I. OVERVIEW OF THE FUNDING OPPORTUNITY

United States Special Operations Command

Department of Defense

BROAD AGENCY ANNOUNCEMENT (BAA)
for Extramural Biomedical and Human Performance
Research and Development

Funding Opportunity Number: HT9425-23-S-SOC1

Announcement Type: Initial

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

KEY DATES

Release/Posted Date: Initial 01 August, 2023

Closing Date: 31 July, 2028, 11:59 p.m. Eastern Time

This Funding Opportunity Announcement is a BAA. It is continuously open for a 5-year period, from 1 August 2023 closing 31 July 2028, 11:59 p.m. Eastern Time. Note: This BAA will be updated annually.

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

Instructions, which are available for downloading from Grants.gov. The General Submission Instructions are located under the "package" tab and can be downloaded by selecting the "Download Instructions" icon when previewing the submission package.

TABLE OF CONTENTS

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

The Fiscal Year 2023 – Fiscal Year 2028 (FY23-FY28) United States Special Operations Command (USSOCOM), BAA for Extramural Biomedical and Human Performance Research and Development contains several changes from previous USSOCOM BAAs. Read each section carefully. Note the following:

- The total individual project estimated cost ceiling has been increased from $4,000,000 to $5,000,000, and generally anticipated project cost has been increased from $700,000 to $1,500,000.
- The "Program Description" that describes the "Research Areas of Interest (RAIs)" have been updated.

II.A. Program Description

This BAA is intended to solicit extramural research and development ideas using the authority provided by United States Code, Title 10, Section 4001. This BAA is issued under the provisions of the Competition in Contracting Act of 1984 (Public Law 98-369), as implemented in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016. In accordance with FAR 6.102, projects funded under this BAA must be for basic and applied research to support scientific study and experimentation directed toward advancing the state-of-the-art or increasing knowledge or understanding rather than focusing on development of a specific system or hardware solution. Research and development funding through this BAA is intended and expected to benefit and inform both military and civilian medical practice and knowledge.

This BAA provides a general description of the USSOCOM's research and development programs, including RAIs, evaluation and selection criteria, pre-proposal/preapplication and full proposal/application preparation instructions, and general administrative information. Submission of a pre-proposal/pre-application is required. After review, if the USSOCOM is interested in receiving a full proposal/application, the Applicant or Offeror will be invited to submit a full proposal or full application. 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 utilizes the tools and processes provided by the Congressionally Directed Medical Research Programs (CDMRP). The CDMRP manages the electronic Biomedical Research Application Portal (eBRAP) system and retrieval and processing of full proposal/application submissions from Grants.gov. Refer to Section II.G, Agency Contacts, for additional information.

The USSOCOM's supporting contracting office, the U.S. Army Medical Research Acquisition Activity (USAMRAA) will be the awarding and administering office for proposals selected for funding.

II.A.1. Research Area of Interest

A primary emphasis of the USSOCOM Biomedical, Human Performance, and Canine Research Program is to identify and develop techniques, knowledge products, and materiel (medical devices, drugs, and biologics) for early intervention in life-threatening injuries; prolonged field care (PFC); human performance optimization; canine medicine/performance; brain health; immune response; automation of systematic reviews and metanalysis; and novel post-traumatic stress, depression, and anxiety treatment.. Special Operations Forces (SOF) medical personnel place a premium on medical equipment that is small, lightweight, ruggedized, modular, multi-use, and designed for operation in extreme environments. The equipment must be easy to use, require minimum maintenance, and have low power consumption. Drugs and biologics should optimally not require refrigeration or other special handling. All materiel and related techniques must be simple, effective, and easily modified for commercialization. Research projects may apply existing scientific and technical knowledge for which concept and/or patient care efficacy have already been demonstrated to meet SOF requirements. The proposed research must be relevant to active-duty service members, veterans, military beneficiaries, and/or the American public. Relevant research must be responsive to the health care needs of the U.S. Armed Forces, family members of the U. S. Armed Forces, U.S. Veterans, and civilian populations. Proposals must address a relevant health problem responsive to one of the RAIs identified below. Additional RAIs may be added during the life of the BAA (FY23-FY28). The following RAIs are in no particular order:

1. Damage Control Resuscitation:

SOF medical personnel require capabilities for far-forward medical care to reduce the mortality and morbidity associated with critical wounds and injuries. The proposed research, application, and/or development of medical techniques and materiel (medical devices and biologics) for optimal triage and early intervention in critical life-threatening injuries when casualty evacuation is not possible or is delayed. The project areas under "Damage Control Resuscitation" to which the USSOCOM 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, noncompressible 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 transfusions (i.e., person to person, pre-hospital blood banking, and blood substitutes) forward of normal logistics support; (e.g., evaluating blood for type/cross matching and for the presence and/or reduction of pathogens, leucocytes, and AB antibodies to improve safety of whole blood transfusion at the point of injury). Projects that will be considered also include other blood components such as freeze-dried plasma and platelets, cryoprecipitate, fibrinogen, prothrombin complex concentrate, and injectable medications to address the coagulopathy of trauma such as Tranexamic acid. Research should focus on extending shelf life of whole blood beyond current limitations. A long-term objective is a blood substitute that is comparable in size, weight of traditional blood products, and effectively functions like fresh whole blood without requiring refrigeration. Strategies to find the delivery of these prototypes individually or in concert will also be considered. 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 can carry oxygen in quantities similar to healthy red blood cells.

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 (this can translate to remote civilian areas). 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, including support equipment such as sterilization, with emphasis on equipment with greater capabilities than currently fielded devices, smaller size and weight, low power demands, and flexibility in power supplies. Additionally, research and development efforts should include telehealth technologies linking forward surgical providers with higher medical authority consultation and effective, relevant, and dynamic surgical training capabilities. Research may also include a human systems approach to define limitations and mitigation strategies of surgical capability in austere environments (i.e., low light, temperature variability, surgery in flight, etc.).

