United States Army Medical Research and Materiel Command

DEPARTMENT OF DEFENSE

BROAD AGENCY ANNOUNCEMENT
for Extramural Medical Research

W81XWH-BAA-14-1

October 2013

Fort Detrick, Maryland

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I. Overview of the Funding Opportunity

A. Overview Content

1. **Federal Agency Name:** Department of Defense (U.S. Army Medical Research and Materiel Command)

2. **Funding Opportunity Title:** U.S. Army Medical Research and Materiel Command Broad Agency Announcement for Extramural Medical Research

3. **Announcement Type:** Broad Agency Announcement (BAA)

4. **Funding Opportunity Number:** W81XWH-BAA-14-1

NOTE: Proposal/Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal funding must be submitted electronically through Grants.gov (http://www.grants.gov) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide. **Proposal/Applications may not be submitted in paper format.**

This FOA must be read in conjunction with the application guidelines in Grants.gov/Apply for Grants (hereafter called Grants.gov/Apply).

A registration process is necessary before submission and applicants are highly encouraged to start the process early to allow for resolution of system problems.

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

5. **Catalog of Federal Domestic Assistance (CFDA) Number:** 12.420

6. **Key Dates:**

Release/Posted Date: October 1, 2013
Opening Date: October 1, 2013
Closing Date: September 30, 2014

NOTE: This is a continuously open announcement; pre-proposal/pre-applications and full proposal/full applications may be submitted at any time throughout the 12-month period. However, no proposal/application submitted under this BAA will be considered for funding after 24 months from the date of submission.

B. Additional Overview Content

The U.S. Army Medical Research and Materiel Command's (USAMRMC) mission is to provide solutions to medical problems of importance to the American Service member at home and

abroad, as well as to the general public at large. The scope of this effort and the priorities attached to specific projects are influenced by changes in military and civilian medical science and technology, operational requirements, military threat assessments, and national defense strategies. The extramural research and development program plays a vital role in the fulfillment of the objectives established by the USAMRMC. General information on USAMRMC can be obtained at https://mrmc.detrick.army.mil/.

This BAA is intended to solicit extramural research and development ideas, and is issued under the provisions of the Competition in Contracting Act of 1984 (Public Law 98-369), as implemented in Federal Acquisition Regulation 6.102(d)(2) and 35.016. This BAA provides a general description of USAMRMC's research and development programs, including: research areas of interest; general information; evaluation and selection criteria; and proposal/application preparation instructions. Research and development funded through this BAA is intended and expected to benefit and inform both military and civilian medical practice and knowledge.

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

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

The USAMRMC's supporting acquisition office, the U.S. Army Medical Research Acquisition Activity (USAMRAA), will process proposal/applications selected for funding. The Grants and Contracting Officers at USAMRAA are the only individuals authorized to obligate funds and bind the Government for awards to be funded under this announcement unless USAMRMC Principal Assistant Responsible for Contracting approval is obtained to allow another Federal acquisition office to execute and administer an award.

Pre-Proposal/Pre-Applications: Before submitting full proposal/applications, organizations are **strongly encouraged** to explore USAMRMC interest by submitting preliminary research proposal/applications (pre-proposal/pre-applications). Pre-proposal/pre-applications may be submitted at any time prior to the BAA closing date. Pre-proposal/pre-applications should describe specific ideas or projects that pertain to any of the research areas of interest outlined in the BAA. A pre-proposal/pre-application must include a brief description of the scientific methods and design to address the problem. 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 Principal Investigator (PI) **MUST** register at http://www.usamraa.army.mil/pages/Baa_Forms/index.cfm first in order to submit a pre-proposal/pre-application. The pre-proposal/pre-application electronic form is also located at http://www.usamraa.army.mil/pages/Baa_Forms/index.cfm, and will appear on the site after you complete your registration.

The following fields are required within the pre-proposal/pre-application form: Proposal Information; Keywords; Problem to be Studied (4000 character limitation); Theoretical Rationale, Scientific Methods and Design (4000 character limitation); Significance and/or Uniqueness of the Proposed Effort (4000 character limitation); Potential Military Relevance (4000 character limitation); Duration of Project to be Studied; Estimated Total Cost of Project (which includes both direct and indirect costs); Participating Personnel and Effort; Capital Equipment; Brief Description of Animal and Human Use (4000 character limitation); Conclusions (4000 character limitation); Brief Curriculum Vitae for PI & Key Personnel (4000 character limitation); and List of Relevant Publications (4000 character limitation). The PI should delineate between a bibliography and additional relevant publications. Figures, charts, graphs or other additional material will not be accepted during the pre-proposal/pre-application process.

The PI should receive a disposition letter or e-mail regarding the pre-proposal/pre-application within 120 days of submission.

Full Proposal/Applications: Invited full proposal/applications should be submitted within 90 days of the invitation. Receipt of full proposal/applications will be acknowledged by e-mail. The proposal/application log number for the full proposal/application will be the same number used for the pre-proposal/pre-application (if submitted). The PI should receive a disposition letter or e-mail regarding the full proposal/application within 180 days of submission

Conference or Symposium Support: The USAMRMC may, on a very limited basis, provide financial support for conferences or symposia that are critical to USAMRMC's mission accomplishment. Funding for conference support may require approval outside of USAMRMC and will only be considered if the event significantly furthers the mission of the Department of Army and has a quantifiable benefit or return on investment. The BAA instructions for submitting a conference or symposium proposal/application can be found at http://www.usamraa.army.mil under the BAA link. The BAA Conference or Symposium Support electronic form can be found at http://www.usamraa.army.mil/pages/baa_forms/index.cfm.
All conference or symposium proposal/applications will be assigned a proposal/application log number, and an e-mail will acknowledge receipt of a proposal/application. The PI should receive a disposition letter or e-mail regarding the proposal/application within 180 days of submission.

NEW FOR FISCAL YEAR 2014:

This fiscal year's BAA contains several changes from previous USAMRMC BAAs. Read each section carefully.

- Research areas of interest have been updated.

- Instructions are provided for marking proprietary information if included in full proposals/applications. No proprietary information should be included in pre-proposals/pre-applications.

- Information and instructions regarding Conflicts of Interest have been added.

- In addition to current and pending support information, PIs and key personnel are required to provide prior (within the last 5 years) support information.

- Areas addressing Representations and Certifications have changed.

- Attachment entitled "Organizational Data" is added.

- Attachment previously entitled "Certificate of Environmental Compliance" is changed to "Environmental Compliance Assurance."

- Attachment entitled "Facility Safety Plan Instructions" has been updated.

II. Funding Opportunity Description

A. Research Areas of Interest

1. Military Infectious Diseases Research Program

The Military Infectious Diseases Research Program (MIDRP) focuses on vaccines, anti-parasitic drugs, deployable field clinical diagnostics (human and vector), prophylactics and novel therapeutics to treat multi-drug resistant organisms in combat wound infections, and vector control - pertinent to naturally-occurring endemic diseases with demonstrated or potential capability to decrease military operational effectiveness. Diseases of principal interest to the MIDRP are malaria, dengue, and diarrheal disease caused by bacteria and norovirus. The MIDRP also has smaller research programs focused on cutaneous leishmaniasis, scrub typhus, adenovirus and hemorrhagic fever viruses that are not on the Defense Threat Reduction Agency (DTRA) biothreat list. Proposal/applications involving viral and bacterial biowarfare threats, chemical threats, and cancer research cannot be supported by the MIDRP.

Research efforts are needed in novel technologies for prevention, treatment and detection of naturally occurring infectious diseases. Areas of interest include: Norovirus and other viral diarrhea, Q fever (*Coxiella burnetii*), Crimean-Congo hemorrhagic fever, protozoal diarrhea, Rickettsiosis, Chikungunya virus and technologies that leverage current research efforts in malaria, dengue and bacterial diarrhea.

a. Research and Development towards Preventive Measures for Infectious Diseases includes:

(1) Vaccines. The MIDRP supports studies to: characterize infectious agents that can result in a vaccine product; identify mechanisms of pathogenesis and protective immune responses in support of vaccine development; candidate field site development in conjunction with evaluation of vaccine efficacy in humans; and evaluation of methods of vaccine delivery.

(2) Anti-parasitic Drugs. Studies applicable to the discovery, design, and development of drugs to prevent malarial and cutaneous leishmanial infections (including drug synthesis, screening of compounds, characterization of mode of action, and mechanisms of drug resistance) are of interest to the MIDRP. Additional topics for possible support include investigations of parasitic metabolism, structural biology, genomics, proteomics, and metabolomics directed towards the identification of potential novel molecular targets for intervention.

(3) Vector Control Products. The MIDRP supports investigations focusing on arthropod vectors and vector-borne diseases (with primary emphasis on malaria, dengue and scrub typhus). Current studies target vector-pathogen-human interactions, vector control (including personal protective measures), and risk assessment (including identification and classification of vectors, improved surveillance techniques, and field worthy assays for detecting pathogens in vectors).

(4) The MIDRP supports research toward products to prevent wound infections and promote wound healing, including effective wound cleansing techniques that are proven not to cause tissue irritation. In addition, novel chemotypes (chemical classes/materials) and/or biologics as potential prophylactics for wound infection and/or biofilm formation are of interest.

b. Research and Development of Therapeutic Measures for Infectious Diseases. Therapeutic drug development (including studies to screen, synthesize, and develop therapeutic drugs for malaria and other militarily-relevant infectious agents) is secondary to the prophylactic development program [see a(2), above]. However, proposals/applications dealing with novel drug delivery systems (i.e., sustained-release and methods of targeting drugs to reduce toxicity or delivery of drugs of clinical importance to the active sites) would be considered. In addition, MIDRP supports investigations focusing on development of novel medical countermeasures and innovative treatment approaches (e.g., chelators, antibody, phage, anti-microbial peptides, quorum-sensing inhibitors, and host immunoaugmentation, etc.) for multi-drug resistant organisms in combat wound infections and/or biofilm formation, maintenance, or propagation. Given the tepid interest of the pharmaceutical industry to develop and market vaccines for diseases in areas of low commercial gain, the MIDRP is also interested in proposals/applications and products incorporating a systems biology approach towards finding treatment options for infectious diseases that are likely to lead to US Food and Drug Administration (FDA)-licensable, broadly-active therapeutics against multiple endemic disease threats.

2. Combat Casualty Care Research Program

The Combat Casualty Care Research Program (CCCRP) provides integrated capabilities for far-forward medical care to reduce the mortality and morbidity associated with major battlefield wounds and injuries from point of injury through discharge from the acute care hospital. A primary emphasis of the CCCRP is to identify and develop medical techniques and materiel (medical devices, drugs, and biologics) for early intervention in life-threatening battle injuries. Because battlefield conditions impose severe constraints on available manpower, equipment, and medical supplies available for casualty care, CCCRP places a premium on medical interventions that can be used within the battle area or as close to it as possible, before or during medical evacuation. Preferred medical techniques and materiel that can be used by combat medics must be easily transportable (i.e., small, lightweight, and durable in extreme environments and handling); devices must be easy to use, low maintenance, with self-contained power sources as necessary. Drugs and biologics, ideally, should not require refrigeration or other special handling. All materiel and techniques must be simple and rapid to employ. The CCCRP is interested in existing materiel for which concept and/or patient care efficacy have already been demonstrated, but require improvement to meet military constraints.

Research efforts are needed in principles and technology to enhance self- and buddy-aid; techniques, methods, or materials to improve basic and advanced life support for severely injured persons; monitoring, sustainment, and management of severely injured casualties during episodes of delayed or protracted evacuation; and enhanced capability for triage of large numbers of casualties and staged treatment in the field.

The principal causes of death among Service members who die within the first hour of wounding are hemorrhage and traumatic brain injury. As a consequence, the following areas are of particular interest to the CCCRP:

a. Research and development of technologies to stop blood loss, to resuscitate the casualty, and to limit the immediate, short- and long-term deleterious consequences of severe hemorrhage. Included in this area of interest are diagnostics and therapeutics to predict, diagnose, prevent, and treat trauma coagulopathy and noninvasive or minimally invasive sensors to detect and warn of impending vascular collapse and/or significant tissue damage due to perfusion deficits. Examples of specific products include: local and systemic hemostatic agents for the control of compressible and non-compressible hemorrhage, treatments to enhance oxygen delivery and perfusion of tissue, equipment and procedures for effective fluid resuscitation of casualties, and enhanced resuscitation fluids. Also of interest is the improved preservation, storage, transportability, and processing of red blood cells, platelets, and plasma.

b. Research and development of technologies to diagnose and to limit the immediate, short- and long-term impairments that follow traumatic brain injury and spinal cord injury. Included in this area of interest are non- or minimally-invasive sensors or assays to rapidly diagnose the severity of brain and spinal cord injury within the battle area (or as close to it as possible), and drugs, biologics, or other agents to mitigate post-injury neural and immune cell overstimulation, inflammation, cell loss, and/or neurologic dysfunction.

c. Secondary damage to organs frequently occurs after trauma. The CCCRP is interested in materiel that can reduce acute secondary damage such as ischemia/reperfusion injury, cell death, general organ failure, and secondary brain/spinal cord damage. This objective includes methods to reduce cellular demand for oxygen and metabolic substrates and therapeutics to modulate the immune response to traumatic injury. The effects of medical evacuation upon the critically injured casualty are also of interest. These include but are not limited to: hypobaria, hypoxia, physiological effects of vibration, shock and G-forces.

d. The CCCRP supports additional aspects of casualty care. These include drugs, devices, or novel surgical techniques to decontaminate, debride, protect, and stabilize hard and soft tissue wounds to mitigate secondary tissue damage, orthopedic and maxillofacial trauma repair strategies, and the prevention and treatment of dental injury or disease in austere environments. The CCCRP is also interested in the development of non-invasive sensors, diagnostic and prognostic algorithms, and processors to improve our capability for remote triage, monitoring, and management of casualties; and in products to maintain casualties during prolonged evacuation.

3. Military Operational Medicine Research Program

The Military Operational Medicine Research Program (MOMRP) conducts biomedical research to deliver products and solutions to the Service member that address health and fitness throughout the Deployment Cycle. The MOMRP is centered on cutting-edge scientific research and bringing science to the Service member on the battlefield in a relevant, timely manner. The MOMRP is divided into four research focus areas: Injury Prevention and Reduction,

Psychological Health and Resilience, Physiological Health, and Environmental Health and Protection.

The mission of the MOMRP is to develop effective countermeasures against stressors and to maximize health, performance and fitness. Our mission is protecting the whole Service member head-to toe, inside and out, at home and on the battlefield.

