is needed.

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

- **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) associated with the proposal/ application. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this

application" in Block 5 of the Grants.gov SF-424 form). The Business Official must either be selected from the eBRAP list or invited in order for the pre- proposal/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.

- To preserve the integrity of its peer and programmatic review process, the CDMRP discourages inclusion of any employee of its review contractors having any role in application preparation, research, or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess.shtml). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to General Submission Instructions, Appendix 1, for detailed information.

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

- **Tab 4 – Conflicts of Interest**

  List all individuals other than collaborators and key personnel who may have a COI in the review of the proposal/application (including those with whom the PI has a personal or professional relationship). Refer to Appendix 1, Section C, of the General Submission Instructions for further information regarding COIs.

- **Tab 5 – Pre-Application Files:**

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

  **Pre-Proposal/Pre-Application Narrative (6-page limit):** The Pre-Proposal/ Pre-Application Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Narrative and

could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-proposal/pre-application.

**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.

- **Submit Pre-Application – Tab 6:** This tab must be completed for the pre-proposal/pre-application to be accepted and processed.

### C. Pre-Proposal/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:

- **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.

- **Significance, Relevance, and Innovation:** To what degree the proposed research is relevant and innovative, including whether the proposed research is duplicative of existing research.

- **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.

- **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.

- **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.

Following the pre-proposal/pre-application screening, PIs will be notified as to whether or not they are invited to submit full proposals/applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-proposals/pre-applications. Within 120 days of submission, PIs should receive email notification via eBRAP regarding disposition of their pre-proposals/pre-applications.

### D. Full Proposal/Application Submission Content and Forms

***A proposal/application will not be accepted unless the PI has received an invitation to submit.*** If the USSOCOM is interested in receiving a full proposal/application, the PI will receive an invitation to submit via email from eBRAP. An invited full proposal/application must be submitted through Grants.gov (http://www.grants.gov/). It should be submitted within 90 days of the PI's receipt of an invitation to submit. Agency receipt of a full proposal/application will be acknowledged by an email sent to the PI via eBRAP. The proposal/application log number for the full proposal/application will be the same number as used for the pre-proposal/pre-application, e.g., BA16xxxx.

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 (Section VII.A., Rejection).

Each proposal/application submission must include the completed submission package of forms and attachments provided in Grants.gov for this BAA. The submission package is to be submitted by the Authorized Organizational Representative through the Grants.gov portal (http://www.grants.gov/). Refer to the General Submission Instructions, Section II, for submission information.

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

### E. Grants.gov Proposal/Application Package Components

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

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

2. **Attachments Form**

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

- **Attachment 1: Project Narrative (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, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the proposal/application.

  Describe the proposed project in detail using the outline below.

  - **Background:** 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.
  - **Hypotheses/Objectives:** State the hypotheses or research/evaluation questions and overall objective(s) to be reached.
  - **Specific Aims:** Concisely explain the project's specific aims to include expected timeframe of each aim. If this proposal/application is part of a larger study, present only tasks 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.
- **Additional Information**: If human subjects are involved in the research, proposals/applications may be submitted prior to human protocol institutional approvals. However, protocols with required institutional approvals must be submitted no later than 60 days after award to demonstrate continued progress and ensure continuation of payment. The Contracting or Grants Officer may make exceptions in situations where human and/or animal use is not expected to begin until after the first year of the research project. In such cases, a timeframe for submission of the appropriate protocols and institutional approvals will be established prior to award.

***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.***

- 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 time required for submission and/or approval of documents (e.g., Investigational New Drug and Investigational Device Exemption) to the U.S. Food and Drug Administration or appropriate Government agency.
- For studies involving human subjects, allow at least 2 to 3 months for regulatory review and approval by the USAMRMC HRPO; this does not include the additional time required for local IRB/EC review and approval.

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

- **Attachment 2: Supporting Documentation: Start each document on a new page. Combine and upload as a single file named "Support.pdf."** If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; items not requested will be removed and may result in administrative withdrawal of the proposal/application.***

  - **Bibliography and References Cited:** List the references in the order they appear in the Project Narrative. Use a reference format that gives the title of the citation. Do not send or attach copies of articles in print. There is no form for this information. The attachments should be in PDF in accordance with the formatting guidelines specified for full proposal/application preparation.