2. Prolonged Field Care (PFC):

SOF medical personnel require capabilities for far-forward medical care to reduce the mortality and morbidity associated with critical wounds, injuries, diseases, and associated sepsis. PFC should focus on novel treatments that support the ability to manage 3-5 patients across the spectrum of illness to

multi-system injury for a minimum of 5-7 days. Significant consideration will be given to proposals focused on PFC that may also relate to Sections 1 (a-d) and 3(a) of this BAA.

a. Medical Sensors and Devices:

The primary emphasis is to research, apply and/or develop medical techniques, pharmaceuticals, biologics, and field-sustainable, rapidly deployable medical sensors and/or 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. In addition, proposals that investigate or develop wireless biosensors should demonstrate physiological monitoring capabilities to include, but not limited to, heart rate, blood pressure, pulse oximetry, respiration rate, capnography, core temperature, heart rate variability and compensatory reserve index (CRI). Research and development of devices and sensors should include or plan for the capability to transmit (Bluetooth) to Android handheld devices and tablets. (NOTE: Ideally, sensor and equipment technologies should be electronically readable, scannable, or transmittable to the Battlefield Assisted Trauma Distributed Observation Kit (BATDOK), an Android-driven, multi-patient, point of injury casualty monitoring capability being fielded by the U.S. Air Force (USAF) Pararescuemen and other SOF Medics. Novel devices are required which aid in measuring physiologic decompensation and/or adequacy of treatment/resuscitation in the field environment and/or provide a trigger for a pre-hospital medical intervention (i.e., validation of tissue (muscle) oxygen saturation (StO2), CRI, traumatic brain injury (TBI) measures, etc.

3. 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. Additionally, novel wireless, transmittable or scannable solutions such as patches, scanner/readers or other noninvasive technologies as described in paragraph 3.a. below are encouraged.

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

4. 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 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 the SOF unique mission sets.

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

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

b. Operational Monitoring:

The proposed project must seek to develop wireless biosensors for monitoring SOF personnel in extreme environments (i.e., high altitude, whether in-flight or the environment itself, excessive heat or cold, etc.), and potentially hazardous material exposure. Sensors should address physiological measurements and/or chemical, biological and/or radiological hazards. For hazards monitoring, a personal dosimetry device is desired that can detect and alarm based on radiation and chemical presence. The alarming function can be pre-determined to account for known environmental conditions (i.e., natural occurring radiation levels that are below threshold/detrimental health levels) and Parts Per Million (PPM) counts that would trigger an alert. This detection device needs to be able to alarm differently to identify the "type" of hazard(s), and to trigger a back-off and/or donning of additional PPE. Monitoring should be capable of wirelessly communicating via Bluetooth to Android handheld devices, tablets, or compatible wrist-mounted displays.

5. Brain Health:

Brain Health research efforts include, but are not limited to: development and validation of fieldable Neurocognitive Assessment Tools (NCATs) and baseline testing, Comprehensive Symptom History (CASH) collection, blast exposure and impact monitoring, determination of safe acceptable limits for blast exposure, development and validation of capabilities to easily identify/diagnose mild, moderate, and severe TBI, methods to prevent, screen for, monitor, and correct neuroendocrine dysfunction, methods to prevent TBI from impact and blast such as redesign of helmets, body armor, and munitions, development of pharmaceuticals to prevent and/or treat brain injury, validation of brain injury prevention strategies, and development of return to duty decision support tools.

a. Environmental Exposures:

Research that develops novel material and/or approaches to protect SOF personnel from the neurological effects of single and repetitive auditory (impulse noise) and non- auditory

(overpressure) blast exposures and other environmental factors determined to affect nervous system function.

b. Environmental Exposure Effects:
Research that determines the neurocognitive and nervous system effects from single and repetitive blast exposures, impulse noise, and other potential hazardous environmental factors.

c. Biomarkers:
Research to determine which biomarkers are indicative of mild, moderate, and severe TBI; sequelae from TBI causing further injury; recovery status; and recovery rate from TBI. Testing and validating diagnostic biomarkers for TBI. Proposals should also consider incorporation of validated biomarkers onto existing or future diagnostic platforms. Use of machine learning and/or model development to interpret and report biomarkers that are indicative of TBI are of interest.

d. Genetic Factors:
Research to determine if there are genetic predispositions, epigenetic changes and/or, genomic modulators that affect the susceptibility to and recovery from TBI and neurotrauma.

e. Neuropsychological Testing:
Research to validate Neurocognitive Assessment Tools (NCATs) to determine baseline neurocognitive status, readiness, neurocognitive degradation, sensitivity to various exposures, TBI and recovery status post injury. Proposals to improve the speed, accuracy, specificity, and proximity to injury for the use of NCATs, as well as to compare new technologies and/or modalities (including passive assessment of cognition) to existing NCATs.

f. Affect testing. Research to develop and validate baseline and transient affect testing or assessment tools to measure emotion and/or mood, to monitor change in emotion and/or mood after TBI, and to investigate the effects of emotion or mood status on functional performance.

g. Olfactory, Oculomotor, Auditory, Vestibular, Cranial Nerve, and Vocal-Acoustic Performance:
Research and proposals to perform and validate oculomotor, auditory, vestibular, cranial nerve, and vocal acoustic assessments. Research and proposals to assess the effect of nervous system injury to oculomotor, auditory, vestibular, cranial nerve, and vocal-acoustic performance and strategies to restore their performance after injury and prevent injury or further decline.