The four focus areas of research emphasis include the following:

a. Injury Prevention and Reduction: This area of research addresses the requirement to provide the biomedical basis for countermeasures that prevent and mitigate Service member injury and decrease attrition, medical cost, and minimize personal impact to the Service member. Specifically, this includes the need to: prevent vision and hearing loss along with blast-related injuries and training injuries; identify validated fitness for duty/"return-to-duty" standards following neurosensory and musculoskeletal injury; develop biomedically valid injury criteria and performance standards for individual (helmet and body armor) and crew protection systems; develop injury risk criteria and tools for health hazard and Service member survivability assessors; and Service member monitoring/sensor with accompanying algorithms that predict the likelihood of neurosensory, musculoskeletal, and brain injury.

b. Psychological Health and Resilience: This research area focuses on the development and validation of effective evidence-based prevention and training, screening and assessment strategies, and treatment and rehabilitation interventions that reduce the negative impact of behavioral health disorders and concussion/mild traumatic brain injury. Research also aims to develop psychological resilience among Service members and families to promote well-being and prevent negative behavioral health outcomes. Additional research areas that are often overlooked but relevant include: foundation studies to validate theories and elucidate underlying mechanisms of disorders; studies addressing co-morbidities (to include, but not limited to post-traumatic stress disorder [PTSD], concussion, alcohol and other drug abuse, sleep disturbance, and mood disorders); studies focused on enhancing translation, implementation and uptake of evidence-based strategies and treatments; and research focused on establishing validated objective return-to-duty standards following psychological injury. Technologies include telemedicine, remote monitoring, biosensors, advance immunologic testing, health information technologies for care management and decision support and technologies for patient empowerment and education. Also of interest are studies on integrative medicine and Complementary and Alternative Medicine (CAM) approaches covering a range of research areas such as acupuncture to meditation techniques, along with validation studies of CAM therapies. CAM therapies and methodologies may lower dependency on medications to treat pain and mental health disorders, to include stress and anxiety. This area also supports research to support the development of strategies for the diagnosis, treatment, and mitigation of cognitive dysfunction associated with traumatic brain injury (TBI) and war-related psychological injuries. Research topics of particular interest include those directed at the development of a systematically applied set of therapeutic services designed to reduce cognitive dysfunction and restore functions that can be restored and/or assist individuals in compensating for the impact on daily living when functions cannot be restored to pre-injury level.

c. Physiological Health: This area of research develops biomedical countermeasures to sustain Service Member health and operational effectiveness, including: state-of-the-art policy, training, and materiel solutions to establish, sustain, optimize, and monitor Service member health, physiological resilience, cognitive abilities throughout training, deployment, reset, and injury recovery cycles. This research aims to prevent or mitigate the effects of physiological stressors on the performance and fitness of Service member. Studies include use of dietary supplements, and nutritional and behavioral interventions to mitigate threats to operational health and performance. Research also aims to develop advanced biomedical modeling and networked physiological status monitoring capabilities, healthy sleep and fatigue management strategies, individual differences in sleep loss resilience, and individualized resilience to various operational stressors. Technologies and strategies to monitor and promote Service member and family health to support the Surgeon General's Performance Triad are of interest.

d. Environmental Health and Protection: This area of research includes assessment and sustainment of health and the operational effectiveness of Service members exposed to harsh operational environments including altitude, cold, heat, and exposure to environmental health hazards. In addition, this research includes development of policy, training, planning/management tools, materiel solutions, interventions and reset solutions, to sustain Service Member resilience, health and operational effectiveness to environmental stressors; additional research identifies biomarkers of exposure to environmental health hazards and development of hand-held, fieldable devices for rapid identification of exposure effect biomarkers in bodily fluids in support of military operational requirements.

The MOMRP supports research toward solving critical problems facing the Army today and in the future. Service- and platform-specific issues are addressed through close coordination with Navy and Air Force counterparts to prevent duplication of effort.

4. Clinical and Rehabilitative Medicine Research Program

The Clinical and Rehabilitative Medicine Research Program (CRMRP) focuses on the innovations required to reset our wounded Service members, both in terms of duty performance and quality of life. Innovations developed from CRMRP supported research efforts are expected to improve restorative treatments and rehabilitative care to maximize function for return to duty (RTD) or civilian life. The interest is in medical technologies (drugs, biologics, and devices) and treatment/rehabilitation strategies (methods, guidelines, standards and information) that will significantly improve the medical care provided to our wounded Service members within the DoD healthcare system. Implementation of these technologies and strategies should improve the rate of RTD of Service members, the time to RTD, clinical outcome measures, and quality of life (QoL), as well reduce the hospital stay lengths, clinical workload (patient encounters, treatments, etc.), and initial and long-term costs associated with restorative and rehabilitative or acute care. Development and validation of *in vitro* and *in vivo* assessment models that represent militarily relevant conditions in wounded Service members is of interest to CRMRP when they can be used to identify and describe in a predictable manner the safety and efficacy of novel technologies in patients.

The CRMRP focuses its efforts on the following four research areas: neuromusculoskeletal injury (including amputees), sensory systems (including hearing, balance, tinnitus and vision), acute and chronic pain, and regenerative medicine. While research topics of highest priority interest are listed below for each of these areas, proposal/applications for topics that align within an overall research area will also be considered except as specifically noted. Traumatic brain injury (TBI) research proposal/applications will only be considered if the focus is related to one or more of the following: hearing, balance, tinnitus, vision or pain related to TBI. Novel manufacturing technologies necessary to translate innovative therapies or devices into clinical development are a focus.

All projects should adhere to a core set of reporting standards for rigorous study design. CRMRP strongly encourages grant holders to follow the Animal Research: Reporting *In Vivo* Experiments (ARRIVE) guidelines (http://www.nc3rs.org.uk/page.asp?id=1357). While these standards are written for animal studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies and should be applied to those projects as well.

a. Neuromusculoskeletal Injury Rehabilitation: Research directed toward functional outcome assessments focusing on return-to-duty and/or community reintegration. Of particular interest are technologies and rehabilitative strategies that restore function after sustaining neuromusculoskeletal injuries. Topics of interest include but are not limited to amputation, limb salvage, spinal cord and column injuries, polytrauma, contractures, and injuries such as sprains and strains that represent a significant burden of injury. Additional areas of interest include therapies to restore tissue and function, amputee-specific technologies and strategies that address/assess fitness sustainment and residual limb health, the prevention and treatment of heterotopic ossification, and mechanistic approaches to optimizing function in rehabilitative techniques and technologies.

b. Vision Restoration and Rehabilitation: Research aimed at treating traumatic and war-related injuries (including blast and burn injuries) to ocular structures and the visual system. Research focused on the diagnosis, treatment, and mitigation of TBI-associated visual dysfunction. Additional areas of interest include studies supporting diagnostic capabilities and assessment strategies, restoration of the visual system (including regeneration and tissue repair following traumatic injury), and vision rehabilitation strategies (including but not limited to rehabilitation for multi-sensory dysfunctions, low vision and blindness, and oculomotor and binocular vision disorders).

c. Hearing Loss/Dysfunction, Balance Disorders and Tinnitus: Research to support the development of strategies and technologies (including but not limited to medical devices, pharmaceuticals, and regenerative medicine based approaches) to restore and/or rehabilitate patients with hearing loss, balance disorders, and/or tinnitus due to trauma (including TBI). Research focused on the etiology of injury including studies to support an understanding of the molecular, cellular, and physiological mechanisms underlying hearing loss, balance disorders, and tinnitus. Additional areas of interest include studies supporting the development and evaluation of objective diagnostics for hearing loss, balance disorders, and tinnitus and research identifying and addressing the biopsychosocial aspects of auditory and vestibular dysfunction (including but not limited to the impact of co-morbidities and polypharmacy).

d. Pain Management: Primary interest is in management of pain associated with traumatic or war-related injuries. CRMRP's specific needs include: Development of alternatives to current opioid analgesics for severe pain management by the medic/corpsman on the battlefield/remote locations, development of strategies for management of chronic pain under the care of a clinician in non-deployed settings, identification of pain generators, development of strategies for acute pain management in deployed locations, including battlefield and resource-limited environments, development of strategies for identifying and addressing biopsychosocial aspects of pain, development of strategies for management of acute pain under the care of a clinician in non-deployed settings, development of strategies for chronic pain management in deployed locations, including battlefield and resource-limited environments, and development of substance misuse and abuse assessments and treatments in pain management.

e. Regenerative Medicine and Composite Tissue Engineering: Regenerative medicine involves the use of innovative technologies such as scaffolds and tissue engineering, growth factors, and cell-based treatments to restore Service members who have suffered extremity injuries, craniomaxillofacial injuries, burn injuries, or genitourinary / lower abdomen injuries. Research topics of particular interest include those directed toward the use of regenerative medicine-based technologies to repair functional nerve deficits (other than central nervous system or spinal cord), repair/replace neuromuscular tissue units of the extremities or face including composite facial features (eyelids, lips, and nares), regenerate bone defects (weight bearing and alveolar), regenerate skin, address vascular repair/revascularization, regenerate cartilage/musculoskeletal connective tissues for the prevention of post-traumatic arthritis, muscle protection/regeneration, repair/replace composite tissue units composed of two or more of the above mentioned tissues, vascularized tissue allotransplantation, immunomodulation and tolerization related to vascularized tissue allotransplantation and wound management and tissue preservation such as promotion of scarless wound healing (not to include infection control). Research topics of particular interest addressing genitourinary / lower abdomen injuries focus on pelvic reconstruction and urogenital reconstruction. Pelvic reconstruction efforts should focus on promoting technologies that address injury to the anus. Urogenital reconstruction efforts should focus on promoting technologies that address injury to genitalia (penile, scrotal, urethral tissues), perineal tissue, and bladder.

5. Medical Biological Defense Research Program

The Defense Threat Reduction Agency (DTRA) Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD) manages research directed towards medical biological defense. The DTRA JSTO-CBD has limited funding for proposals/applications submitted through the USAMRMC BAA. DTRA also solicits proposals/applications for its requirements through the Federal Business Opportunities (FedBizOpps) and the DoD Small Business Innovation Research (SBIR) Program solicitations. For information regarding DTRA business opportunities, visit the website at: http://www.dtra.mil/Business.aspx.

The Medical Biological Defense Research Program provides medical countermeasures for biological warfare agents. These countermeasures include specialized medical materiel or procedures designed to enhance protection. The priorities of the program are: (a) prophylaxis or pretreatment to prevent any casualty; (b) identification and diagnosis of biological agents; and (c) treatment or supportive care regimens.

Examples of some of the infectious agents of interest are those causing anthrax, plague, glanders; the Ebola, Marburg, Venezuelan, western and eastern equine encephalitis viruses; and poxvirus models of variola virus. Examples of toxins of interest include those from plants (Ricin), and bacteria (Staphylococcal enterotoxins, botulinum).

The following are the overarching research and development goals:

a. **Viral, Toxin and Bacterial Studies:**

(1) Identification and characterization of organisms and toxins. Molecular antigenic analysis; development of diagnostic assays; studies on structure and function that are related to mechanism of action, binding, internalization and interaction with the immune system and neutralizing antibodies; investigation of pathogenesis and immunology that will allow decision regarding the optimal approach to disease prevention and control. Specific long-term goals include development of physiological support methodologies, diagnostic tests, rational prevention and control strategies, and improvement of existing products.

(2) Vaccine development, with emphasis on protection from agents in aerosol exposure, molecular approaches for development of vaccines, measurement of relevant cellular and humoral protective immune responses, and expression or production of protective antigens using recombinant technology. Development of vaccines for specific toxins and disease agents involving the generation, selection and characterization of attenuated strains or inactivated purified antigen preparations, to include polyvalent vaccines that are more broadly effective. Safer means of passive immunization such as production of human monoclonal or modified antibodies that are despeciated are also of interest. Identification of surrogate markers of protection for the agents identified above and development of assays to assess such protection are needed.

(3) Development of improved methods for delivery of vaccines, including adjuvants, nucleic acid vaccines, methods for oral or nasal immunization with inactivated, live and subunit antigens; sustained release formulations; and methods for delivery of antigens for specific induction of mucosal immunity and development of methods to enhance appropriate immune responses to include co-delivery of cytokines.

(4) Preparation of research quantities of highly purified and characterized toxins as well as studies on basic chemistry, mechanisms of action, metabolism and excretion.

b. **Drug Development**: Development, synthesis and testing of compounds that possess antiviral, antibacterial, immunomodulatory or antitoxin activities, with emphasis on compounds that provide broad, nonspecific protection against viruses, bacteria and toxins described above. Studies of their pharmacokinetics and other measurements relevant to more effective drug use are also of interest. Development of lead compound(s) that are potent, active-site inhibitors that may include combinatorial-derived organic molecules and/or rationally designed transition-state substrate analogs. Testing for potency is required. Approaches that will be considered include but are not limited to computational chemistry, combinatorial organic synthesis, high throughput *in vitro* screening and X-ray analysis of ligand-toxin co-crystals.

(1) Discovery of novel or unique biochemical elements or compounds with antiviral, antibacterial or antitoxin activity against the listed organisms.

(2) Development of testing models for evaluation of compounds effective against toxins of several classes, including pre- and post-synaptic toxins, membrane-damaging toxins, toxins which inhibit protein synthesis and others.

(3) Mechanism of action studies of immunomodulators, including characterization of effector cells (lymphocytes, macrophages) effector mechanisms, ancillary effects on other cells of the immune system and production and characterization of cytokines released as a consequence of immunomodulation.

c. **Identification and Diagnosis**: The investigation and evaluation of sensitive and specific methods of identifying and diagnosing both antigens and antibodies of viruses, bacteria and rickettsia in biological materials. Development of sensitive and specific immunologic, chemical or biological assays for the rapid (within minutes) and reliable diagnoses of: (1) acute diseases due to agents of potential biological threat; and (2) the identification of toxins or their metabolites in biological samples. Assay may include antigen, antibody or metabolite detection or the use of nucleic acid probes or synthetic antigens. In addition, there is interest in the development of rapid identification and diagnostic methods for the assay of toxins, metabolites and analogs in clinical specimens.

d. **Biosurveillance (BSV):** The process of gathering, integrating, analyzing and communicating a range of information that relates to health threats for people, animals and plants to help inform decisions and provide for increased global health security. The Joint Biosurveillance Common Framework (JBCF) will be the first materiel solution and provides a single enterprise environment that supports collaboration, data sharing and coordination between multiple BSV stakeholders. The JBCF and future BSV applications, tools, and devices will provide a conduit between the medical, physical, and operational communities. Research areas of interest include:

- Algorithms for rapid identification of baseline deviation; novel/unknown pathogens, naturally-occurring versus intentional release
- Models to predict the likelihood of an outbreak, forecast the associated epidemic curves and impacts of interventions, and update forecast based on field (and simulated) data
- Applications to engage citizens via social media, crowd sourcing, gaming, etc.

In addition, two specific topics currently of interest are:

(1) Next-generation analytic capabilities for Biosurveillance (BSV): The objective is to develop next-generation methodologies to enhance analytic capabilities in the detect-identify-respond timeline for a bioevent. Research should be exploratory, with low Technology Readiness Level, and should address long-term challenges in threat surveillance. Efforts should significantly contribute to the current body of knowledge and lead to new concepts for technology application that may have impact on future BSV analytic capabilities.

(2) Biosurveillance Ecosystem (BSVE) Analytics 2.0: The objective is to ensure state of the art technologies are made rapidly accessible through the BSVE. This topic seeks to develop analytic applications to synthesize and interrogate multiple sources of data to provide high confidence in the prediction, early warning and forecasting (inclusive of mitigation strategies) of disease events. Metrics shall be devised such that successful utilization of these analytic tools will result in a measureable impact on the bioevent timeline. Efforts in this area should result in flexible, extensible, and sustainable analytics and models that are designed to plug into the BSVE as a la carte services rather than as standalone capabilities.