  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.

  - **Facilities and Other Resources:** Describe the facilities available for performance of the proposed request and any additional resources proposed for acquisition at no cost to the Government. Indicate if a Government-owned facility is proposed for use. Reference should be made to the original or present award under which the facilities or resources are now accountable. There is no form for this information. The attachments must be in PDF in accordance with the formatting guidelines outlined for full proposal/application preparation.

    **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, FY16 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.

- **Equipment:** Include a description of existing equipment to be used for the proposed research project.
- **Publications and/or Patent Abstracts (five-document limit):** Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be attached.
- **Letters of Organizational Support:** Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. A letter for each organization involved in the project should be provided.
- **Letters of Collaboration:** Provide letter(s) supporting stated collaborative efforts necessary for the project's success, even if provided at no cost. ***If the project involves collaboration with a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center), special requirements apply.*** A 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. Refer to the General Submission Instructions, Section II.D, Research & Related Budget, for additional information.
- **Joint Sponsorship (if applicable):** Describe present or prospective joint sponsorship of any portion of the program outlined in the proposal/application. In the absence of agreements among sponsors for joint support, the proposal/application should be structured so that the research can be carried out without the resources of any other sponsor. If, however, it is desirable to request partial support from another agency, the proposed plan should be stated and the reasons documented. If the plan cannot be formulated at the time the proposal/application is submitted, information should be sent later as an addendum to the proposal/application. Prior approval from both agencies must be secured for research to be undertaken under joint sponsorship. Provide letters of support related to recruitment, subject access, and data access plans.
- **Intellectual Property (if applicable)**: Refer to the General Submission Instructions, Appendix 3, for additional information. Provide the following:
  - Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:

1. Clearly identify all such property;
2. Identify the cost to the Federal government for use or license of such property if applicable; or
3. Provide a statement that no property meeting this definition will be used on this project.

- Intellectual and Material Property Plan: If applicable, provide a plan for resolving intellectual and material property issues among participating organizations.

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

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

  - **Background:** Provide a brief statement of the ideas and theoretical reasoning behind the proposed work.
  - **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 SOW outlines and establishes the PI's and an organization's performance expectations for the work to be funded under this award. The SOW in an assistance agreement award establishes general objectives. The SOW in a contract sets rather specific goals and conditions for each year of the contracted project; the PI and contractor are expected to meet the provisions and milestones of the SOW. The SOW for all award types will be incorporated into the award document and, as such, is subject to release under the Freedom of Information Act.

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

- **Attachment 6: Outcomes and Impact Statement (one-page limit): Upload as "Impact.pdf."** Explain in detail why the proposed research project is important, as follows:
  - ***Short-Term Impact:*** Describe the anticipated outcome(s)/results(s)/theoretical framework, design, and/or plan that will be directly attributed to the results of the proposed research.

- ***Long-Term Impact:*** Describe the anticipated long-term clinical/ patient gains or commercial end product from the proposed project. What is the indication and will the project lead toward transforming the standard of care? Are there non-trauma-related indications that would expand the market for the proposed product?

- ***Military Relevance:*** Clearly articulate how the proposed project or product meets the needs of 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."** Describe how the proposed project is innovative. Research deemed innovative may introduce a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other creative qualities. Investigating the next logical step or incremental advancement on published data is not considered innovative. This may include a proposed conceptual framework, design, and/or plan of key components and how they integrate/communicate with each other. 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 unique and/or final research data 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 3, for additional information.

- **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.

a. The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication.

b. The anticipated regulatory strategy (e.g., additional nonclinical or clinical studies anticipated/required, FDA or regulatory authority meetings desired, industry partnerships) for movement of the research into later phases of development and to support a potential marketing application [e.g., New Drug Application, Biologics License Application, Premarket Approval Application, 510(k)].

c. Details of the funding strategy that will be used to bring the outcomes to the next level of development and/or commercialization (e.g., specific potential industry partners, specific funding opportunities to be applied for).

d. For knowledge products, a description of how the knowledge will be further developed, disseminated, and incorporated into clinical care.

e. A description of collaborations and other resources that will be used to provide continuity of development.

f. A brief schedule and milestones for bringing the outcome(s) to the next phase of 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.

g. A risk analysis for cost, schedule, manufacturability, and sustainability.