h. Postural Stability:
Research to assess the effects of blast exposure on postural stability including the proprioceptive component. Novel treatment strategies, therapies, and therapeutics to prevent and/or correct detriment to postural stability from TBI and neurotrauma caused by blast, impact, and/or other environmental exposures.

i. Neuroendocrine Dysfunction:
Methods to prevent, screen for, monitor, and correct neuroendocrine dysfunction.

j. Neuroimaging:
Research into novel imaging and imaging interpretation techniques including, but not limited to Computed Axial Tomography (CAT), Magnetic Resonance Imaging (MRI), and Positron emission tomography (PET) scans, to diagnose brain tissue pathologies including, but not limited to, axonal injury, myelin injury, and astroglial scarring without the need for immunohistochemistry, immunofluorescence, or histopathology testing.

k. Analytics:
Research into analysis including Machine Learning, Natural Language Processing, and Artificial Intelligence enabled analysis of data including, but not limited to, NCATs; environmental exposures likely to affect brain health; blast, impact, and noise exposures; auditory, vestibular, and vocal acoustic assessments; postural stability assessments; and neuroimaging.

l. Neuromodulation:
Research into the use of neuromodulation techniques for treating TBI, neurotrauma, pain, restoring and improving function, and improving behavioral health.

m. Brain Lymphatics and Glymphatics:
Research into measuring the fluid dynamics of the brain lymph system, diagnosing dysfunction, and validation for tools or techniques to improve brain lymph clearance.

n. Pupillometry, Pupillary Response and Microsacaades:
Research into field capable pupillary response measurement capture and analysis, with or without the ability to capture microsacaades in order to assess central nervous system loading and/or damage.

6. Immune Response:
The use of modified and novel strategies to cause, strengthen, or supplement immunity through the use of, but not limited to mRNA vaccines, nanolipoprotein particles (NLPs), polyvalent vaccines, and phages.

7. Chronic Pain:
The proposed research must address the development of novel, non-opioid treatments for chronic pain with or without the presence of migraines, allodynia, or fibromyalgia; but not with accompanying myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) or cancer.

8. Automation of Systematic Reviews and Metanalysis:
Research into Automation of Systematic Reviews and Metanalysis using the Preferred Reporting Items for Systematic Reviews and Meta Analyses (PRISMA) or a similar method.

9. Medical Simulation and Training Technologies:
The proposed project must research, apply and/or develop improved pre-hospital tactical combat casualty care (TCCC) training with an emphasis on the SOF pre-hospital providers. Medical simulations should replicate all phases of the pre-hospital combat environment, including care under

fire, tactical field care and casualty evacuation. Human-like simulators should bleed, breath, void, have a physiologically relevant temperature, pulse, and response to medical care with little to no operator/controller input, should be all-weather capable and should evoke an emotional response from those with whom it interacts. Medical training simulations should capture and be capable of providing a report on the timing, appropriateness, and effectiveness of medical treatment. All material solutions should meet joint airworthiness standards. Additionally, there is interest in research focused on validating or measuring the effectiveness of current medical simulation and training technologies and in determining the best methods of acquiring and maintaining PFC skills as well as the impact of these skills on patient outcomes. In addition, the proposed project must research the efficacy of using stress inoculation training (vs traditional didactics or other instructional methods) to teach key TCCC skills (e.g., tourniquets, IV placement, etc.). Of particular interest are the effects on stress response, performance, and decision making of the student as well as best methods for optimizing performance in high stress situations as well as mitigating negative aspects of stress.

10. Human Performance Optimization:

USSOCOM requires SOF personnel to withstand extraordinary physical demands and psychological stress to complete their missions. The optimization of SOF personnel's ability to perform at very high levels for long durations, in addition to processing information and making critical decisions in a timely manner, while operating in extreme environments, will significantly improve their overall operational effectiveness. This research area explores alternatives and/or new approaches to sustain and optimize SOF human performance.

a. Improved Sleep:

The proposed project must research, apply and/or develop novel approaches to achieve the restorative effects of sleep. This may include methods to induce, maintain, or improve the quality of sleep throughout the entire night. Additionally, the ability to accelerate the effects of sleep through methods requiring less time (e.g., the effects of sleeping eight hours are realized in four hours' time) or enabling the SOF personnel to quickly reach and adequately cycle through the stages of sleep where the highest restorative effects occur (i.e., Stage 3/ deep sleep, and Stage 4/rapid eye movement sleep).

b. Optimal Acclimatization Strategies:

The proposed project must research, apply, and/or develop novel approaches and/or technologies that provide rapid and sustainable human acclimatization in austere environments, to include fatigue countermeasure, extremes in temperature, extremes in altitude, and time-zone change (i.e., circadian acclimatization).

c. Wearables:

The proposed project must research , apply, and/or develop novel approaches and/or wearable technologies that will monitor physiological measures of human performance to include, but not limited to, caloric expenditure, heart rate/heart rate response, heart rate variability, body fat percentage, sleep hygiene (deep and REM sleep duration) in real-time. Measures should be accurate with low fixed bias, wirelessly communicated via Bluetooth, Near Field Magnetic Induction or

Radio Frequency technology in real-time and provide the command the capability to utilize the data for analysis of individuals and/or team performance via the USSOCOM Human Performance Data Management System (i.e., Smartabase). The device should be able to be turned on/off and/or have an inactive mode, provide real-time feedback on a display screen, be capable of displaying time, and be adjustable to fit users of different statures. Of parallel interest to address is a proposed project to track aircrew sleep, fatigue, and performance degradations through a wearable device that provides quantitative data (rather than qualitative surveys often seen in USAF Fatigue Studies), that in turn will be gathered and amalgamated from entire units, in order to track individual performance, unit performance, mission impacts to performance levels, length of time for acclimatization (if it is ever achieved), and potential risk of mishaps.