6. Medical Chemical Defense Research Program

The Defense Threat Reduction Agency (DTRA) Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD) manages research directed towards medical chemical defense. The DTRA JSTO-CBD has limited funding for proposals/applications submitted through the USAMRMC BAA. DTRA also solicits proposals/applications for its requirements through the Federal Business Opportunities (FedBizOpps) and the DoD Small Business Innovation Research (SBIR) Program solicitations. For information regarding DTRA business opportunities, visit their website at: http://www.dtra.mil/Business.aspx.

The Medical Chemical Defense Research Program seeks to preserve combat effectiveness by timely provision of medical countermeasures in response to Joint Service chemical warfare defense requirements. The fundamental orientation of the program is to protect U.S. forces from the effects of chemical warfare agents by developing protective, pretreatment, and prophylactic products, providing products usable by the individual Service member for immediate treatment of chemical warfare agent exposures, developing antidotes/therapeutics to chemical warfare agents, defining care procedures for chemical warfare agent casualties, and advancing management of these casualties. The medical countermeasures are intended to preserve and sustain the Service members' combat effectiveness in the face of combined threats from chemical and conventional munitions on the integrated battlefield.

The broad goals of this program are:

a. Maintain the Technologic Capability to meet present requirements and counter future chemical warfare agent threats. The program will maintain the scientific base and technological capability to develop timely medical countermeasures for both current and future chemical warfare agent threats. Research funded by this program will be used to identify concepts and candidate medical countermeasures for use by the individual Service member or by medical personnel. Basic and applied research are both supported, and may address topics as diverse as determining sites/mechanisms of action and effects of exposure to chemical warfare agents with emphasis on exploitation of neuroscience technology, and respiratory, ocular, and dermal pathophysiology; identifying sites and biochemical mechanisms of action of medical countermeasures; exploiting molecular biological and biotechnological approaches for development of new approaches for medical countermeasures to chemical warfare agents; and exploiting molecular modeling and quantitative structure-activity relationships in support of drug discovery and design.

b. Provide Medical Countermeasures for the individual Service member to maintain combat effectiveness and prevent or reduce injury from chemical warfare agents. This goal

encompasses research supporting development of new concepts for prophylaxes, pretreatments, antidotes, and therapeutic countermeasures; development of skin protectants and decontaminants; identification of factors which influence safety and efficacy of candidate medical countermeasures; and development and maintenance of preformulation, formulation, and radiolabeling capabilities.

c. Provide Medical Management of Chemical Casualties to enhance survival and expedite the return-to-duty of chemical warfare agent casualties through definitive therapies and life support technologies. This goal includes: developing concepts and therapeutic regimens and procedures for the management of chemical warfare agent casualties; developing diagnostic and prognostic indicators for chemical warfare agent casualties; and developing life-support equipment for definitive care of chemical warfare agent casualties.

Recent changes in the security situation facing the United States have not materially reduced the threat that chemical weapons present to American forces in the field. Many third world countries and terrorist groups have the capability of producing and delivering chemical warfare agents thus posing a substantial and serious threat to the armed forces of the United States.

Classical chemical agent threat categories include vesicant or blister agents (e.g., sulfur mustard), blood agents (e.g., cyanide), respiratory agents (e.g., phosgene) and nerve agents (e.g., GA or Tabun, GB or Sarin, GD or Soman, and VX).

Examples of pertinent research topics and areas currently of interest are:

(1) Characterizing the mechanisms of vesicant agent pathophysiology to identify medical countermeasures against vesicant agents.

(2) Developing innovative models of the pathophysiology of vesicant agent injury.

(3) Identifying and/or evaluating innovative candidate medical countermeasures against vesicant agents.

(4) Identifying, exploring, and developing innovative clinical diagnostic, prognostic, and management approaches to vesicant agent casualties.

(5) Characterizing the ocular lesions associated with vesicant agent exposures; developing treatments to ameliorate these injuries.

(6) Characterizing the mechanisms of nerve agent-induced seizures and resulting pathophysiology; to identify medical countermeasures against nerve agent-induced seizures.

(7) Identifying, synthesizing, and/or evaluating innovative candidate medical countermeasures against nerve agent-induced seizures.

(8) Developing innovative models of the pathophysiology of nerve agent induced seizures.

(9) Developing catalytic and/or stoichiometric chemical warfare agent scavengers from biological molecules (e.g., antibodies and enzymes) which provide protection against nerve agent incapacitation and lethality for extended periods following their administration.

(10) Developing innovative models for evaluation of chemical warfare agent scavengers.

(11) Identifying, expressing, synthesizing, and/or evaluating biotechnologically-derived or pharmaceutically-based scavengers as candidate medical countermeasures against chemical warfare agents.

(12) Developing and evaluating custom-synthesized pharmaceuticals based on a detailed understanding of the pathophysiology and mechanisms of action of the chemical warfare agent structure and the function of the intended target molecule.

(13) Developing catalytic and/or stoichiometric additives for use in skin protectants, or decontaminants, to protect against chemical warfare agents, especially vesicant and nerve agents.

(14) Developing innovative models for evaluation of catalytic and/or stoichiometric additives in skin protectants or decontaminants.

(15) Developing candidate formulations for skin protectants or decontaminants containing catalytic and/or stoichiometric additives and evaluating these formulations against chemical warfare agents.

(16) Characterizing the pathophysiology and natural progression of chemical warfare agent-induced damage to human tissues.

(17) Developing and validating innovative techniques for rapid and accurate analysis of human tissues and body fluids for detection of chemical warfare agent exposures.

(18) Characterizing the effects of long-term or chronic exposures to chemical warfare agents and/or medical countermeasures to these agents.

(19) Identifying, exploring, and developing innovative clinical diagnostic, prognostic and management approaches to nerve agent casualties.

(20) Developing and validating field usable procedures for diagnosis, prognosis, and treatment of chemical warfare agent casualties under both field and laboratory conditions.

7. Medical Training and Health Information Sciences Research Program

The mission of the Medical Training and Health Information Sciences Research Program (MTHIS) is to manage research programs to explore the implications for the use of technology

for medical training and for the provision, management and support of health services in the military. The MTHIS research program plans, coordinates, and oversees a responsive world-class, tri-service science and technology program focused on two areas of research. One area is focused on improving military medical training through medical simulation, educational gaming, and objective training metrics. The second area is focused on improving the use and sharing of health related data for better strategic planning, process development, and software applications. It is organized into two portfolios, one for each of the two focus areas. Each portfolio is further organized into subfocus areas as follows:

- **The Medical Simulation and Training Technologies Portfolio** is divided into the following sub-focus areas:

  a. Combat Casualty Training Initiative
  b. Medical Practice Initiative
  c. Health Focused Initiative
  d. Developer Tools for Medical Education Initiative

- **The Health Informatics and Health Information Technology Portfolio** is divided into the following sub-focus areas:

  a. Theater Health Services and Support
  b. Health Operations Resourcing
  c. Health Services and Population Health
  d. Health Enterprise Infrastructure

The Medical Simulation and Training Technologies Portfolio:

Combat Casualty Training Initiative: This initiative strives to advance pre-hospital combat casualty training with an emphasis on the combat medic. Research involves technology based approaches and development of an advanced generation trauma task trainers and robotic training systems and validation of system and training metrics / evaluation outcomes compared to currently used models. The effort includes research into best practices and new technologies for stress inoculation to medical personnel. Goals include:

- Improving critical lifesaving skills training and confidence of assessment
- Emphasizing approaches toward "anytime readiness" in a near-future era of reduced deployment
- Building psychological resilience into pre-deployment training

Medical Practice Initiative: This initiative focuses on the maintenance of military and medical skills over a medical provider's health care career. Research efforts are aligned with maximizing health care professionals' training and investigating degradation of medical cognitive and psychomotor skills to minimize loss of existing skills. The initiative seeks to develop and validate automated methods to measure likely skills and knowledge loss to enable retraining and automate maintenance of certification. The initiative will lead to further development in reusable virtual standardized patients, immersive scenario training, and game-based cooperative training methods. Goals include:

- Leveraging and creating training technology advances to keep U.S. military medicine on top
- Understanding competency and how to best maintain it
- Pioneering automated adaptive learning to tailor training to health care providers' needs
- Leading the way to a sustainable medical education life cycle

Health-Focused Initiative: This initiative seeks to improve patient care beyond the clinical environment. This effort is working to improve the human–machine interface to help bridge the gap between patients and clinicians. It includes research on the use of a wide variety of advanced medical technologies to manage patients with ongoing health problems and technologies to monitor health status of beneficiaries based upon the Surgeon General's "triad initiative" (nutrition, exercise, and sleep). Research efforts include underlying technologies to support telemedicine, remote monitoring, biosensors, health information technologies for care management, decision support and technologies for patient empowerment and education, advanced user interface and interactive technologies for healthy living and patient rehabilitation and education. Research and development is towards simulation-based educational tools for health monitoring, rehabilitation compliance, and home fitness & nutrition provided via interactive systems that provide feedback to the patient through a virtual character and the health professional's remote monitoring. Goals include:

- Researching innovative areas such as graphics; user interfaces; and computer interaction with a practical, patient beneficial application
- Learning from patient applications to apply innovation to training
- Emphasizing high-risk/high-reward research

Developer Tools for Medical Education Initiative: This initiative builds open-source/open-licensed development toolkits that are freely available to all, allowing developers to focus on content generation rather than on developing basic technology. This will reduce content development costs and encourage a more diverse authorship community. Widely accepted standardization will enable instructors to greatly increase the available training opportunities at reduced cost. Validation of the proposed system is encouraged and may be considered as a possible option. Goals include:

- Ensuring that advanced medical simulation capabilities are ubiquitous
- Encouraging the highest level of innovation across all initiatives
- Democratizing access to advanced Medical Simulator technology so that it can be used by large and small innovators alike
- Saving money by eliminating wasteful and redundant research and development

The Health Informatics and Health Information Technology Portfolio:

Theater Health Services and Support: Research in Theater Health Services and Support provides services to the armed forces to promote, improve, conserve, and restore the mental or physical well-being of personnel through improved information management and the use of emerging technologies in the following categories:

- **Medical Command & Control** – Exploration of technologies to enable commanders to efficiently and effectively manage medical information and medical work flows.
- **Medical Logistics and Blood Management** – Exploration of technologies for providing more efficient medical logistics and blood management to support military medicine.
- **Theater health information capture, documentation and transmission -** Investigation of innovative approaches for capturing physiologic data and care documentation from role 1 through role 3 and the transmission of that **data** to support patient care and evacuation.
- **Humanitarian Assistance/Support Operations -** Investigation of technologies to provide assistance throughout the world during natural or manmade disasters.

Health Operations Resourcing: Research to improve financial and personnel management for better delivery of healthcare services.

- **Personnel Resources** – Research to improve the management and training of personnel for efficient delivery of healthcare services.
- **Financial Resources** – Research to improve the management financial resources to support the efficient delivery of healthcare services.

Health Services and Population Health: Research into how health care providers and patients can better use health services and population health related information and technologies to improve health:

- **Healthcare Delivery and Management** – Improve the delivery of accessible, high-quality healthcare services through better documentation and improved accessibility and analysis of health information for medical encounters and to support prevention and population health.
- **Medical Device Interoperability** – Improve the ability for medical devices to securely and reliably exchange information with other devices and with medical documentation and management systems.
- **Mobile Health (mHealth)** – Investigation of information technologies and/or applications that are not bound by fixed structures or geographic location and promotes mobile health standards and accessibility.
- **Open Electronic Health Record (EHR)** – Research on technologies as well as governance and/or policy issues that inhibit the development of an open framework for EHRs.
- **Telemedicine** – Discover, study, test, field, and evaluate technologies and processes that will enable and enhance biosensory monitoring and communicative capabilities to include the delivery of remote care and consultation throughout the healthcare systems from the point of injury to the medical centers and throughout and between the Theater and Garrison environments.
- **Computational Biology and Advanced Analytics -** Efforts that focus on the development and application of methods for analysis, interpretation, prediction and modeling of biological data. The objective is to use mathematical tools to

extract practical information from data produced by high throughput biological techniques.

Health Enterprise Infrastructure: Research to improve health enterprise infrastructure by improving information technology and communications infrastructure.

- **Health Information Technology (HIT) Infrastructure** – Identifies processes and methods to improve staffing, facilities, and computing and communications systems.
- **Healthcare Data Management** – Improves data definition, standards, and methods for maintenance and management to enhance data quality in information-intensive and information-reliant healthcare systems.
- **Architecture** – Emphasizes architecture principles, including governance, policies, rules, business requirements, and system designs.

8. Radiation Health Effects Research Program

The Radiation Health Effects Research Program focuses on developing medical countermeasures for acute ionizing radiation injury. The program has interest in the following research focus areas: (a) post-exposure mitigation of radiation injury within 4 hours of exposure; (b) protection and prevention of injury from ionizing radiation exposure (prophylaxis); (c) mechanism of radiation injury; and d. development of novel biodosimetry tools.

9. Special Investment Areas/Innovation Funding

USAMRMC is continually seeking new and innovative science that promises benefit to military health and medicine. Many efforts are now integrated into programs of record or current research areas of interest as noted in this BAA. USAMRMC initiatives of interest include, but are not limited to, cross-cutting new science and technologies that may not have an apparent place elsewhere in this announcement, non-hypothesis driven research, development of enabling technologies, and new uses of current science that have not been considered in the past for a given application. A part of the investment process involves activist management that encourages Service member-centered projects that can be eventually integrated into the current research area taxonomy.

Innovation Funds may be available to support proposals/applications that offer proof of concept, proto-type development, and other activities that initiate or enhance potentially "game-changing" technologies and systems. Innovation funds generally range from $100,000 to $500,000 per project and are for a limited period of performance, generally eighteen months or less. Innovation Funding requests may include out-years, but these must be expressed as options to the Government. Proposals/applications must be written in such a way as to ensure a valuable deliverable after the first period of performance; multi-year longitudinal plans with incremental deliverables do not fit the Innovation Funds paradigm and should be submitted as a standard BAA submission, consistent with guidance elsewhere in this BAA.

Examples include approaches based upon convergence science principles and may address investment areas such as:

Medical Logistics: The objective is to research potentially transformational technologies to apply to core logistics systems, focusing on devices, practices and business processes that will improve military medical logistics. Research priorities include information systems and the application of automatic identification technologies (AIT) to the management of medical materiel. This will include supply chain management and asset management (inventory and life-cycle management) business processes and technologies. Technologies to support improved delivery of critical medical supplies including blood, oxygen, intravenous fluids, biologics and other medical materiel that has specific environmental handling requirements and limitations, as well as medical assemblages to the battlefield are of interest. Improvements in the storage of these commodities in the austere environment are also of interest.

Innovations which improve and support optical fabrication, hospital services, facilities and biomedical management and repair will be considered. Special attention may be given to the extension of advanced and transformational technologies to support the operational/deployed force. Areas of special interest include cold chain management in extreme conditions and the safe destruction/ management of medical, biological and pharmaceutical waste in austere environments. The ability to treat and potentially recycle/reuse waste water, both gray water and black water, which may contain medical (biological) and/or chemical (pharmaceutical) contaminants may be included in this area of special interest.