- **Attachment 12: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as "MFBudget.pdf."** If a Military Facility will be a collaborator in performance of the project complete the Collaborating DoD Military Facility Budget Form (available for download on eBRAP "Funding Opportunities and Forms" web page), including a budget justification for each year. If more than one Military Facility is proposed, submit a separate budget form for each site. Refer to the General Submission Instructions, Section II.D.5., Research & Related Budget, for detailed information.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Submission Instructions, Section II.D.4., for detailed information.

- PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf."
- PI Previous/Current/Pending Support (three-page limit page limit): Upload as "Support_LastName.pdf."
- Key Personnel Biographical Sketches (five-page limit each): Upload as

"Biosketch_LastName.pdf."

- Key Personnel Previous/Current/Pending Support (three -page limit each): Upload as "Support_LastName.pdf."

4. **Research & Related Budget:** Refer to the General Submission Instructions, Section II.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.

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

- **For Federal Agencies:** Proposals/Applications from **Federal agencies** must include in their budget justifications a **Federal Financial Plan (Plan)**. The Plan must address how all funds will be obligated before their period for obligation expires, and how funds will be available to cover research costs over the entire award period. The Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.
- **For Collaborating Military Facilities:** Proposals/Applications from organizations that include **collaborations with DoD Military Facilities** (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) must submit Collaborating DoD Military Facility Budget Form(s) as instructed in Attachment 12.

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

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

## F. Verification of Grants.gov Proposal/Application in eBRAP

Organizational representatives and PIs can view their proposals/applications as submitted through Grants.gov within a period of 5 calendar days of proposal/application submissions to Grants.gov, i.e., ***the verification period***. This will enable applicants to make modifications to proposals/applications until the end of the verification period, prior to scientific and programmatic evaluations.

After proposal/application submission to Grants.gov, eBRAP will retrieve and validate the submission. eBRAP will notify the organizational representatives and PI via email and instruct

them to log into eBRAP to review, modify, and verify the proposal/application. Files that fail eBRAP validation will be noted in both the email and in the Full Application Files tab. eBRAP does not validate the accuracy or completeness of content in the files. PIs are strongly encouraged to review all proposal/application components. ***If either the Project Narrative exceeds the page limit or the Budget form contains only zeros, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID.*** Refer to the General Submission Instructions, Section II.C., for more information.

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

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

### H. Submission Dates and Times

The USSOCOM BAA is an open and continuous announcement for a 12-month period, from, April 15, 2016 through 14 April 2017. Two programmatic review cycles will occur during the open period and one following the closing of this announcement. Pre-proposal/pre-applications must be submitted by the due dates listed in the "Key Dates" section of the BAA. A full proposal/application may only be submitted if the PI has submitted a pre-proposal/pre-application and received an invitation to submit. No pre-proposal/pre-application or full proposal/application can be submitted to this BAA after April 14, 2017 at 11:59 p.m. Eastern Time. If an invited proposal/application is not submitted by April 14, 2017, it will have to be submitted under the FY17 USSOCOM BAA (anticipated to be posted to Grants.gov on April 15, 2017).

### I. Intergovernmental Review

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

### J. Funding Restrictions

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 to exceed $1,500,000 (Including Indirect Costs).

Refer to the General Submission Instructions, Section II.C.4, "Research & Related Budget," for discussion of allowable costs, including pre-award costs and collaborations with Military Facilities.

### K. Other Submission Requirements

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

## VI. PROPOSAL/APPLICATION REVIEW AND SELECTION INFORMATION

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.

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

### A. Peer and Programmatic Review

1. **Peer Review:** To determine technical merit, all proposals/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.

**2. Programmatic Review**: To make funding recommendations, the following criteria will be 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.