d. Diagnostics for Performance Sustainment:
The proposed project must research, apply, and/or develop minimally invasive diagnostic devices to provide actionable information on nutritional gaps, hormonal response to training, physiological response to performance interventions and recovery, and epigenetic predictors of potential injury.

e. Performance Nutrition:
The proposed projects must research, apply and/or develop methods to accurately measure nutritional status of SOF personnel. The proposed project should focus on cost effectiveness, accuracy, and end-user compatibility (i.e., user friendly) methods or devices for identifying and optimizing an individual's nutrient status. Consideration of alternative fuel (energy) sources, dietary supplementation, and nutrient volume/timing are specific areas of interest.

f. 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 (i.e., over-the-counter (OTC) or prescription (Rx) and commonly ingested/commercially available nutritional supplements).

g. Physiological Performance:
The proposed project must research, apply, and/or develop novel approaches and/or technologies to maximize the physiological performance of SOF personnel in austere and/or training environments, to include increased endurance, enhanced senses, tolerance to environmental extremes, and enhanced overall fitness, in order to maintain operational posture/ability in high stress scenarios without noticeable augmentation, and without hampering personnel mobility.

h. Cognitive Performance:
The proposed project must research, apply, and/or develop novel approaches and/or technology that provide greater mental acuity or neuroenhancement (i.e., targeted enhancement and extension of cognitive and affective abilities). Encompasses pharmacological and non-pharmacological methods of improving cognitive, affective, motor functionality and performance, to include neuromodulation.

i. Psychological Performance and Suicide Prevention:

The proposed project must research, apply, and/or develop novel approaches to the assessment and improvement of behavioral health within the force. Examples include but are not limited to, novel approaches to treatment and rehabilitation from acute and/or chronic post-traumatic stress, depression, and anxiety, improved emotional and nervous system self-regulation, digital/virtual engagement strategies, methods to measure behavioral health performance over time, and improved suicide prevention tools/strategies.

j. Family Readiness and Social Connectedness:
The proposed project must research, apply, and/or develop novel approaches to increase healthy SOF family functioning. Family functioning includes positive interpersonal relationships, personal resilience, self-efficacy, and the development of supportive social networks. Potential research could determine what educational and didactic experiences best improve these factors of healthy SOF family and relational functioning.

k. Spiritual Resilience:
The proposed project must research, apply, and/or develop innovative approaches to increase SOF spiritual resilience or add scientific rigor to support current approaches. Spiritual resilience includes religious practice, morals, ethics (such as just war tradition), connectedness, sense of purpose and belonging. Potential research could determine what types of spiritual training or engagements best improve these factors of spiritual resilience.

11. Canine Medicine and Performance:
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 eight "Canine Medicine and Performance" project areas, to which SOF will give consideration, in priority order, are:

a. Trauma Resuscitation:
The proposed project must support development of innovative techniques/strategies for canine trauma resuscitation (e.g., hypotensive resuscitation, whole blood/blood component replacement, and 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.

b. Non-Traditional Anesthesia Protocols:
The proposed project must 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.

c. Canine Performance Optimization

The proposed project must research, apply, and/or develop novel approaches and/or technologies that address optimization of canine performance through improved physical conditioning programs, enhanced nutrition, and genetics research.

d. 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.

e. Chemical, Biological, Radiological, Nuclear, and Explosive (CBRNE) Canine Decontamination, Treatment, and PPE Against Possible Exposure:
The proposed projects must research, apply, and/or develop novel approaches that will diagnose, treat, decontaminate, and protect canines from exposure to chemical, biological, radiological, nuclear, and high yield explosives.

f. Environmental Extremes:
Project proposals must research, 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.

g. Brain Health and TBI
Brain health research efforts include but are not limited to development and validation of NCATs, blast exposure and impact monitoring, determination of safe acceptable limits for blast exposure, validation of neurocognitive baseline testing, capabilities to easily determine mild, moderate, and severe TBI, pharmaceuticals to prevent or treat brain injury, validation of brain injury treatment strategies, and procedures to determine safe return to duty decisions for SOF canines.

h. Pre- and Post-Trauma Training / Behavioral Issues:
The proposed project must 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.

i. Canine Simulation Technologies:
Develop improved pre-hospital canine combat casualty simulation training devices with an emphasis on Special Operations Forces (SOF) pre-hospital providers. The proposed projects must research and apply/or develop novel approaches for high-fidelity canine trauma training simulation devices with physiologically relevant feedback to include temperature, pulse, lifelike size and weight, realistic fur, active bleeding, anatomically accurate airways, and haptic technology. Canine training devices should respond to medical treatments with little to no operator/trainer intervention and capture and provide accurate casualty care feedback. All simulators/simulations should meet Joint Airworthiness Standards.

II.B. Federal Award Information

The Anticipated total costs budgeted for the entire period of performance inclusive of all contract awards made in response to this BAA, will not exceed $10 Million annually. The number of awards is indeterminate and **contingent upon funding availability**. Any funding that is received by the USSOCOM that is appropriate for a research area described within this BAA may be utilized to fund awards. Refer to Section II.D.5. Funding Restrictions, for detailed funding information.

The USAMRAA will negotiate the contract awards for proposals selected for funding. A contract is required when the principal purpose of the instrument is to acquire supplies or services for the direct benefit or use of the U.S. Government. The contract type, along with the start date, will be determined during the negotiation process.

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

Research involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human Research Oversight (OHRO),, prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is not required. The OHRO Human Research Protections Offiical (HRPO) review is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for OHRO HRPO regulatory review and approval processes.*** Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted proposal/application as a stand-alone study. Submission to OHRO of protocols involving more than the scope of work in the DoD-funded award will require review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Refer to the General Submission Instructions, Appendix 1, and the Human Subject Resource Document available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

Typically, a clinical trial is not associated with this BAA. A clinical trial is defined as a prospective accrual of patients (human subjects) in which an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USSOCOM Veterinarian Review Office (VRO) which ensures that research conducted, contracted, sponsored, supported, or managed by the DoD involving animal care are conducted in accordance with federal, DoD, Army, USSOCOM VRO, and international regulatory requirements. The USSOCOM VRO is responsible for administrative review, approval, and oversight of all animal research protocols, including all changes made during the life of the protocol.

Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The VRO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol. ***Allow at least 1 to 2 months for regulatory review and approval processes for animal studies.***

Questions concerning animal use and review should be directed to the USSOCOM VRO: Phone: 813-826-6031; Email: socom_vet@socom.mil.

Refer to the General Submission Instructions, Appendix 1, for additional information.

The USSOCOM intends that information, data, and research resources generated under awards funded by this BAA be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organizations:

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

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

The USSOCOM is committed to supporting small businesses. Small business, Veteran-owned small business, Service-disabled Veteran-owned small business, HUBZone small business, small disadvantaged business, and woman-owned small business concerns must be given the maximum practical opportunity to participate through subawards on research proposals submitted through the BAA.

II.C.1.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.

There are no limitations on the number of proposals for which an investigator may be named as a Principal Investigator (PI).

The USAMRAA makes awards to eligible organizations, not to individuals.
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 and; (2) verifying that the investigators are qualified to conduct the proposed study and to use humans or animals as research subjects, if proposed.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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

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

Use of the System for Award Management (SAM) and the Responsibility/Qualification (R/Q): To protect the public interest, the Federal Government ensures the integrity of Federal programs by striving to conduct business only with responsible organizations. The USSOCOM uses the "Exclusions" within the Performance Information functional area of the SAM and data from the R/Q, a component within SAM, to verify that an organization is eligible to receive Federal awards. More information about the SAM and the R/Q is available at https://www.sam.gov/. Refer to the General Submission Instructions, Appendix 3, for additional information.

Conflicts of Interest: All awards must be free of conflicts of interest (COIs) that could bias the research results. Prior to award of a 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 Contracting Officer that COIs cannot be adequately managed. Refer to the General Submission Instructions, Appendix 3, for additional information.

Review of Risk: The following areas may be reviewed in evaluating the risk posed by 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.

Subcontracting Plan: If the resultant award is a contract that exceeds $750,000 and the offeror is other than a small business, the contractor will be required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.704 and DFARS 219.704. A mutually agreeable plan will be incorporated as part of the resultant contract.

II.D. Proposal/Application Submission Information

II.D.1. Where to Obtain the Proposal/Application 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 **HT9425-23-S-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 or eBRAP, depending on the type of application being submitted.

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

Classified Submissions: Classified proposals are not expected. However, in an unusual circumstance the applicant may be notified that access to classified information and/or controlled unclassified information will occur under the work proposed. In those instances where a contract is awarded requiring access to classified information and/or controlled unclassified information, clause FAR 52.204-2 shall be in effect, as well as a DD Form 254, if issued.

Care must be exercised to ensure that classified, sensitive, and critical technologies are not included in a proposal/ application package. If such information is required, appropriate restrictive markings and procedures should be applied prior to submission of the proposal/ application package. Portions of the proposal/ application package may be subject to release under terms of the Freedom of Information Act, 5 U.S.C. 552, as amended.

Pre-application content and forms must be accessed and submitted at eBRAP.org. Full application packages must be accessed and submitted at Grants.gov.

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

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

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

Pre-Application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (https://eBRAP.org/).

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

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

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

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

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

During the pre-proposal/pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number is required during the full application submission process. To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

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

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 eBRAP Help Desk via email 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 Officer. Change in Principal Investigator during contract performance unless otherwise restricted, will be allowed at the discretion of the USAMRAA Contracting Officer, provided that the intent of the award is met.

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 eBRAP 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 may be submitted at any time prior to the BAA closing date. Pre-proposals 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 the 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 the 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 form is designed to fill in common required fields across other forms, such as the applicant name, address, and Unique Entity Identifier (UEI) Number. Once it is completed, the information will transfer to the other forms.

  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 applicant 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.

- **Tab 4 – Conflicts of Interest (COI):**
  List all individuals other than collaborators and key personnel who may have a conflict of interest (COI) in the review of the pre-proposal/pre-application (including those with whom the PI has a personal or professional relationship). 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, 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. Military Facility is defined as Military Health System (MHS) facility, research laboratory, medical treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center. However, these Military Facility personnel cannot be involved in the review process and/or with making funding recommendations.*** Refer to the General Submission Instructions, Appendix 3.D, for additional information. For questions related to COI, contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

- **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 RAIs 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/preapplication to be accepted and processed.

II.D.2.b. Pre-Proposal/Pre-Application Screening Criteria

The USSOCOM scientists or outside experts will screen pre-proposals for technical merit and programmatic considerations. Based on the screening of the preproposal, a PI may be invited to submit a full proposal/application. Pre- proposal 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; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-proposals. Within 180 days of submission, PIs should receive email notification via eBRAP regarding disposition of their pre-proposals.

A. II.D.2.c. Step 2: Full Proposal/Application Submission Content

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. It should be submitted within **60 days** of the PI's receipt of an invitation to submit, as directed in II.D.2. 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., BA23XX.
The USSOCOM cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

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

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.

II.D.2.c.i. Full Guidelines

Organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in the Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the ***same version*** of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Submission Instructions, Section III, and the "Apply For Grants" page of Grants.gov (https://www.grants.gov/web/grants/applicants/apply-for-grants.html) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

Table 1. Full Submission Guidelines

Submissions
Download application package components for **HT9425-23-S-SOC1** from Grants.gov (http://www.grants.gov) and create a Grants.gov Workspace. The Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.
SF424 Research & Related Forms (R&R) Application for Federal Assistance Form: Refer to the General Submission Instructions, Section III.A.1, for detailed information.