Biomonitoring Technologies: Research focus is in the development and integration of systems and/or platforms of technologies that will enable (remote and wireless) monitoring of a person's health to include assessing environmental factors in any setting including at home, in hospital, or in the field. This also includes development of algorithms and decision support tools.

Cross-cutting Technologies in Neuroscience: Research in this area includes training, treatment, prevention, protection, assessment, and diagnosis, using a variety of methodologies, techniques, materials, and technologies. Efforts in this area may fall in the following categories: Brain-machine interfaces; Neurodegenerative conditions; and Neuroimaging.

Medical Robotics and Intelligent Systems: Objectives target adapting, integrating or developing intelligent systems, human computer interfaces, and robotic technologies for medical applications. These include but are not limited to capabilities for location, assessment, treatment and rescue of battlefield casualties and development and integration of clinical robotic/intelligent system capabilities to improve patient medical outcomes. These technologies are also enablers for other scientific and technology domains such as advanced prosthetics & human performance, trauma, health information technology, simulation & training, medical logistics, and nanomedicine & biomaterials.

Nanomedicine and Biomaterials: The objective is to identify novel developments in materials science and biomaterials that can lead to new drugs and improved devices for diagnosing diseases and treatments. This includes nanotechnology and material fabrication with properties that mimic biological tissues.

B. Award Information

1. Mechanisms of Support. The USAMRMC executes its extramural research program primarily through the award of contracts and assistance agreements (grants and cooperative agreements). The type of instrument used to reflect the business relationship between the contractor/recipient and the Government will be a matter of negotiation prior to award. The Federal Grant and Cooperative Agreement Act of 1977, 31 USC 6301-6308, provides the legal criteria to select a procurement contract or an assistance agreement. A procurement contract is required when the principal purpose of the instrument is to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the United States Government (31 USC 6303). An assistance agreement (grants or cooperative agreements) is appropriate when the Federal Government transfers a "thing of value," to a "state, local government or "other recipient," to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the United States Government. The nature of the research, as well as all the recipient's obligations to the Government under an assistant agreement, indicates that the principal purpose of this award is to stimulate research of a public purpose. If there is "no substantial involvement" on the part of the funding agency, a grant award will be made (31 USC 6304). Conversely, if there is substantial involvement on the part of the funding agency, a cooperative agreement will be made (31 USC 6305). USAMRMC's supporting acquisition office, the U.S. Army Medical Research Acquisition Activity (USAMRAA), will process proposal/applications selected for funding.

2. Funds Available and Anticipated Number of Awards. Funding has NOT been set aside specifically for this BAA and the number of awards are indeterminate and contingent upon funding availability. Selection of research projects is a highly competitive process and is based on the evaluation of the proposal/application's technical merit, programmatic considerations and **the availability of funds**. The quantity of meaningful proposal/applications (both pre-proposal/pre-applications and full proposal/applications) received exceeds the number of awards that the available funding can support. Any funding that is received by USAMRMC and is appropriate for a research area described within this BAA may be utilized to fund proposal/applications.

3. Budget and Period of Performance. Researchers are encouraged to submit proposal/applications that span the period of performance of the entire research project. Budgets must include all direct and indirect costs. The total period of performance may be up to five years in length. Because the nature and scope of the proposed research will vary from proposal/application to proposal/application, it is anticipated that the size and duration of each award will vary.

There are no specified funding limitations identified for the proposal/applications submitted under this BAA, however, the budget should be commensurate with the nature and complexity of the proposed research, using supportable, verifiable estimates which include direct and indirect costs. The budget for the full proposal/application should not differ significantly from the "Estimated Total Cost of Project" provided in the pre-proposal/pre-application submission.

C. Eligibility Information

1. Eligible Applicants: Awards are made to organizations only. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.

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

2. Eligible Investigators:

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

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

3. **Cost Sharing or Matching** is not required for this announcement.

4. **Dun & Bradstreet Universal Numbering System (DUNS) Number, Commercial and Government Entity (CAGE) Code and System for Award Management (SAM):**

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

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

c. **Applicant Organization Must be Registered as an Entity with the System for Award Management (SAM)** and have an "Active" status before submitting a proposal/application through Grants.gov or receiving an award from the Federal Government. The SAM validates institution information and electronically shares the secure and encrypted data with Federal agencies' finance offices to facilitate paperless payments through electronic funds transfer. The organization's Representations and Certifications must be current at the time of proposal/application submission. The SAM registrations have an annual expiration; it is recommended that you verify the status of your organization's Entity registration in SAM well in advance of the proposal/application submission deadline. An organization can register online at https://www.sam.gov.

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

5. Other Eligibility Information

a. To protect the public interest, the Federal Government ensures the integrity of Federal programs by striving to conduct business only with responsible organizations. The USAMRMC uses the Exclusions within the Performance Information functional area of the System for Award Management (SAM), formerly the Federal Awardee Performance and Integrity Information System (FAPIIS), to verify that an organization is eligible to receive Federal awards. More information about the Exclusions reported in SAM is available at https://www.sam.gov.

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

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

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

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

All conflicts or potential conflicts of interest must be disclosed, along with a plan to mitigate the conflict, with the application submission. (See Section II.D.2.f., R&R Other Project Information Form, Block 11, for submission instructions.) An assistance agreement or contract may not be awarded if it is determined by the respective Grants or Contracting Officer that a conflict of interest cannot be avoided or mitigated.

D. Application and Submission Information

1. Address to Request Application Package

Applicants must download the SF424 (R&R) application forms and the SF424 (R&R) Application Guide for this Funding Opportunity Announcement (FOA) through http://grants.gov/apply.

NOTE: Only the forms package directly attached to this FOA can be used. You will not be able to use any other SF424 (R&R) forms (e.g., sample forms, forms from another FOA), although some of the "Attachment" files may be useable for more than one FOA.

Applications submitted in response to this FOA for Federal funding must be submitted electronically through Grants.gov (http://www.grants.gov). An Authorized Organizational Representative (AOR) must be registered with Grants.gov and is the only person authorized to submit a proposal/application. In order to safeguard the security of your electronic information, Grants.gov requires an organization representative to register for a username and password. Your **SAM registration must be complete and active** before you can obtain a username and password.

General information, tutorials, and checklists on the registration process are available at: http://www.grants.gov/applicants/get_registered.jsp. An organization's E-Business point of contact (POC), identified during SAM registration, must authorize someone to become an AOR. This safeguards the organization from individuals who may attempt to submit proposal/applications without permission. The AOR's username and password serve as "electronic signatures" when an application is submitted on Grants.gov.

To complete a Grants.gov profile and obtain a username and password, an AOR must first register with the Grants.gov credential provider at https://apply07.grants.gov/apply/OrcRegister. After you have created an account with Grants.gov, the E-Business POC listed on your organization's SAM registration will receive an email notification stating that you have registered and requesting assignment of user privileges. The AOR will also receive a copy of this email. The E-Business POC will need to log in to Grants.gov at

https://apply07.grants.gov/apply/OrcRegister and confirm you as an Authorized Organization Representative (AOR).

NOTE: There can be more than one AOR for your organization. However, in some organizations, a person may serve as both an E-Business POC and an AOR. When an E-Business POC approves an AOR, Grants.gov will send the AOR a confirmation email. You will NOT be able to submit applications until the E-Business Point of Contact has completed the authorization of your Grants.gov profile.

2. Content and Form of Application Submission

a. Conference or Symposium Support: The USAMRMC may, on a very limited basis, provide financial support for conferences or symposia that are critical to USAMRMC's mission accomplishment. Funding for conference support may require approval outside of USAMRMC and will only be considered if the event significantly furthers the mission of the Department of Army and has a quantifiable benefit or return on investment. The BAA Instructions for submitting a conference or symposium proposal/application can be found at http://www.usamraa.army.mil under the BAA link. The BAA Conference or Symposium Support electronic form can be found at http://www.usamraa.army.mil/pages/baa_forms/index.cfm. All conference or symposium proposal/applications will be assigned a proposal/application log number, and an e-mail will acknowledge receipt of a proposal/application. The Principal Investigator (PI) should receive a disposition letter or e-mail regarding the proposal/application within 180 days of submission.

b. Research and Development of Devices or Technologies: The USAMRMC may provide financial support (if funds are available) for research and development related to medical devices or technologies. Such projects should be for scientific study and experimentation directed toward advancing the state-of-art or increasing knowledge or understanding rather than focusing on a specific system or hardware solution (see FAR 6.102). Additional information is required for such projects as indicated below:

- Discussion of the technical feasibility of the proposed project including background of the problem, theoretical model/approach, previous and current solutions, an awareness of similar projects previously undertaken and knowledge of related activities.

- Discussion of the engineering/technical design to achieve the project goals demonstrating the feasibility of the proposed product development. Discussion of the perceived engineering/design strengths and flaws and recommendations for overcoming/preventing them.

- Discussion of the background intellectual property (IP) relevant to the project and provide in an attachment to Block 11 of the Research and Related Other Project Information Form.

- Discussion of the plans for translation, implementation and/or commercialization for the device or technology and provide the translation,

implementation and/or commercialization strategy information in an attachment to Block 11 of the Research and Related Other Project Information Form.

c. Pre-proposal/Pre-applications: Before submitting full proposal/applications, organizations are **strongly encouraged** to explore USAMRMC interest by submitting preliminary research proposal/applications (pre-proposal/pre-applications). Pre-proposal/pre-applications may be submitted at any time prior to the BAA closing date. Pre-proposal/pre-applications should describe specific ideas or projects that pertain to any of the research areas of interest outlined in the BAA. Pre-proposal/pre-applications must include a brief description of the theoretical rationale, scientific methods and design to address the problem. 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.**

You **MUST** register at http://www.usamraa.army.mil/pages/Baa_Forms/index.cfm first in order to submit a pre-proposal/pre-application. The pre-proposal/pre-application electronic form is also located at http://www.usamraa.army.mil/pages/Baa_Forms/index.cfm, and will appear on the site after you complete your registration.

The following fields are required within the pre-proposal/pre-application form: Proposal Information; Keywords; Problem to be Studied (4000 character limitation); Theoretical Rationale, Scientific Research Methods and Design (4000 character limitation); Significance and/or Uniqueness of the Proposed Effort (4000 character limitation); Potential Military Relevance (4000 character limitation); Duration of Project to be Studied; Estimated Total Cost of Project (which includes both direct and indirect costs); Participating Personnel and Effort; Capital Equipment; Brief Description of Animal and Human Use (4000 character limitation); Conclusions (4000 character limitation); Brief Curriculum Vitae for PI & Key Personnel (4000 character limitation); and List of Relevant Publications (4000 character limitation). The PI should delineate between a bibliography and additional relevant publications. Figures, charts, graphs or other additional material will not be accepted during the pre-proposal/pre-application process.

The PI should receive a disposition letter or e-mail regarding the pre-proposal/pre-application within 120 days of submission. **Applicants will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-proposal/pre-applications**.

d. **Full Proposal/Applications:** Full proposal/applications should be submitted within 90 days of the invitation and disposition should be rendered by the Government within 180 days of submission. Receipt of full proposal/applications will be acknowledged by e-mail. The proposal/application log number for the full proposal/application will be the same number used for the pre-proposal/pre-application. **The government does not routinely release the results of scientific peer review to the applicants and, therefore, may or may not provide feedback on full proposal/application submissions.**

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

FORMS: Each submission must include the completed package of forms identified in http://www.grants.gov for the Funding Opportunity W81XWH-BAA-14-1.

Mandatory R&R Forms:

SF 424 (R&R) Application for Federal Assistance
Research & Related Budget
Research & Related Project/Performance Site Location(s)
Research & Related Senior/Key Person Profile Form
Research & Related Other Project Information.

Optional R&R Forms:

R&R Subaward Budget Attachment(s)
Attachments

Mandatory Agency Forms:

Biographical Sketch
Proposal Abstract
Environmental Compliance Assurance
Facility Safety Plan (FSP) documents, as applicable;
instructions regarding the required FSP documents can be found in Section II.D.2.f.
Representations for Assistance Agreements
Organizational Data

NOTE: Mandatory Agency Forms are located under the Full Announcement tab of the FOA. All attachments that require signatures must be filled out electronically, printed, signed, and scanned, and then uploaded as an attachment to the proposal/application as a PDF file. Do not place password security on documents.

Grants.gov now validates attachment file name characters. Valid file names may only include the following UTF-8 characters: A-Z, a-z, 0-9, underscore (_), hyphen (-), space ( ) and period (.). If applicants use any other characters when naming their attachment files, their proposal/applications will be rejected. **Grants.gov does not validate for missing attachments.**

Full proposal/applications may be submitted without protocols for human and animal use. 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 Grants/Contracting Officer may make exceptions in situations where human and/or animal use are not expected to begin until after the first year of the research project. In such cases, a timeframe for submission of the appropriate protocols should be established during discussions/negotiations, prior to award**.**

PIs and partnering organizations may not use, employ, or subcontract for the use of any human participants, including the use of human anatomical substances and/or human data, or laboratory animals until applicable regulatory documents are requested, received, reviewed, and approved by USAMRMC to ensure that DoD regulations have been met.

e. **Formatting Guidelines:** Full proposal/applications should be submitted within 90 days of being invited and a disposition should be rendered by the Government within 180 days of submission. Forms and information supporting the submission of a full proposal/application are located at http://www.grants.gov.

The proposal/application must be clear and legible. Attachments must conform to the following guidelines:

(1) **Type Font:** 12 point (Times New Roman is strongly recommended)

(2) **Spacing:** Single-spaced between lines of text, no more than five lines of type within a vertical inch

(3) **Margins:** Minimum of 0.5 on all sides

(4) **Color, Resolution and Multimedia Objects:** Proposal/applications may include color, high resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects must not exceed 15 seconds in length and a size of 10 megabytes (MB). Since some reviewers work from black and white printed copies, applicants may wish to include text in the proposal/application directing the reviewer to the electronic file for parts of the proposal/application that may be difficult to interpret when printed in black and white. Photographs, illustrations, etc. must be submitted in JPEG format only (no bitmaps or TIFF).

(5) **Acronyms:** Spell out all acronyms the first time they are used. One page following the proposal/application body is allocated to spelling out acronyms, abbreviations and symbols.

(6) **Language:** Proposal/applications and all supporting documentation must be provided in English.

(7) **Print Area:** 7.5 x 10.0 inches (approximately 19.05 cm x 25.4 cm)

(8) **Attachments:** Must be in PDF format

f. **Mandatory Proposal/Application Forms**: Each submission must include the completed package of forms identified in http://www.grants.gov for the Funding Opportunity W81XWH-BAA-14-1. The Package includes: SF 424 (R&R) Application for Federal Assistance; Research & Related Budget; Research & Related Project/Performance Site Location(s); Research & Related Senior/Key Person Profile; and Research & Related Other Project Information.

NOTE: Attachments are located under the Full Announcement tab of the FOA. All attachments that require signatures must be filled out electronically, printed, signed, scanned and then uploaded as an Attachment to the proposal/application as a PDF file.