### B. Submission Review Dates

This is an open announcement from April 15, 2016 through 14 April, 2017. Two pre-proposal reviews cycles will occur throughout the year. Pre-proposals/pre-applications should be submitted by the submission deadlines listed in the "Key Dates" section of the BAA. An invited full

proposal/application should be submitted by the due date listed in the "Key Dates" section. No pre-proposal/pre-applications may be submitted under this BAA after April 15, 2017. If an invited proposal/application is not submitted by the due dates for full proposals, it will have to be submitted under the FY17 BAA (anticipated to be posted to Grants.gov April 15, 2017). No proposal/application received under this BAA will be considered for funding after 24 months from the date of submission.

### C. Proposal/Application Selection Process

After the two-tier evaluation, proposals/applications recommended for funding may be prioritized. A prioritized listing of alternates (deferred decisions) may also be prepared, when warranted. Subsequent awards depend upon the availability of funds and fulfillment of requirements and priorities determined to exist at the time of award. In some cases, funding priorities may change as certain scientific tasks are addressed and new mission assignments arise.

If selected for funding, the award may also be dependent upon the organization providing adequate additional regulatory documentation, such as human subjects/anatomical substances/use of cadavers protocols and approvals, animal subjects protocols and approvals, and environmental information. The award may also be dependent upon additional supporting administrative and budgetary information.

### D. Notification of Proposal/Application Review Results

Each PI and organization will receive email notification via eBRAP of the funding recommendation. Notifications should be sent within 120 days of submission. Each PI will receive a peer review summary statement on the strengths and weaknesses of the proposal/application.

**A recommended for funding notification is NOT an authorization to begin performance or a guarantee of an award.** Awards are contingent upon availability of funding, adequacy of supporting documentation submitted, fulfillment of all requirements, and upon completion of successful negotiations. Authorization to begin performance will be received via an award document (contract, grant, or cooperative agreement, as applicable) signed by the USAMRAA Contracting or Grants Officer. Awards may be issued at any time throughout the year.

## VII. ADMINISTRATIVE ACTIONS

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

### A. Rejection

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

- Project Narrative exceeds the page limit.

- Project Narrative is missing.
- Budget form contains only zeros.

### B. Modification

- Pages exceeding the specific limits may be removed prior to review for all documents other than the Project Narrative.
- Documents not requested may be removed.
- Following proposal/application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the proposal/application submitted to Grants.gov. During this verification period, the PI may upload missing documents (excluding those listed in Section VII.A., Rejection), replace files, and re-categorize files. These modifications must be completed by the end of the application verification period; otherwise, the proposal/application will be reviewed as submitted

### C. Withdrawal

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

- Federal agency personnel involved in the review process and/or with making funding recommendations are named as being involved in the research proposed or found to have assisted in the pre-proposal/pre-application or proposal/application processes, including, but not limited to, concept design, proposal/application development, budget preparation, and the development of any supporting documentation. ***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 are prohibited from being involved in the review process and/or with making funding recommendations.***
- 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 PI does not meet the eligibility criteria as described in this BAA.
- 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.

### D. Withhold

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

## VIII. AWARD ADMINISTRATION INFORMATION

### A. Award Notice

The PI should receive disposition regarding the full proposal/application via an email from eBRAP within 180 days of submission. **A recommended for funding notification is NOT an authorization to begin performance nor a guarantee of an award.**

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

Awards will be made at any time throughout the year and are contingent upon availability of funding, adequacy of supporting documentation submitted, fulfillment of requirements, and completion of successful negotiations. No proposal/application submitted under this BAA will be considered for funding after 24 months from the date of submission to Grants.gov.

Refer to the General Submission Instructions, Appendix 3, for additional information.

### B. Administrative Requirements

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

### C. National Policy Requirements

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

### D. Reporting Requirements

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

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 now a requirement of all DoD contracts. Offerors are allowed to include a nominal fee in their cost/price proposal for providing these data. A "nominal fee" is defined as a computation of an administrative assistant equivalent labor category providing approximately 6-8 hours to complete data input. Offerors may opt to not separately price this required annual data input. CMR costs/price will not be evaluated as part of the total evaluated proposal cost/price.
  - The contractor shall report ALL contractor labor hours (including subcontractor labor hours) required for performance of services provided under each contract via a secure data collection site. The contractor is required to completely fill in all required data fields using the following web address: http://www.ecmra.mil/.
  - Reporting inputs will be for the labor executed during the period of performance during each Government fiscal year (FY), which runs October 1 through September 30. While inputs may be reported any time during the FY, all data shall be reported no later than October 31 of each calendar year, beginning with 2016. Contractors may direct questions to the help desk at: contractormanpower@hqda.army.mil or via phone at 703-377-6199.