Submissions

Descriptions of each required file can be found under Full Application Submission Components:

- Attachments
- Research & Related Personal Data
- Research & Related Senior/Key Person Profile (Expanded)
- Research & Related Budget
- Project/Performance Site Location(s) Form
- R&R Subaward Budget Attachment(s) Form (if applicable)
- *(if applicable)* Additional Application Component(s)

Complete a Grants.gov Workspace.
Add participants (investigators and Business Officials) to the Workspace, complete all required forms, and check for errors before submission. The Workspace progress bar will display the state of your application process as you apply. As you apply using Workspace, you may click the blue question mark icon near the upper-right corner of each page to access context-sensitive help.

Mandatory Fields in Forms: In the forms, you will note fields marked with an asterisk and a different background color. These fields are mandatory fields that must be completed to successfully submit your application.

Submit a Grants.gov Workspace Package. An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission.

Note: If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative

or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.
Submissions
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified.
Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission. Refer to the General Submission Instructions, Section III, for further information regarding Grants.gov requirements.

985

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

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

II.D.2.c.ii. Full Proposal/Application Submission Components

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

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

2. Attachments Form

Each attachment to the full proposal/application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Submission Instructions, Appendix 4.
For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB, and the file size for the entire full proposal/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 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 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 OHRO and or USSOCOM VRO 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 USAMRDC OHRO; this does not include the additional time required for local Institutional Review Board (IRB)/Ethics Committee (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. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings.

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 standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate. Do not send or attach copies of articles in print. There is no form for this information. The attachments should be in PDF in accordance with the formatting guidelines specified for full proposal/application preparation.

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

- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.

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

- **Publications and/or 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 a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a

letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement. Refer to the General Submission Instructions, Section III.A.8., 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."

The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. Use the outline below.

o **Background:** Provide a brief statement of the ideas and theoretical reasoning behind the proposed work. o **Objective/Hypothesis:** State the objective/hypothesis to be tested. Provide evidence or rationale that supports the

objective/hypothesis. o **Specific Aims/Milestones:** State concisely the specific aims/milestones of the project.

- **Project Design:** Briefly describe the project design. o **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. o **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."** The lay abstract is used by all reviewers. ***Do not include proprietary or confidential information***. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the 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 family members.

- **Attachment 5: Statement of Work (SOW) (two-page limit): Upload as "SOW.pdf."** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). 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 USAMRDC OHRO's regulatory review and approval processes for studies involving human subjects. Allow at least 1 to 2 months for the USSOCOM VRO regulatory review and approval processes for studies involving animals.

- **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, 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 2, 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 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 eBRAP Help Desk via email at help@eBRAP.org or 301-682-5507. Refer to the General Submission Instructions, Appendix 3, 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 studies conducted on human subjects and the ability to 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 USSOCOM 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.

Extramural Applications

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 et seq.), the DoD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

Research & Related Personal Data: For extramural submissions (via Grants.gov), refer to the General Submission Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Submission Instructions, Section IV.A.2, for detailed information.

Research & Related Senior/Key Person Profile (Expanded): Refer to the General Submission Instructions, Section III 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."

Research & Related Budget: Refer to the General Submission Instructions, Section III 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.
  - IAW FAR 35.016(e), "The primary basis for selecting proposals for acceptance shall be technical, importance to agency programs, and fund availability. Cost realism and reasonableness shall also be considered to the extent appropriate".
  - For contracts, statutory limits for fees are specified in FAR 15.404-4(c)(4).

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 from **Federal agencies** must include in their budget justifications a **Federal Financial Plan**. The Federal Financial 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 Federal Financial Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.

- **For Collaborating DoD Military Facilities:** Proposals 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.

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

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

R&R Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III. for detailed information.

Collaborating with DoD Military Facilities (if applicable): Refer to the General Application Instructions, Section III. for detailed information.

II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)

All organizations applying online through Grants.gov must register with the System for Award Management (SAM) and will receive a unique entity identifier (UEI) number. Failure to register with SAM will prevent your organization from applying through Grants.gov.

Applicant organizations and all subrecipient organizations must have an active registration in the System for Award Management (SAM) number to submit proposals to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit proposals through the Grants.gov portal. Verify the status of the applicant's organization's Entity registration in SAM well in advance of the proposal/application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Submission Instructions, Section III, for further information regarding Grants.gov requirements.

Organizations must have an active System for Award Management (SAM) registration, and Grants.gov account to apply for contracts. If individual applicants are eligible to apply for this funding opportunity, then you may begin with step 3, Create a Grants.gov Account, listed below.

Creating a Grants.gov account can be completed online in minutes, but SAM registrations may take additional time. Therefore, an organization's registration should be done in sufficient time to ensure it does not impact the entity's ability to meet required application submission deadlines.