The SF 424 (R&R), Application for Federal Assistance, is required for each proposal/application submission. All appropriate information must be entered into this form to allow for auto-population of all subsequent forms in this proposal/application package.

- **Block 1 – Type of Submission.** For original submissions, the "Application" box should be chosen. For substantial changes that must be made after the original submission, the complete application package must be resubmitted with the "Changed/Corrected Application" box checked and the Grants.gov tracking number entered in Block 4 - Federal Identifier.

- **Block 2** – **Date Submitted**. Enter the date the proposal/application is submitted.

- **Applicant Identifier.** Enter the submitting Institution's Control Number, if applicable. This information can be obtained from the Institution's Office of Sponsored Research. If there is no Institution Control Number, this field should be left blank.

- **Block 3 – Date Received by State.** Not applicable.

- **State Application Identifier.** Not applicable.

- **Block 4a – Federal Identifier Box** will be populated by Grants.gov for an original application.

- **Block 4b – Agency Routing Identifier**. Not applicable.

- **Block 5 – Applicant Information**. Enter the information for the applicant organization. The "Person to be contacted on matters involving this application" is the Contract Representative or Business Official.

- **Block 6 – Employer Identification**. Enter the Employer Identification Number (EIN) or Tax Identification Number (TIN) as assigned by the Internal Revenue Service. If applying from an organization outside the U.S., enter 44-4444444.

- **Block 7 – Type of Applicant.** Enter the information for the applicant organization.

- **Block 8 – Type of Application.** Select "New" for all submissions.

- **Block 9 – Name of Federal Agency.** Populated by Grants.gov.

- **Block 10 – Catalog of Federal Domestic Assistance Number.** Populated by Grants.gov.

- **Block 11 – Descriptive Title of Applicant's Project.** Enter a brief but descriptive title of the project that accurately reflects the purpose of the research.

- **Block 12 – Proposed Project.** An estimated start date and end date must be entered. The actual start and end dates will be determined during negotiations if the proposal/application is recommended for funding.

- **Block 13 – Congressional District Of Applicant**. If the applicant organization is outside the U.S., enter 00000.

- **Block 14 – Project Director/Principal Investigator Contact Information.** Enter information for the individual PI responsible for the overall scientific and technical direction of the proposal/application. If outside the U.S., select the appropriate country from the dropdown menu.

- **Block 15 – Estimated Project Funding.** Enter the total funds (including all direct + indirect/facilities and administrative costs) requested for the entire performance period of the project. These figures should match those in the Research and Related Budget Form, and not vary significantly from the "Estimated Total Cost of Project" identified in the pre-proposal/pre-application.

- **Block 16** – **Is Application Subject to Review by State Executive Order 12372 Process?** Select option "b. NO, program is not covered by E.O.12372."

- **Block 17** – **Complete Certification.** Select the "I agree" box to provide the required certifications and assurances.

- **Block 18 – SFLLL or other Explanatory Documentation.** If applicable, complete and attach Standard Form LLL to disclose lobbying activities pursuant to 31 U.S.C. 1352.

- **Block 19 – Authorized Representative.** Enter the contact information for the applicant organization's authorized representative. The "Signature of Authorized Representative" is not an actual signature and is automatically completed upon submission of the electronic application package.

- **Block 20 – Pre-application** box and attachment should be used to attach the USAMRAA letter requesting the full proposal/application. **The letter file name should be the eight digit log number assigned to the pre-proposal/pre-application so the number will automatically populate to the pre-proposal/pre-application box.**

Research & Related Budget Form: An estimate of the total proposed research project cost, with a breakdown of all cost categories for each year, must accompany each proposal/application. Provide sufficient detail and budget justification so that the Government can determine the proposed costs to be allowable, allocable, and reasonable for the proposed research. ***Include a detailed budget and budget justification.*** The budget justification for the entire period of performance must be uploaded to the Research & Related Budget form after completion of the budget for Period 1. Submit additional documentation in PDF format only. Use the Research & Related Budget form that is available for download on the Grant Application Package page for this Funding Opportunity in Grants.gov. All costs must be entered in U.S. dollars. Recipients performing outside of the U.S. should include the cost in local currency, the rate

used for converting to U.S. dollars and justification/basis for the conversion rate used. Multiple year proposal/applications are encouraged to cover the total estimated duration of the project. Incremental funding may be provided by USAMRMC for efforts performed during each Federal fiscal year.

At the time of proposal/application submission to Grants.gov, the Authorized Organizational Representative is certifying to the best of his/her knowledge that all costs are current, accurate, and complete.

Budget Regulations: The following must be adhered to regarding budget calculations:

• **Maximum Obligation:** For Assistance Agreement awards pursuant to this BAA, the USAMRMC does not modify awards to provide additional funds for such purposes as reimbursement for unrecovered indirect/facilities and administrative costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.

• **Administrative and Cost Principles:** Applicants are required to comply with the following, as applicable:

- Federal Acquisition Regulation (FAR) Part 31
- Defense FAR Supplement Part 231
- Department of Defense Grant and Agreement Regulations 3210.6-R
- CFR, Title 2, Part 220, "Cost Principles for Educational Institutions (OMB Circular A-21)"
- CFR, Title 2, Part 225, "Cost Principles for State, Local, and Indian Tribal Governments (OMB Circular A-87)"
- OMB Circular A-102, "Grants and Cooperative Agreements with State and Local Governments"
- CFR, Title 2, Part 215, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-profit Organizations (OMB Circular A-110)"
- CFR, Title 2, Part 230, "Cost Principles for Non-profit Organizations (OMB Circular A-122)." [For those nonprofit organizations specifically excluded from the provisions of OMB Circular A-122, Subpart 31.2 of the Federal Acquisition Regulations (FAR 48 CFR Subpart 31.2) shall apply.]
- OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations"

The cost of preparing proposal/applications in response to this BAA is not considered an allowable direct charge to any resultant award. It is, however, an allowable expense to the bid and proposal/application indirect cost specified in FAR 31.205-18 and 2 CFR Title 2 Parts 220 and 230.

Section A: Senior/Key Person

• **Prefix; First, Middle and Last Name; and Suffix:** Beginning with the PI, list all senior/key persons from the applicant organization who will be involved in the proposed research project, whether or not salaries are requested. Include all investigators, research associates, etc. If applicable, all investigators outside the applicant organization should be included on the R & R Subaward Budget Attachment(s) Form. Consultant costs should be listed under section F.3.

• **Project Role:** Identify the role of each senior/key person listed. Describe his/her specific functions in the budget justification.

• **Base Salary:** Enter the current annual organizational base salary (based on a full time appointment) for each individual listed for the proposed research project.
Establish labor costs using current labor rates or salaries. Identify and explain in the budget justification any proposed adjustments to salary/wages.

• **Calendar, Academic, and Summer Months:** For each senior/key person including unpaid personnel, list the number of months to be devoted to the proposed research project in the appropriate box.

• **Requested Salary:** Enter the amount of salary requested for this budget period.

• **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines. Provide documentation to support the fringe benefits (e.g., the current Department of Health and Human Services [DHHS] Rate Agreement or other policy document).

• **Funds Requested:** Enter the total funds requested for each senior/key person listed for the proposed research project.

Section B: Other Personnel

• **Number of Personnel:** For each project role category indicate the number of personnel for the proposed research project, including unpaid personnel.

• **Project Role:** Identify each project role category. Within the budget justification, describe the specific functions of the personnel in each project role.

• **Calendar, Academic, and Summer Months:** For each project role category, including unpaid personnel, list the number of months to be devoted to the proposed research project in the appropriate box.

• **Requested Salary:** Enter the amount of salary requested for this budget period.

• **Fringe Benefits:** Enter the fringe benefits requested for each project role category in accordance with organizational guidelines. Provide documentation to support the fringe benefits (e.g., the current DHHS Rate Agreement or other policy document).

• **Funds Requested:** Enter the total funds requested for each project role category listed for the proposed research project.

Section C: Equipment Description

Equipment is any article of nonexpendable, tangible property having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit (unless the applicant organization has established a lower limit). Organizations are encouraged to provide all equipment necessary to conduct the proposed research project. Commercial organizations are expected to possess the necessary facilities and equipment to conduct the proposed research. Equipment purchases for commercial organizations will be supported only in exceptional circumstances. Equipment must be purchased in accordance with the organization's approved purchasing system.

If equipment is requested, provide a detailed list showing the cost of each item. The budget justification for all equipment must include, as applicable:

- Vendor Quote: Provide a copy of the successful vendor's quote.

- Historical Cost: Identify vendor, date of purchase, and whether or not cost represented the lowest bid. Include reason(s) for not soliciting current quotes.

- Estimate: Include rationale for estimate and reasons for not soliciting current bids.

- Special test equipment to be fabricated for specific research purposes and its cost.

- Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs, listing separately.

- Existing equipment to be modified to meet specific research requirements, including modification costs. Do not include as special test equipment those items of equipment that, if purchased by the contractor/recipient with contractor/recipient funds, would be capitalized for Federal income tax purposes.

- Unless otherwise specified in the award, the title to equipment or other tangible property purchased with Government funds will vest in institutions of higher education or with non-profit organizations whose primary purpose is conducting scientific research. Normally, the title will vest in the recipient if vesting will facilitate scientific research performed by the organization for the Government. Title to equipment or other tangible property purchased by for-profit organizations will conditionally vest in the organization subject to the requirements of the DODGAR 3210.6-R, Part 34.21. However, if the award is subsequently transferred to a new

organization, the Department of Defense reserves the right to require the transfer of equipment purchased with the award funds to the Federal Government or to an eligible third party.

Section D: Travel

The justification supporting travel costs should list the number of trips, number of people per trip, the destinations and the purpose for all proposed travel annually. Estimate round trip fare and per diem costs for each trip. Travel to scientific meetings requires identification of the specific meeting and purpose. The number of trips funded for scientific meetings is limited. **Travel outside the United States, including between foreign countries, may require prior approval from the Grants/Contracting Officer at least 90 days before travel.**

NOTE: The PI may be required to participate in an in-progress programmatic/science review. The PI shall budget for, prepare for, and participate in an in-progress programmatic/science review, lasting not more than two days and including up to two overnight stays, for each year of the project's term, at the Grants Officer's Representative's / Contracting Officer's Representative's (GOR/COR) request. The invitation and format for the programmatic/science review will be provided by the GOR/COR at least (90) days prior to the meeting. The meetings will generally be held in the Fort Detrick, MD area but could occur elsewhere in the U.S.

Any travel costs for DoD employees that are necessary for a project will be paid by the Government via a direct funds transfer. No funds are permitted to be paid by the recipient to the DoD to cover DoD employee or military travel costs.

Section E: Participant/Trainee Support Costs: Enter the funds requested for tuition/fees, health insurance, stipends, travel, subsistence, and other costs.

Section F: Other Direct Costs

Section F.1. – Materials and Supplies (Consumables): The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies for each year. For materials and supplies costing $5,000 and over per year, provide additional breakdown. If animals are to be purchased, state the species, strain (if applicable), number to be used, cost per animal and total costs, proposed vendor, and a copy of the animal per diem cost/rate agreement. If human cell lines are to be purchased, state the source, cost, and description.

Section F.2. – Publication Costs: Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution.

Section F.3. – Consultant Services: Regardless of whether funds are requested, include in the budget justification the names and organizational affiliations of all consultants, and include the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project. A letter of commitment will be required prior to award.

Section F.4. – ADP/Computer Services: Include the cost of computer services, including computer-based retrieval of scientific, technical, and educational information. Include in the budget justification the provider's computer service rates.

Section F.5. – Subaward/Consortium/Contractual Costs:

Include the total funds requested for (a) all subaward/consortium organization(s) proposed for the research project and (b) any other contractual costs proposed for the research project. This amount should be supported in the subaward/consortium/contractual costs provided in the R & R Subaward Budget Attachment(s) Form.

All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.

NOTE: Supporting Information such as subaward agreements, consultant agreements, vendor quotes, and personnel work agreements may be required in order to support proposed costs or to determine the employment status of personnel under the award. The Government's receipt of this information does not constitute approval or acceptance of any term or condition included therein. The terms and conditions of the award take precedence over any term or condition included in supporting information.

USAMRMC 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 proposal/applications submitted through the BAA.

If the resultant award is a contract that exceeds $650,000 and the offeror is a large business or an educational institution (other than Historically Black Colleges and Universities/Minority Institutions HBCU/MI), the contractor is required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.7. A mutually agreeable plan will be incorporated as part of the resultant contract.

Section F.6. – Equipment or Facility Rental/User Fees: List proposed equipment or facility rental/user fees. Include appropriate information (hours and rates) in the budget justification.

Section F.7. – Alterations and Renovations: Alteration and renovation (A&R) costs can be requested if the costs are essential to accomplish the objectives of the research project and are a minor portion of the overall budget. A description of the existing facility and detailed description of the requested changes, along with a cost estimate, must be included in the budget justification. Costs for the construction of facilities are not allowable unless authorized by specific statute.

Section F. (8 – 10) – Research-Related Subject Costs: Include itemized costs of subject participation in the research study. These costs are strictly limited to expenses

specifically associated with the proposed study. The USAMRMC will not provide funds for ongoing medical care costs that are not related to a subject's participation in the research study.

Section F. (8 – 10) – Itemize other anticipated direct costs such as communication costs and organizationally provided services. These items should be described in detail and clearly justified. Unusual or expensive items should be fully explained and justified in the budget justification. Organizationally provided services should be supported by the organization's current cost/rate schedule. Computers and software are considered to be general office supplies and are not normally allowable direct cost charges unless the computer/software is essential and unique to the proposed research project. If a computer/software purchase is requested, include the following in the budget justification:

• Detailed description regarding why the computer/software purchase is required to complete the proposed research project.

• Statement verifying that the requested computer/software is not currently available for use by the PI.

• Statement that the requested computer/software will be purchased in accordance with applicable cost principles and the organization's purchasing policy.

Section G – Direct Costs: Include the total direct costs (A-F).

Section H – Indirect Costs (overhead, general and administrative, and other):

The indirect costs category may include Facilities and Administrative (F&A) costs, overhead, General and Administrative (G&A), and other. The most recent Federal agency approved rate(s) should be applied. If the rate(s) has been approved by other than a Federal agency, indicate the source of the approval. Provide details of the direct cost base (modified total direct costs, salary and wage, or other). Identify any costs that have been excluded from the base (in accordance with the approved rate agreement). Also indicate if the rate(s) is an on- or off-site rate(s). If more than one rate is applicable, provide a breakdown of the calculation. Provide documentation to support the indirect cost rate (e.g., the current Department of Health and Human Services [DHHS] Rate Agreement or other policy document).

If a negotiated approved rate(s) does not exist, provide sufficient detail for a proposed rate (adhering to the applicable cost principles) in the budget justification. For information regarding indirect costs, organizations can also visit the following websites: DHHS http://rates.psc.gov/fms/dca/negotiations.html; Office of Naval Research http://www.onr.navy.mil/Contracts-Grants/manage-grant/indirect-cost-proposal.aspx); and the Defense Contract Audit Agency http://www.dcaa.mil/.

Section I – Total Direct and Indirect Costs: Include total costs for the proposed research project.