### E. Changes of Principal Investigator and Organization

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

## IX. AGENCY CONTACTS

### A. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

### B. Grants.gov Contact Center

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

Phone: 800-518-4726

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

## X. OTHER INFORMATION

### A. Recipient Qualification

Refer to the General Submission Instructions, Appendix 1, for general information on required qualifications.

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

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

***Should the PI of a funded project leave the award organization, both the PI and organization must contact the USAMRAA Contracting or Grants Officer as soon as possible to discuss options for continued support of the research project. Every effort should be made to notify the USAMRAA prior to the PI leaving the organization. An organizational transfer of an Assistance Agreement award will not be allowed in the last year of the (original) period of performance or any extension thereof. An organizational transfer of a Contract award will not be allowed.***

### B. Proprietary Information

***Do not*** include any proprietary information in the pre-proposal/pre-application or full proposal/application. Proprietary information should ***only be included*** in the full proposal/application ***if necessary for evaluation purposes.*** Abstracts of all funded

proposals/applications may be posted; ***therefore, proprietary information should not be included in the abstract.***

Conspicuously and legibly mark any proprietary information that is included in the full proposal/application. Identify any proprietary information that will be provided to the government and whether the applicant will request a waiver of government purpose rights.

### C. Common Submission Problems

- Failure to enter an email address for change notifications under the BAA Funding Opportunity Announcement in Grants.gov for notifications on any modification made to the initial posting.
- Attachments are uploaded into the incorrect form on Grants.gov forms. (See Proposal/Application Submission Checklist below.)
- Failure to contact the Grants.gov Help Desk when needed.
- Failure to send attachments.
- Inability to locate attachment forms. (Select "Search Grants" at http://www.grants.gov and enter W81XWH-16-R-SOC1 in the "Funding Opp #" block. When the Funding Opportunity appears, select the Funding Opportunity #. When you reach the "View Grant Opportunity" screen, select "Full Announcement." The forms will be listed on the following screen.)
- Use of "illegal" characters in attachment titles.
- Attachments exceed size limits.
- Upload attempts of unacceptable attachments: bitmap, TIFF, etc.
- Duplicate upload of documents.

## XI. PROPOSAL/APPLICATION SUBMISSION CHECKLIST

| Grants.gov Submission Package Components | Upload Order | Action | Completed |
|---|---|---|---|
| SF-424 (R&R) Application for Federal Assistance | | Complete as instructed. | |
| | 1 | Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf." | |
| | 2 | Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf." | |
| | 3 | Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf." | |
| | 4 | Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf." | |

| | | | |
|---|---|---|---|
| Attachments Form | 5 | Statement of Work: Upload as Attachment 5 with file name "SOW.pdf. | |
| | 6 | Outcomes and Impact Statement: Upload as Attachment 6 with file name "Impact.pdf." | |
| | 7 | Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf." | |
| | 8 | Data and Research Resource-Sharing Plan: Upload as Attachment 8 with the file name "Sharing.pdf." | |
| | 9 | Conflicts of Interest: Upload as Attachment 9 with file name "COI.pdf," if applicable. | |
| | 10 | Data Management: Upload as Attachment 10 with file name "DataManage.pdf." | |
| | 11 | Post-Award Project Transition Plan: Upload as Attachment 11 with file name "Transition.pdf." | |
| | 12 | Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 12 with the file name "MFBudget.pdf," if applicable. | |
| Research & Related Senior/Key Person Profile (Expanded) | | Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field. | |
| | | Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field. | |
| | | Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field. | |
| | | Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field. | |
| Research & Related Budget | | Attach Budget Justification (BudgetJustification.pdf) to the appropriate field. Complete form as instructed. | |
| Project/Performance Site Location(s) Form | | Complete form as instructed. | |
| R&R Subaward Budget Attachment(s) Form (if applicable) | | Complete form as instructed. | |