Complete organization instructions can be found on Grants.gov here:
https://www.grants.gov/web/grants/applicants/organization-registration.html

1) *Register with SAM* for all awards: SAM registration must be renewed annually. For more detailed instructions for registering with SAM, refer to:
https://www.grants.gov/web/grants/applicants/organization-registration/step-2-register-with-sam.html

2) *Create a Grants.gov Account*: The next step is to register an account with Grants.gov. Follow the on-screen instructions or refer to the detailed instructions here:
https://www.grants.gov/web/grants/applicants/registration.html

3) *Add a Profile to a Grants.gov Account*: A profile in Grants.gov corresponds to a single applicant organization the user represents (i.e., an applicant) or an individual applicant. If you work for or consult with multiple organizations and have a profile for each, you may log in to one Grants.gov account to access all of your grant applications. To add an organizational profile to your Grants.gov account, enter the UEI Number for the organization in the UEI field while adding a profile. For more detailed instructions about creating a profile on Grants.gov, refer to: https://www.grants.gov/web/grants/applicants/registration/add-profile.html

4) *EBiz POC Authorized Profile Roles*: After you register with Grants.gov and create an Organization Applicant Profile, the organization applicant's request for Grants.gov roles and access is sent to the EBiz POC. The EBiz POC will then log in to Grants.gov and authorize the appropriate roles, which may include the AOR role, thereby giving you permission to complete and submit applications on behalf of the organization. You will be able to submit your application online any time after you have been assigned the AOR role. For more detailed instructions about creating a profile on Grants.gov, refer to:
https://www.grants.gov/web/grants/applicants/registration/authorize-roles.html

5) *Track Role Status*: To track your role request, refer to:
https://www.grants.gov/web/grants/applicants/registration/track-role-status.html

b. *Electronic Signature*: When applications are submitted through Grants.gov, the name of the organization applicant with the AOR role that submitted the application is inserted into the signature line of the application, serving as the electronic signature. The EBiz POC must authorize people who are able to make legally binding commitments on behalf of the organization as a user with the AOR role; this step is often missed and it is crucial for valid and timely submissions.

For additional training resources, including video tutorials, refer to:
https://www.grants.gov/web/grants/applicants/applicant-training.html

Applicant Support: If you are experiencing difficulties with your submission, it is best to call the Grants.gov Support Center and get a ticket number. The Support Center ticket number will assist the USSOCOM with tracking your issue and understanding background information on the issue. Grants.gov provides applicants 24/7 support via the toll-free number 1-800-518-4726 and email at support@grants.gov. For questions related to the specific grant opportunity, contact the number listed in the application package of the grant you are applying for.

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

II.D.4. Submission Dates and Times

This is a continuously open announcement through 31 July 2028; therefore, reviews occur throughout the year. Pre-proposals may be submitted at any time throughout the 5-year period noted above. An invited full proposal/application should be submitted within **60 days** of the PI's receipt of an invitation to submit. No pre-proposal/pre-application or full proposal/application may be submitted under this BAA after 31 July 2028, 11:59 p.m. Eastern Time. If an invited proposal/application is not submitted by 31 July 2028, 11:59 p.m. Eastern Time, the applicant must wait for the next available opportunity for submission, i.e., the release of the FY28 BAA (to be posted to Grants.gov 31 July 2028). No proposal/application received under this BAA will be considered for funding after 24 months from the date of submission.

II.D.5. Funding Restrictions

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

Proposed projects longer than five (5) years will not be considered.

Most projects are anticipated to have a total cost at or below $1,500,000 (including indirect costs). Projects that have a total cost higher than $1,500,000 (including Indirect costs) with outstanding scientific merit that meet a critical need may be accepted; however the total cost of these projects are not to exceed $5,000,000.00 (including Indirect costs).
No budget will be approved by the Government exceeding $5,000,000.00 (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.

Offerors or Applicants seeking additional or continuation funding must submit new pre-proposals and be invited to submit full proposals.
See the General Submission Instructions, Section III, for additional information regarding the research and related budget.

All direct and indirect costs of any subaward, contract, or subcontract must be included in the costs of the primary award.

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum five years.

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

- Salary
- Research – related subject costs
- Research supplies
- Support for multidisciplinary collaborations, including travel
- Travel costs
- Equipment

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed. Funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Submission Instructions, Section III. for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations collaborating with***

Federal agencies, budget restrictions apply as are noted in the General Submission Instructions, Section III.

For additional information refer to Section II.F.1, Federal Award Notices.
Funds to be obligated on any award resulting from this BAA will be available for use for a limited time period based on the fiscal year of the funds. Awards will identify expiration of the funds.

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

II.D.6. Other Submission Requirements

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

II.E. Proposal/Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Research Objectives:** The degree to which the stated objectives are clear, valid, and logical. For development of devices and technologies, the degree to which the performance objectives are plausible; the proposed effort demonstrates familiarity with the historical background of the problem and previous/current solutions; and the awareness of similar projects previously undertaken and related activities. The extent that the proposed research projects demonstrate an innovative approach and relate to the Research Areas of Interest identified in Section II.A.

- **Scientific Design Excellence:** The degree to which proposed plans, methods, techniques and procedures are feasible, clear, valid, adequately referenced, and state-of-the-art. The merit of the statistical features of the study. The extent to which literature searches were used to document the strengths of the proposed project. For development of devices and technologies, the feasibility of the proposed prototype/technology development plan; how well the engineering/technical design is likely to achieve the goals indicated; adequacy of the engineering/design solutions; and how well the perceived engineering/design strengths and flaws are addressed.

- **Impact/Outcomes:** The potential impact of the research in the field, the significance of this impact, and when it can be anticipated. For development of devices and technologies, the potential translation, implementation, and/or commercial use for the prototype/technology being developed.

- **Budget:** The degree to which the budget reflects the actual needs of the proposed work, is thoroughly detailed and fully justified so that the government can evaluate and determine the cost commensurate with the complexity and nature of the research proposed.

- **PI and Key Personnel Qualifications:** The qualifications, capabilities, and experience of the proposed PI and other key personnel to demonstrate that the proposed staff has the knowledge, technical expertise, and management skills to achieve the proposed objectives as well as the time available for the percentage of efforts indicated for the project.

- **Facilities:** The proposed facilities and equipment, or unique combinations of these, to demonstrate that the organization has the necessary facilities required for the accomplishing the proposed objectives.