Section J – Fee: A profit or fixed fee is not allowable on grants or cooperative agreements. If a contract will be awarded, a profit/fee may be negotiated. Any profit/fee applied to the

research project must be listed, and any claimed Facilities Capital Cost of Money must be supported by **DD Form 1861** and submitted with the full proposal/application. The website for the form is: http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd1861.pdf.

Section K – Budget Justification:

Provide a clear budget justification for each item in the budget over the entire period of performance and attach as a single PDF file to section K of the Research & Related Budget form. Organizations must provide sufficient detail and justification so that the Government can determine the proposed costs to be allocable, allowable and reasonable for the proposed research effort. Attach one file that addresses each of the cost elements proposed.

The budget justification must include information for all budget periods. This file must be uploaded for budget period one before you will be allowed to access subsequent budget periods.

Federal Financial Plan (no page limit): Any proposal/application from or that includes collaborations with federal agencies must include in the budget justification a plan delineating how all funds will be obligated before their expiration for obligation, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as through agreements with foundations, non-federal organizations, universities, or through other means.

NOTE: It is contrary to USAMRMC policy to allow for any contractor/recipient to reimburse the DoD for any costs except under very limited circumstances.

Research & Related Project/Performance Site Location(s) Form:

Indicate the primary site where the work will be performed. If a portion of the work will be performed at any other site(s), include the name and address for each collaborating location in the data fields provided. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach to this form. Each additional research site requesting funds will require a subaward budget.

Research & Related Senior/Key Person Profile Form: Include the requested information for each senior/key person proposed on the project and attach:

(a) **Biographical Sketch (USAMRAA Form 85-E-R),** and

(b) **Prior/Current/Pending Support**: This should include prior support on which this person worked within the last 5 years, current support on which this person is working, and pending support on which this person is proposed. The list of Prior/Current/Pending Support should be attached in PDF format and should include the title, time commitments, supporting agency and level of funding for all prior, existing and pending research projects involving the PI and key personnel. Provide justification for USAMRMC support and interest where the projects potentially overlap or parallel.

Research & Related Other Project Information Form: The following information must be included as attachments to this form:

Blocks 1 - 5: This section addresses the use of human subjects, the use of animals, proprietary information and environmental impact of the research.

Block 6 – Project Summary/Proposal Abstract (USAMRAA Form 86-E-R):

The abstract is vitally important to both the scientific peer and programmatic review processes. It is paramount that the investigator submit an abstract that fully describes the proposed work. The abstract must contain the title of the project and the name of the PI. Do not include figures or tables in the abstract. Use only characters available on a standard QWERTY keyboard. Spell out all Greek or other non-English letters. Abstracts of all funded proposal/applications may be posted**; therefore, proprietary information should not be included in the abstract.**

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

a. Background: Provide a brief statement of the ideas and theoretical reasoning behind the proposed work.

b. Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

c. Specific Aims: State concisely the specific aims of the study.

d. Study Design: Briefly describe the study design.

e. 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.

A sample technical abstract can be found at www.usamraa.army.mil/pages/pdf/2001_BAA_sample_technical_abstract.pdf.

Block 7 – Project Narrative (limit 21 pages) – The Project Narrative includes the Statement of Work and the Body of the Proposal/Application, in that order. There is no form for this information. The attachments must be in PDF in accordance with the formatting guidelines specified for full proposal/application preparation.

Statement of Work (SOW) (limit 1 page) – The SOW is the section of a research award that outlines and establishes the PI and an organization's performance expectations for which USAMRMC may provide funding. Unlike the general objectives which are agreed to in a grant or cooperative agreement SOW, the contract SOW 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 will be incorporated into the award document and, as such, is subject to release under Freedom of Information Act (FOIA).

A series of relatively short statements should be included which 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 which shows the work statements to be accomplished in each year of the award. Allow at least 2 months for Government regulatory review and approval processes for studies involving animal and human subjects.

Body of Proposal/Application (limit 20 pages) - A detailed description of the research to be undertaken should be submitted. This will include background, hypothesis, objectives, approach, methods, and their relationship to the state of knowledge in the field and to comparable work in progress elsewhere. Evaluation of the proposed research will be influenced by the adequacy of this information. Literature references and curriculum vitae will be shown in separate addenda entries. The following general outline should be followed:

1. **Background**. Provide a brief statement of ideas and theoretical reasoning behind the proposed study. Describe previous experience most pertinent to this proposal/application. Cite relevant literature references. Include discussion of any findings (if available) from relevant pilot or preliminary work or any related work underway. For development of devices and technologies, provide an intellectual property plan in an attachment at Block 11;

2. **Hypothesis**. State the hypothesis to be tested and the expected results. For development of devices and technologies, discuss the technical feasibility of the proposed project including background of the problem, previous and current solutions, similar projects previously undertaken and related development activities;

3. **Technical Objectives.** State concisely the question to be answered by each research objective;

4. **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 in an attachment to Block 11;

5. **Military Significance.** State precisely the estimates as to the immediate and/or long-range usefulness of this study to the Armed Forces, as distinguished from general advancement of knowledge in medicine;

6. **Public Purpose**. If appropriate, provide a concise, detailed description of how this research project will benefit the general public;

7. **Methods.** Give details about the experimental design and methodology. If the methodology is new or unusual, describe in sufficient detail for evaluation. For synthetic chemistry proposal/applications, include a clear statement of the rationale for the proposed syntheses. Outline and document the routes to the syntheses. For development of devices and technologies, discuss the engineering/technical design 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. For studies involving human subjects, describe recruitment plan and access to populations. The proposal/application should describe a plan for data access. (Access to subjects and data is the sole responsibility of the investigator.) As relevant, describe plans for addressing issues unique to working with military populations.

Block 8 – Bibliography & References Cited. List the references in the order they appear in the proposal/application narrative. Use a reference format which gives the title of the citation. Do not send or attach copies of articles in print. There is no form for this information. The attachments should be in PDF in accordance with the formatting guidelines specified for full proposal/application preparation.

Block 9 – Facilities & Other Resources. Describe the facilities available for performance of the proposed request and any additional resources proposed for acquisition at no cost to USAMRMC. Indicate if a Government-owned facility is proposed for use. Reference should be made to the original or present award under which the facilities or resources are now accountable. There is no form for this information. The attachments must be in PDF in accordance with the formatting guidelines outlined for full proposal/application preparation.

Block 10 – Equipment. Include a description of existing equipment to be used for the proposed research project. There is no form for this information. The attachments should be in PDF, in accordance with the formatting guidelines outlined for full proposal/application preparation.

Block 11 – Other Attachments. Include in this section all items listed below as well as any other documentation not specified elsewhere, that supports the research proposed and could influence the evaluation and selection process.

- **Acronyms and Symbol Definition -** Provide a glossary of acronyms and symbols.

- **Collaboration and Joint Sponsorship -** Provide letter(s) supporting stated collaborative efforts, even if provided at no cost, that are necessary for the project's success. 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)** – Provide a list of all background intellectual property relevant to the project. Identify any proprietary information that will be provided to the Government and whether the applicant will request a waiver of Government purpose rights.

- **Conflict of Interest (if applicable) –** Provide details with the proposal/application submission of all organizational or individual investigator conflicts of interest, or potential

conflicts of interest, along with a plan to mitigate the conflicts. All conflicts of interest on the part of an organization or individual investigator must be resolved prior to the award of an assistance agreement or contract. An assistance agreement or contract may not be awarded if it is determined by the respective Grants or Contracting Officer that a conflict of interest cannot be avoided or mitigated.

- **Translation, Implementation and/or Commercialization Strategy (as applicable)** - Describe the translation, implementation and/or commercialization plan. The plan should include intellectual property, market size, market potential and cost of research and development, strengths and weaknesses, barriers to market, competitors and management team. Discuss the significance of this development effort, when it can be anticipated and the potential translation, implementation and/or commercial use for the technology being developed.

- **Environmental Compliance Assurance –** Complete and submitted with the full proposal/application.

- **Facility Safety Plan Instructions –** Instructions regarding the required documents to be submitted with the proposal/application are included in the attachment entitled "Facility Safety Plan Instructions." Instructions are also located at https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.safety.

- **Representations for Assistance Agreements - "**Representations Regarding Unpaid Federal Tax Liabilities and Conviction of Felony Criminal Violations under any Federal Law." The applicant is required to complete and attach these Representations to the full proposal/application. (*Applicable to corporations only.*)

- **Organizational Data** – The applicant is required to complete this information and attach with full proposal/application.

- **Multimedia Objects, Photographs, Illustrations, Graphs, etc.** - Proposal/applications may include color, high resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects must not exceed 15 seconds in length and a size of 10 megabytes (MB). Since some reviewers work from black and white printed copies, applicants may wish to include text in the proposal/application directing the reviewer to the electronic file for parts of the proposal/application that may be difficult to interpret when printed in black and white. Photographs and illustrations, graphs etc. must be submitted in Microsoft Office or JPEG format only (no bitmaps or TIFF). **If photographs of identifiable patients are provided, release forms must also be submitted with the photographs.**

g. Optional R&R Forms: R&R Subaward Budget Attachment(s) Form; Attachments Form

R&R Subaward Budget Attachment(s) Form:

Attach the R&R Subaward Budget files for your proposal/application. Complete the subaward budget(s) in accordance with the Research & Related budget instructions. Files to be attached to the R&R Subaward Budget Attachment(s) Form must be PDF documents.

NOTE: Attach your subaward budget file(s) with the file name of the subawardee organization. Each file name must be unique. The **DUNS number for each subaward site must be included on this form**.

You may use this form, or attach subaward budgets in PDF format as part of Budget Justification on Tab K of the Research & Related Budget form. Extract an R&R Subaward Budget Attachment for each subaward using the button provided on this form. Save each attachment to your computer and complete the form(s).

The Budget Justification for each subaward must be attached as a PDF file named "Justification_LastName.pdf" (where "LastName is the investigator of the subaward) to the Research & Related Budget – Section K for that subaward. Each subaward budget justification must include information for all budget periods. This file must be uploaded for budget period one before you will be allowed to access subsequent budget periods for the subaward. Once all subaward budget files are completed, attach all subaward budget file(s) to the R&R Subaward Budget Attachment(s) Form.

A description of services or materials that are to be awarded by subcontract or subgrant is required. Organizations must provide sufficient detail and justification so that the Government can determine the proposed costs to be allocable, allowable and reasonable for the proposed research effort.

If the resultant award is a contract that exceeds $650,000 and the organization is a large business or an educational institution (other than a Historically Black College or University/Minority Institution), the organization is required to submit a subcontracting plan for small business and small disadvantaged business concerns in accordance with FAR 19.7. A mutually agreeable plan will be incorporated as part of the resultant contract.

NOTE: Supporting Information, such as subawards, consultant agreements, vendor quotes, and personnel work agreements, may be required in order to support proposed costs or to determine the employment status of personnel proposed. The Government's receipt of this information does not constitute approval or acceptance of any term or condition included therein. The terms and conditions of the award take precedence over any term or condition included in supporting information.

Attachments Form: Use form as needed.

h. Research Involving the Use of Animals, Human Subjects, or Human Anatomical Substances/Human Data

Principal Investigators (PIs) and applicant organizations may not commence performance of research involving the use of animals, human subjects, human anatomical substances, and/or human data, or expend funding on such efforts, until and unless applicable regulatory documents are reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) to ensure that Department of Defense (DoD) regulations are met. All expectations described below are consistent with the DoD Instruction (DoDI) 3216.01, "Use of Animals in DoD Programs," as issued September 13, 2010 available at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro_regulations and DoDI 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," as issued on November 8, 2011, and available at http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf.

Studies involving animals and non-exempt research involving human subjects (to include direct intervention/interaction, obtaining individually identifiable information, and obtaining individually identifiable anatomical substances) must be approved through a regulatory review process by the PI's local Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB) and by the USAMRMC Office of Research Protections (ORP). The ORP Animal Care and Use Review Office (ACURO) is responsible for administrative review, approval, and oversight of all animal research. The ORP Human Research Protection Office (HRPO) is responsible for administrative review, approval, and oversight of research involving human subjects. ***Research involving human subjects that is anticipated to be exempt from human subjects protections regulations requires a determination from the PI's institution.*** If the study may include research involving human subjects and the PI's institution determines the activity is not research involving human subjects, a determination is also needed from the ORP HRPO at USAMRMC. A timeframe for submission of the appropriate protocols and required approvals will be established during negotiations.

Concurrent with the USAMRAA negotiation, the Office of Surety, Safety and Environment will review the Environmental Compliance Assurance and the Principal Investigator Safety Program Assurance forms (to be submitted upon request).

(1) Research Involving Animal Use

Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. (These documents should not be submitted with the application.) The ACURO, a component of the USAMRMC ORP, must review and approve all animal use prior to the start of working with animals. A PI must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled "Research Involving Animals." For guidance on which version of the appendix to use, as well as links to both, visit the ACURO website at: https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro_Animalappendix. Allow 2 months for Government regulatory review and approval processes for animal studies.

For additional information, send questions via email to ACURO (ACURO@amedd.army.mil).

(2) Use of Human Cadavers or Human Anatomical Substances Obtained from Human Cadavers

Research, development, testing and evaluation (RDT&E), education or training activities involving human cadavers shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 20 April 2012 (https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.overview). The USAMRMC ORP is the Action Office (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil) for this policy. Approval must be obtained from the Head of the Army organization that is supporting/funding the activity involving cadavers as described in the policy. For certain activities involving cadavers, approval must also be obtained from ORP. Award contractor/recipients must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. Written approvals to begin the activity will be issued under separate notification to the contractor/recipient.

(3) Research Involving Human Subjects, Human Subjects Data, or Human Anatomical Substances

In addition to local IRB review, all USAMRMC-funded research involving human subjects and human anatomical substances must receive a USAMRMC Headquarters-level Administrative Review and be approved by the USAMRMC ORP HRPO prior to implementation of the research. The focus of this review is to validate that the IRB review was appropriate and ensure DoD, Army, and USAMRMC regulatory requirements have been met.

Questions regarding applicable human subject protection regulations, policies, and guidance should be directed to the local IRB, the USAMRMC ORP HRPO (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil) and/or the U.S. Food and Drug Administration (FDA), as appropriate. For in-depth information and to access HRPO protocol submission forms, refer to the ORP HRPO website (https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo).

ORP HRPO-specific language must be inserted into the consent form, and compliance with DoD regulations may require additional information be included in the protocol.

The ORP HRPO ensures that DoD supported and/or conducted research complies with specific laws and directives governing research involving human subjects. These laws and directives may require information in addition to that supplied to the local IRB.

During the regulatory review process for research involving human subjects, the ORP HRPO requirements must be addressed, and any changes to the already approved protocol must be approved as an amendment by the local IRB. It is strongly recommended that investigators carefully read the "Information for Investigators" found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo. The time to approval depends greatly on adherence to the requirements described within. If the protocol has not been submitted to the local IRB at the time of award negotiation, these guidelines should be considered before submission.

Documents related to the use of human subjects or human anatomical substances will be requested if the proposal/application is recommended for funding. ***Allow at least 2 months for Government regulatory review and approval processes for studies involving human subjects.***

Specific requirements for research involving human subjects or human anatomical substances can be found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

Assurance of Compliance: Each institution engaged in non-exempt human subjects research must have a current Department of Health and Human Services Office for Human Research Protection (OHRP) Federalwide Assurance (FWA) or DoD Assurance.

Training: Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming completion of appropriate instruction may be required during the regulatory review process.

Informed Consent Form: The following must appear in the consent form:

- A statement that the U. S. Army Medical Research and Materiel Command is providing funding for the study.
- A statement that representatives of the DoD are authorized to review research records.
- In the event that a Health Insurance Portability and Accountability Act (HIPAA) authorization is required, DoD must be listed as one of the parties to whom private health information may be disclosed.

Intent to Benefit: The requirements of Title 10 United States Code Section 980 (10 USC 980), which are applicable to DoD-sponsored research, must be considered. 10 USC 980 requires that "Funds appropriated to the Department of Defense may not be used for research involving a human being as an *experimental subject* unless (1) the informed consent of the subject is obtained ***in advance***; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject."

An individual not legally competent to provide informed consent (e.g., incapacitated individuals, cognitively impaired, minors) may not be enrolled as an ***experimental subject*** in a DoD-supported study unless the research is intended to benefit each subject enrolled in the study, to include subjects enrolled in study placebo arms. Studies designed in a manner that permits all subjects to potentially benefit directly from medical treatment or enhanced surveillance beyond the standard of care can meet the 10 USC 980 requirements. Note that the definition of ***experimental subject*** as defined in the DoDI 3216.02 has a much narrower definition than human subject. Research with experimental subjects must involve an intervention or interaction where the primary purpose of the research is to collect data regarding the effects of the intervention or interaction.

10 USC 980 is only applicable to certain intervention studies. It does not apply to retrospective studies, observational studies, studies that involve only blood draws, and tissue collections. Contact the HRPO at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil if further clarification regarding applicability of 10 USC 980 to the proposed research project is required.

Research Monitor Requirement: For research determined to be greater than minimal risk, DoDI 3216.02 requires **that the IRB approve, by name, an independent research monitor with expertise consonant with the nature of risk(s) identified within the research protocol**. The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities.

The research monitor's duties should be based on specific risks or concerns about the research. The research monitor may perform oversight functions and report their observations and findings to the IRB or a designated official. The research monitor may be identified from within or outside the PI's institution. Research monitor functions may include:

- observing recruitment and enrollment procedures and the consent process for individuals, groups or units,
- overseeing study interventions and interactions,
- reviewing monitoring plans and Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO) reports;
- overseeing data matching, data collection, and analysis

There may be more than one research monitor (e.g., if different skills or experiences are necessary). The monitor may be an ombudsman or a member of the data safety monitoring board. At a minimum, the research monitor:

- may discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research;
- shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report;
- shall have the responsibility to promptly report their observations and findings to the IRB or other designated official and the HRPO.

A curriculum vitae or biographical sketch and human subjects protection training for the research monitor must be provided. There should be no apparent conflict of interest and the research monitor cannot be under the supervision of the PI, other investigators, or research staff associated with the proposed research project. If the duties of the research monitor could require disclosure of subjects' Protected Health Information outside a covered entity (i.e., the research monitor is not an agent of the covered entity), the PI's institution may require the identity and location of the research monitor to be described in the study HIPPA authorization. It is acceptable to provide appropriate compensation to the research monitor for his or her services.

Recruitment of Military Personnel: Civilian investigators attempting to access military volunteer pools are advised to seek collaboration with a military investigator who will be familiar with service-specific requirements.

A letter of support from Commanders of military facilities or units in which recruitment will occur or the study will be conducted will be requested by the HRPO. Some military sites may also require that each volunteer seek written permission from his/her supervisor prior to participation in research studies.

Special consideration must be given to the recruitment process for military personnel. The Chain of Command must not be involved in the recruitment of military personnel and cannot encourage or order Service members to participate in a research study. For greater than minimal risk research, an ombudsman must be employed when conducting group briefings with active duty personnel to ensure that volunteers understand that participation is voluntary; this ombudsman may be recommended in other situations as well, especially when young enlisted Service members who are trained to follow orders are being recruited. Service members are trained to act as a unit, so peer pressure should also be considered and minimized, if possible.

Payment to Federal Employees and Military Personnel: Under 24 USC 30, payment to Federal employees and active duty military personnel for participation in research while on duty is limited to blood donation and may not exceed $50 per blood draw. They may not receive any other payment or non-monetary compensation for participation in a research study unless they are off duty or on leave during the time they are participating in the protocol.

Confidentiality for Military Personnel: Confidentiality risk assessment for military personnel requires serious consideration of the potential to affect the military career. Medical and psychological diagnoses can lead to limitation of duties and/or discharge from active duty. Information regarding alcohol or drug abuse, drunk driving, and sexual or spousal abuse can lead to actions under the Uniform Code of Military Justice, including incarceration and dishonorable discharge.

Site Visits: The USAMRMC ORP HRPO conducts site visits as part of its responsibility for compliance oversight.

Accurate and complete study records must be maintained and made available to representatives of the USAMRMC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues can be found at: https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

Protocol Submission Format: The ORP HRPO accepts protocol submissions in the format required by the local IRB. The IRB protocol application, if separate from the protocol itself,

should be included with protocol submissions. A HRPO protocol submission form should be completed and submitted with each protocol.

If you have difficulty accessing any of the https://mrmc web sites related to Research Protection, go to http://www.usamraa.army.mil, click on Customers, select U.S. Army Medical Research and Material Command, and then the Research Protection link for the appropriate web sites.

i. Regulations and Forms

(1) Copies of the Federal Acquisition Regulation (FAR) and Defense FAR Supplement referenced in this BAA may be purchased from the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 or located at website http://farsite.hill.af.mil.

(2) Office of Management and Budget Circulars referenced in this BAA may be obtained from:

EOP Publication Office
New Executive Office Building
725 17th Street, NW, Room 2200
Washington, DC 20503

Telephone: 202-395-7332
Website http://www.whitehouse.gov/omb

(3) The contracting/grants activity may contact applicants whose proposal/applications are selected for funding for specific certifications and statements required by Federal statutes and regulations. Failure to include all required information and completed forms with submission of the full proposal/application could delay the award process.

(4) Code of Federal Regulations can be found at www.gpoaccess.gov/cfr.

(5) Department of Defense Grants and Agreements Regulations can be found at http://www.dtic.mil/whs/directives/corres/html/321006r.html.

Location of Forms:

Mandatory and Optional R&R Forms: Select "Search Grants" at http://www.grants.gov and enter W81XWH-BAA-14-1 in the "Funding Opp #" block. When the Funding Opportunity appears, select the Funding Opportunity #. When you reach the "View Grant Opportunity" screen, select "Application Package." On the following screen, select "Download" under "Instructions and Application." When the "Download Application Package" screen appears, it is **strongly recommended** that you provide your email address so that you are notified if any changes are made to the FOA. If changes are made, prior application packages may be rejected by grants.gov. Once you complete that screen, on the "Download Application Package" screen, select "Download Application Package" at the bottom of the screen. The list of required/mandatory and optional forms will appear.

Mandatory Agency Forms: Select "Search Grants" at http://www.grants.gov and enter W81XWH-BAA-14-1 in the "Funding Opp #" block. When the Funding Opportunity appears, select the Funding Opportunity #. When you reach the View Grant Opportunity screen, select "Full Announcement." The forms will be listed on the following screen.

3. **Submission Dates and Times:** This is a continuously open announcement; pre-proposal/pre-applications may be submitted and will be evaluated at any time throughout the 12-month period identified on page 1 of this BAA. No pre-proposal/pre-application or full proposal/application may be submitted after September 30, 2014. No proposal/application received under this BAA will be considered for funding after 24 months from the date of submission.

4. **Intergovernmental Review.** This announcement is not subject to Executive Order (EO) 12372.

5. **Funding Restrictions.** All USAMRMC awards are subject to the terms and conditions, cost principles, and other considerations described in the USAMRAA General Terms and Conditions for Assistance Awards, FAR, DFAR, DODGAR, and related regulations.

Pre-award costs are allowable as follow:

Assistance Agreements: A university or non-profit organization may, at its own risk and without the Government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award, if such costs: 1) are necessary to conduct the project, and 2) would be allowable under the award, if awarded, without the Government's prior approval. If specific expenditures would otherwise require prior approval, the recipient must obtain the Grants Officer's approval before incurring the cost. Government prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new award. For-profit organizations must obtain the Grants Officer's approval prior to incurring any obligations and expenditures before the beginning date of the initial budget period of a new award.

Contracts: An organization may request and negotiate pre-contract costs prior to contract award. The pre-contract cost agreement must be executed by the Contracting Officer prior to incurring any cost. The costs incurred must be allowable and allocable under the resultant contract. Payment will not be made until a contract is awarded. If the parties are unable to reach agreement on the award of the proposed contract, the Government shall be under no obligation to reimburse the contractor for any costs incurred.

The incurrence of pre-award/pre-contract costs in anticipation of an award imposes no obligation on the Government either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award/precontract costs incurred. The Government expects the recipient/contractor to be fully aware that pre-award/pre-contract costs result in borrowing against future support and that such borrowing must not impair the organization's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project.

Maximum Obligation: USAMRAA does not modify awards to provide additional funds for such purposes as reimbursement for unrecovered indirect/facilities and administrative costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.

6. Other Submission Requirements. None

E. Proposal/Application Review Information

1. **Criteria.** The criteria described below are listed in descending order of importance and will be considered during the review process.

2. **Review and Selection Process**

Pre-proposal/Pre-application. The USAMRMC scientists or outside experts will evaluate pre-proposals/pre-applications for technical merit and programmatic considerations. Based on the screening of the pre-proposal/pre-application, PIs may be invited to submit a full proposal/application.

Following the pre-proposal/pre-application screening, PIs will be notified as to whether or not they are invited to submit a full proposal; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-proposal/pre-applications.

Full Proposal/Application. Full proposal/applications will be evaluated using a two-tier review process. **An applicant is strongly encouraged to submit a pre-proposal/pre-application prior to submitting a full proposal/application.**

NOTE: Full proposal/applications may be rejected if they do not reflect the stated timeline and the "Estimated Total Cost of Project" amount noted in the pre-proposal/pre-applications.

USAMRMC scientists and/or outside experts will conduct the first tier, scientific peer review. Peer reviewers evaluate proposal/applications and assign scores based on the following factors (in descending order of importance):

a. **Research Objectives:** The stated objectives must be 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; awareness of similar projects previously undertaken and related activities. Research projects that demonstrate an innovative approach are desired and should directly relate to the Research Areas of Interest identified in Section II.A.

b. **Scientific Design Excellence:** The proposed plans, methods, techniques and procedures must be feasible, clear, valid, adequately referenced, and state-of-the-art. The statistical features of the study will be evaluated for merit. Literature searches are recommended for documenting the strengths of the proposed project. For development of devices and technologies: the feasibility of the proposed product/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.

c. **Impact/Outcomes:** Explain the potential impact of the research in the field, the significance of this impact, and when it can be anticipated. Explain how the results of this

research are expected to impact the intended beneficiaries. Expound upon the dual (military and public) purpose for the research, as appropriate. For development of devices and technologies: the potential translation, implementation and/or commercial use for the product/technology being developed.

d. **PI and Key Personnel Qualifications:** Document the qualifications, capabilities, and experience of the proposed PI and other key personnel in sufficient details 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 effort indicated for the project.

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

f. **Budget**: The budget must reflect the actual needs of the proposed work, thoroughly detailed and be fully justified so that the Government can evaluate and determine the cost to be allocable, allowable and reasonable, and commensurate with the complexity and nature of the research proposed.

The second tier of the review, the programmatic review, may be conducted by USAMRMC scientists, other Federal agency representatives, outside scientists with diverse expertise, clinicians, consumers, or combinations thereof. Programmatic review considerations are:

- **Scientific peer review results**
- **Military relevance (mission, health, medicine and beneficiaries)**
- **Portfolio balance**
- **Programmatic priorities**

NOTE: Military-relevant research must be responsive to the health care needs of the Armed Forces, family members of the Armed Forces, and the U.S. Veteran population. Proposal/applications must address a military-relevant health problem responsive to one of the areas of interest outlined in this BAA.

Selection Process: After the two-tiered evaluation, proposal/applications recommended for funding may be prioritized. A prioritized listing of alternates 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. Award is also dependent upon demonstration by the applicant that he/she has adequately addressed the following requirements:

a. Research involving Human Subjects/Anatomical Substances (if proposed)

b. Research involving Animal Subjects (if proposed)

c. Environmental Compliance Assurance

d. Facility Safety Plan

e. Representations for Assistance Agreements, Certifications for Assistance Agreements, or Representations & Certifications for Contracts, as appropriate.

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

Investigators are cautioned that awards are made to organizations, not individuals. A PI must submit a proposal/application through an organization in order to receive support. (FFRDCs are not eligible to directly receive awards under this BAA in accordance with FAR 35.017. However, teaming arrangements between FFRDCs and eligible applicants/organizations are allowed so long as they are permitted under the sponsoring agreement between the Government and the specific FFRDC.)

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

F. Award Administration Information

1. **Award Notices:** The PI should receive a disposition letter or e-mail regarding the full proposal/application within 180 days of submission. All funding decisions on full proposals/applications will be made as soon as possible after completion of evaluations. The funding notification is NOT an authorization to begin performance. Authorization to begin performance will be received via an award document (grant, cooperative agreement, or contract, as applicable) signed by the Grants/Contracting Officer.

2. **Administrative and National Policy Requirements**

a. **Information Release:** A contractor or recipient of an award will be required to agree to the release of information pertaining to the research and development supported by the Federal agency. "Information" includes but is not limited to news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings, and symposia.

(1) In conducting research using human subjects and/or human anatomical substances, the investigator is required to include approvals, documents and information specified on the Human Research Protection Office (HRPO) website. (https://mrmc.detrick.army.mil/index.cfm?pageid=Research_Protections.hrpo)

(2) The following statements must be included in all information releases:

(a) All releases shall identify the award number and include a statement acknowledging the Federal sponsoring agency. The release shall also contain a statement that the opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense. The requirement with specific language will be included in the award notice. Below is an example:

> "This work was supported by the (*identify sponsoring agency*) under Award No. (*identify award number*). Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense."