II.E.1.b. Programmatic Review

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

- Scientific peer review results
- SOF Relevance (mission, health, medicine, and beneficiaries)
- Portfolio balance
- Programmatic priorities

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

All invited proposals 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 against established criteria for determining technical merit. Each proposal/application is evaluated for its own merit, independent of other proposals. The second tier is a **programmatic review** that makes recommendations for funding, based on established criteria for determining relevance to the mission of the USSOCOM and its programs. Programmatic review is a comparison-based process in which proposals with scientific and technical merit compete in a common pool. ***The highest-scoring proposals from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E. Programmatic Review.***

After the two-tier evaluation, proposals 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.

IAW FAR 35.016(e), "The primary basis for selecting proposals for acceptance shall be technical, importance to agency programs, and fund availability. Cost realism and reasonableness shall also be considered to the extent appropriate".

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

II.E.3. Integrity and Performance Information

Prior to making an award where the Federal share is expected to exceed the simplified acquisition threshold (currently $250,000) over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the SAM.gov Responsibility/Qualification (R/Q).

An applicant organization may review R/Q, accessible through SAM, and submit comments to R/Q on any information about the organization that a Federal awarding agency previously entered and is currently available in R/Q.

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

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

Each PI and organization will receive email notification via eBRAP of the funding recommendation. Notifications should be sent within 180 days of submission. Each PI will receive a peer review summary statement on the strengths and weaknesses of the proposal/application.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

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 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,) signed by the USAMRAA Contracting 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 2, Section D, Award Notices, for additional information. Refer to the full text of the USAMRAA General Research Terms and Conditions for Institutions of Higher Education, Hospitals, and Non-Profit Organizations and the USAMRAA General Research Terms and Conditions for For-Profit Organizations available at http://www.usamraa.army.mil/Pages/Resources.aspx for further information.

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

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

Should the PI of a funded project leave the award organization, both the PI and organization must contact the USAMRAA Contracting 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.

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the FAR, found in 48 CFR, Chapter 1, DFARS, found in 48 CFR Chapter 2, and AFARS, found in 48 CFR Chapter 51, apply to contracts resulting from this BAA.

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

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

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

II.F.3. Reporting

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

technical progress reports andquad charts will be required with frequency determined at the contract level.

- quad charts including:
  - Objective, measurable, and easily independently verifiable assessment of metrics to measure progress regarding project cost, schedule, performance, risk, and opportunity.
  - Risk and opportunity assessment of project cost, schedule, and performance. Risk assessments will use objective, measurable, and easily independently verifiable metrics; mitigation plans; triggering event; latest potential successful mitigation date; and impacts of unmitigated risks. Opportunity assessments will use objective, measurable and easily independently verifiable metrics; exploitation plans; triggering event; latest potential successful exploitation; and impact of successful opportunity exploitation.
  - Integrated project Gantt chart with all progress to date, supported by the cost, performance, risk, and opportunity assessments.
  - Budget chart with burn rate, demonstrating funding expended against time, funds remaining, and planned expense plan through the rest of the project schedule against planned milestones.
- technical reports including the following:
  - Full description of architecture and content of new interoperable component, description of scenarios developed, results and method of pilot study.

- A report, document, or list of the terminology and respective definitions used for the variables, metrics, and evaluation criteria and how they were deconstructed. It must provide the measuring tools and, if needed, how they were used to obtain the metric/evaluation criteria. Objective measurements are preferred, but subjective measurements that have rigorous reliability, repeatability, and robustness will be considered.

- Explanation, including definitions and descriptions, of TRIAGE determinants of performance and agility. A report or document with the information and analyzed data of the actual postulated variables, metrics, and evaluation criteria.

- Analyzed pilot study data and the specific aims, methodologies, sample and sample size, inter-rater reliability, assessment criteria, statistical methods, analyzed results, conclusions, and potential next-step recommendations.

- Completion of preliminary/pilot empirical evaluation of the developed proof-of-concept;

- A description of the components of the proof-of-concept that are proprietary and ones that are open source/open architecture. Explanation of Government rights and/or proposed pricing structure to the Government (if applicable).

- Documentation of the translational parameters and the respective definitions (if applicable).

- Description of the gaps that were uncovered during this research as it pertains to the success or improvement measured and an outline of anticipated next steps or recommendations.

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP 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 eBRAP 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

II.G.2. Grants.gov Contact Center

Questions related to extramural 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 eBRAP Help Desk is unable to provide technical assistance with Grants.gov submission.

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

Email: support@grants.gov

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

II.H. Other Information

II.H.1. Administrative Actions

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

II.H.1.a. Rejection

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

- Project narrative exceeds page limit.
- Project narrative is missing.
- Budget form contains only zeros.
- Quad Chart is missing.

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

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

II.H.1.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the pre-proposal narrative and project narrative.

- Documents not requested will be removed.

- 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 (refer to II.H.I.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

II.H.1.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 URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

- 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.

- Full proposals from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.

- 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.

- A proposal submitted by a PI who does not meet the eligibility criteria will be withdrawn.

II.H.1.d. Withhold

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

II.H.2. Proposal/Application Submission Checklist

Grants.gov Submission Package Components	Upload Order	Action	Completed
SF-424 (R&R) Application for Federal Assistance		Complete as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf.	
	6	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 Personal Data		Complete as instructed.	

Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
		Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget		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.	
Collaborating with DoD Military Facilities		Complete form as instructed.	

APPENDIX 1: ACRONYM LIST

BAA	Broad Agency Announcement
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
HRPO	Human Research Protection Office
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
NPC	Non-Profit Corporation
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PFC	Prolonged Field Care
PI	Principal Investigator

RAI	Research Area of Interest
R/Q	Sam.Gov Responsibility/Qualification
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SCR	Service Contract Reporting
SOF	Special Operations Forces
SOW	Statement of Work
UEI	Unique Entity Identifier
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
USSOCOM	United States Special Operations Command
VRO	Veterinarian Review Office

1911