(b) "In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture." Include required assurances, approvals, documents and information specified on the Animal Care and Use Review Office (ACURO) website. (https://mrmc.detrick.army.mil/index.cfm?pageid=Research_Protections.acuro&rn=1)

(c) "In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules." (http://www.nih.gov)

(d) "In the conduct of research involving hazardous organisms or toxins, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories." (http://www.cdc.gov/biosafety)

Failure to include the above statements and adhere to the above regulations, when required, may result in loss of funding.

b. **Freedom of Information Act Requests:**

The Freedom of Information Act (FOIA) (5 USC 552) provides a statutory basis for public access to official Government records. "Records" are defined to include documentation received by the government in connection with the transaction of public business. Records must be made available to

any person requesting them unless the records fall under one of nine exceptions to the Act. (www.usdoj.gov/oip/index.html)

When a FOIA request asks for information contained in a successful proposal/application that has been incorporated into an award document, the submitter will be contacted and given an opportunity to object to the release of all or part of the information that was incorporated. A valid legal basis must accompany each objection to release. Each objection will be evaluated by USAMRMC in making its final determination concerning which information is or is not releasable. If information requested is releasable, the submitter will be given notice of USAMRMC's intent to release and will be provided a reasonable opportunity to assert available action.

c. **Site Visits:** During the term of the award, the PI is encouraged to visit USAMRMC laboratories and institutes to discuss related work with USAMRMC scientists. All such visits must have prior approval and should be coordinated through the USAMRAA Grants/Contracting Officer. Funding for visits may be made available through the award instrument. The USAMRMC laboratory personnel, as well as other DoD personnel, are also encouraged to visit the PI during the award efforts. All visits must be coordinated with the Grants/Contracting Officer and are intended for technical discussion and monitoring of progress of the funded project.

d. **J-1 VISA Waiver**: Organizations located outside of the U.S. may submit in response to the BAA, however, it is the organizations' responsibility to ensure that the research staff is able to complete the work without intercession by the DoD for a J-1 Visa Waiver on behalf of a foreign national in the United States. **In addition, the Government will not provide funds to support scientists from terrorist countries.** Additional information on J-1 VISA Waivers can be located at the following Department of State web site: travel.state.gov/visa/temp.

e. **Funding**: Funding may be provided incrementally during the life of the award.

f. **Titles to Inventions and Patents**: In accordance with the Bayh-Dole Act (Title 35, United States Code, Section 200 et seq.), title to inventions and patents resulting from Federally funded research may be held by the contractor/recipient or its collaborator, but the U.S. Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement or contract concerning license agreements and patents.

g. **Contracted Fundamental Research**: Any awards under this BAA to universities or industry and funded by Basic Research funds (6.1), or to universities for on-campus research and funded by Applied Research funds (6.2), meet the DoD definition of "Contracted Fundamental Research." The results of this research are to be unrestricted to the maximum extent possible. The research shall not be considered fundamental in those rare and exceptional circumstances where the 6.2-funded effort presents a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense, and where agreement on restrictions have been recorded in the award.

h. **Post-Employment Conflict of Interest:** There are certain post-employment restrictions on former Federal officers and employees as defined in Section 207 of Title 18

United States Code and Federal Acquisition Regulation (FAR), Part 3.104-4(c). If a submitter believes a post-employment restriction or conflict of interest exists, the situation should be discussed with the USAMRMC legal staff (telephone 301-619-6598) prior to expending time and effort in preparation of a proposal/application.

i. Organizational and Individual Investigator Conflicts of Interest:

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

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

All conflicts or potential conflicts of interest must be disclosed, along with a plan to mitigate the conflict, with the application submission. (See Section II.D.2.f., R&R Other Project Information Form, Block 11, for submission instructions.) An assistance agreement or contract may not be awarded if it is determined by the respective Grants or Contracting Officer that a conflict of interest cannot be avoided or mitigated.

j. **Disclosure of Information Outside of the Government:** Proposal/applications will only be disclosed outside of the Government for the sole purpose of technical evaluation. Evaluators must agree that information in the proposal/application will only be used for evaluation purposes and will not be further disclosed. Proposal/applications for funded projects will be subject to public release under the FOIA to the extent that they are incorporated into an award document; proposal/applications that are not selected for funding will not be subject to public release.

k. **Marking of Proprietary Information:** Conspicuously and legibly mark any proprietary information that is included in the **full** proposal/application.

l. **Government Obligation:** Only a warranted Grants/Contracting Officer may obligate the Government to the expenditure of funds for awards under this BAA. The Government does not fund preparation of proposal/applications or support research that is inferred from discussions with technical project officers.

m. **Information Service:** Applicants may use the technical reference facilities of the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161; telephone: 703-605-6000 (www.ntis.gov) to acquire information of existing research to avoid duplication of scientific and engineering effort.

n. **Requirements for Federal Funding Accountability and Transparency Act Implementation (2 CFR Part 170):**

Appendix A to Part 170--Award Term

I. Reporting Subawards and Executive Compensation

A. Reporting of first-tier subawards.

1. Applicability. Unless you are exempt as provided in paragraph D. of this award term, you must report each action that obligates $25,000 or more in Federal funds that does not include Recovery funds (as defined in section 1512(a)(2) of the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5) for a subaward to an entity (see definitions in paragraph e. of this award term).

2. Where and when to report.

i. You must report each obligating action described in paragraph a.1. of this award term to http://www.fsrs.gov.

ii. For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 7, 2012, the obligation must be reported by no later than December 31, 2012.)

3. What to report. You must report the information about each obligating action that the submission instructions posted at http://www.fsrs.gov specify.

B. Reporting Total Compensation of Recipient Executives.

1. Applicability and what to report. You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if--

i. the total Federal funding authorized to date under this award is $25,000 or more;

ii. in the preceding fiscal year, you received—

(A) 80 percent or more of your annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

(B) $25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

iii. The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at http://www.sec.gov/answers/execomp.htm.)

2. Where and when to report. You must report executive total compensation described in paragraph b.1. of this award term:

i. As part of your registration profile at https://www.sam.gov.

ii. By the end of the month following the month in which this award is made, and annually thereafter.

C. Reporting of Total Compensation of Subrecipient Executives.

1. Applicability and what to report. Unless you are exempt as provided in paragraph d. of this award term, for each first-tier subrecipient under this award, you shall report the names and total compensation of each of the subrecipient's five most highly compensated executives for the subrecipient's preceding completed fiscal year, if--

i. in the subrecipient's preceding fiscal year, the subrecipient received--

(A) 80 percent or more of its annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

(B) $25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and subawards); and

ii. The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at http://www.sec.gov/answers/execomp.htm.)

2. Where and when to report. You must report subrecipient executive total compensation described in paragraph c.1. of this award term:

i. To the recipient.

ii. By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (i.e., between October 1 and 31), you must report any required compensation information of the subrecipient by November 30 of that year.

D. Exemptions. If, in the previous tax year, you had gross income, from all sources, under $300,000, you are exempt from the requirements to report:

i. Subawards, and

ii. The total compensation of the five most highly compensated executives of any subrecipient.

E. Definitions. For purposes of this award term:

1. Entity means all of the following, as defined in 2 CFR part 25:

i. A Governmental organization, which is a State, local government, or Indian tribe;

ii. A foreign public entity;

iii. A domestic or foreign nonprofit organization;

iv. A domestic or foreign for-profit organization;

v. A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.

2. Executive means officers, managing partners, or any other employees in management positions.

3. Subaward:

i. This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.

ii. The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Sec. ---- .210 of the attachment to OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations").

iii. A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.

4. Subrecipient means an entity that:

i. Receives a subaward from you (the recipient) under this award; and

ii. Is accountable to you for the use of the Federal funds provided by the subaward.

5. Total compensation means the cash and noncash dollar value earned by the executive during the recipient's or subrecipient's preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):

i. Salary and bonus.

ii. Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.

iii. Earnings for services under non-equity incentive plans. This does not include group life, health, hospitalization or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.

iv. Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.

v. Above-market earnings on deferred compensation, which is not tax- qualified.

vi. Other compensation, if the aggregate value of all such other compensation (e.g. severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds $10,000.

o. **Financial Assistance Use of Universal Identifier and Central Contractor Registration (2 CFR Part 25):**

Appendix A to Part 25--Award Term

I. Central Contractor Registration and Universal Identifier Requirements

Note: The Central Contractor Registration process has been moved to the System for Award Management at www.sam.gov.

A. Requirement for Central Contractor Registration (CCR)/System for Award Management (SAM). Unless you are exempted from this requirement under 2 CFR 25.110, you as the recipient must maintain the currency of your information in the SAM until you submit the final

financial report required under this award or receive the final payment, whichever is later. This requires that you review and update the information at least annually after the initial registration, and more frequently if required by changes in your information or another award term.

B. Requirement for Data Universal Numbering System (DUNS) Numbers. If you are authorized to make subawards under this award, you:

1. Must notify potential subrecipients that no entity (see definition in paragraph C of this award term) may receive a subaward from you unless the entity has provided its DUNS number to you.

2. May not make a subaward to an entity unless the entity has provided its DUNS number to you.

C. Definitions. For purposes of this award term:

1. Central Contractor Registration (CCR) (now System for Award Management (SAM)) means the Federal repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM Internet site (currently at http://www.sam.gov).

2. Data Universal Numbering System (DUNS) number means the nine-digit number established and assigned by Dun and Bradstreet, Inc. (D&B) to uniquely identify business entities. A DUNS number may be obtained from D&B by telephone (currently 866-705-5711) or the Internet (currently at http://fedgov.dnb.com/webform).

3. Entity, as it is used in this award term, means all of the following, as defined at 2 CFR part 25, subpart C:

a. A Governmental organization, which is a State, local government, or Indian Tribe;

b. A foreign public entity;

c. A domestic or foreign nonprofit organization;

d. A domestic or foreign for-profit organization; and

e. A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.

4. Subaward:

a. This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.

b. The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Sec. ----.210 of the attachment to OMB Circular A-133, “Audits of States, Local Governments, and Non-Profit Organizations”).

c. A subaward may be provided through any legal agreement, including an agreement that you consider a contract.

5. Subrecipient means an entity that:

a. Receives a subaward from you under this award; and

b. Is accountable to you for the use of the Federal funds provided by the subaward.

p. **Certification Regarding Lobbying Activities:**

Complete form SFLLL, if applicable, and attach to Block 18 of the SF424 (R&R) form.

Submission of this certification is required by Section 1352, Title 31 of the U.S. Code and is a prerequisite for making or entering into a grant or cooperative agreement over $100,000. The recipient certifies, to the best of his or her knowledge and belief, that:

(a) No federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the making of any Federal grant, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal grant or cooperative agreement.

(b) If any funds other than federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal grant or cooperative agreement, the undersigned shall complete and submit Standard Form LLL, 'Disclosure Form to Report Lobbying,' in accordance with its instructions.

(c) The recipient shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subgrants, contracts under grants and cooperative agreements, and subcontracts) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by Section 1352, Title 31 U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

q. **Representations and Certifications (applicable to contract awards):** The applicant must complete the representations and certifications electronically via the SAM website accessed through https://www.acquisition.gov or https://www.sam.gov. The applicant verifies by submission of the proposal/application that the representations and certifications currently posted electronically via SAM have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this BAA as of the date of submission.

r. **Representations (applicable to corporations only, applicable to assistance agreement awards):** The applicant is required to complete the attachment entitled "Representations Regarding Unpaid Federal Tax Liabilities and Conviction of Felony Criminal Violations under any Federal Law." The Representations must be attached to Block 11 of the "Research and Related Other Project Information" form.

3. **Reporting:** Reports are necessary for continuation of the research efforts and funding. Each award instrument will state the necessary reports that are due to the government. Reporting requirements may include the following:

a. Periodic technical reports that outline the accomplishments and progress for that period. This may include updating of a quad chart (if a template was provided at time of award) that details the study aims, objectives, designs, timeline progress, and challenges.

b. Annual technical reports that consist of detailed summaries of scientific issues, accomplishments and animal research usage during the project.

c. Final technical report that details the findings and issues of the completed project.

d. For non-exempt human subjects' research, documentation of local Institutional Review Board (IRB) continuing review (in the intervals specified by the local IRB, but at least annually); approval for continuation must be submitted directly to the USAMRMC Office of Research Protections.

e. Copies of all scientific publications as a result of funding.

f. Abstracts that are suitable for publication in relation to planned meetings.

g. Oral Presentations that detail the status of a project to a panel of subject matter experts.

h. Quarterly Standard Form Report, SF425, Federal Financial Report, used for grants and cooperative agreements that tracks the expenditure of funds on the project.

i. Programmatic Meetings that include discussions regarding findings, accomplishments and direction for the program.

j. Additional Reporting

(1) Federal Interagency Traumatic Brain Injury Research Informatics System (FITBIR). For research projects involving traumatic brain injury, PIs may be required to report data to FITBIR, found at https://fitbir.nih.gov/jsp/about/policy.jsp.

(2) Clinical Trial Registry. For research projects involving clinical trials, PIs may be required to register their trials on the National Institutes of Health database entitled "ClinicalTrials.gov," found at http://clinicaltrials.gov.

G. Agency Contacts

1. BAA Help Desk: Questions related to BAA content or submission requirements as well as questions related to the submission of pre-proposals/pre-applications must be emailed to

USAMRAA@AIBS.org, ATTN: BAA 14-1 at USAMRAA. Response times may vary depending upon the volume of inquires.

2. Grants.gov: Questions related to full proposal/application submission through Grants.gov 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). Phone: 1-800-518-4726 or email: support@grants.gov. Note that the BAA Help Desk is unable to provide technical assistance with Grants.gov submission.

H. Other Information: Common Problems and Proposal/Application Submission Guide

1. Failure to enter an email address for change notifications under the BAA Funding Opportunity for notifications on any modification made to the initial Announcement.

2. Attachments are uploaded into the incorrect form on Grants.gov forms. (Chart below)

3. Files are attached in the wrong location on Grants.gov forms.

4. Failure to contact the Grants.gov help desk.

5. Failure to send attachments.

6. Inability to locate attachment forms. (Select "Search Grants" at http://www.grants.gov and enter W81XWH-BAA-14-1 in the "Funding Opp #" block. When the Funding Opportunity appears, select the Funding Opportunity #. When you reach the "View Grant Opportunity" screen, select "Full Announcement." The forms will be listed on the following screen.)

1. Use of "illegal" characters in attachment titles.

2. Attachments exceed size limits.

3. Upload attempts of unacceptable attachments: bitmap, TIFF, etc.

4. Duplicate upload of documents.

The chart below details the forms that should be submitted and their accompanying attachments:

Form	Attachment	Action
SF-424 (R&R) Application for Federal Assistance Form		Enter the appropriate information in data fields
Research & Related Budget Form	Budget Justification for entire performance period	Attach to Section K in budget period one
Research & Related Project/Performance Site Location(s) Form		Enter the appropriate information in data fields
Research & Related Senior/Key Person Profile Form	PI Biographical Sketch	Attach to Biographical Sketch Block
	PI Prior/Current/Pending Support in PDF format	Attach to Current & Pending Support Block
	Key Personnel Biographical Sketches	Attach to Biographical Sketch Block for each senior/key person
	Key Personnel Current/Pending Support	Attach to Current & Pending Support Block for each senior/key person
Research & Related Other Project Information Form	Proposal Abstract	Attach to Block 6 Project Summary/Abstract
	Project Narrative and Body of Proposal in PDF format	Attach to Block 7 Project Narrative
	Environmental Compliance Assurance	Attach to Block 11 Other Attachments
	All applicable Facility Safety Plan documents	Attach to Block 11 Other Attachments
	Representations for Assistance Agreements	Attach to Block 11 Other Attachments
	Organizational Data	Attach to Block 11 Other Attachments
R&R Subaward Budget Attachment(s) Form (if applicable)	Individual subaward budgets	Attach a separate budget with justification for each subaward