United States Army Medical Research and Materiel Command

DEPARTMENT OF DEFENSE

BROAD AGENCY ANNOUNCEMENT
for Extramural Medical Research

BAA 11-1

October 2010

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

4. **Funding Opportunity Number:** W81XWH-BAA-11-1

NOTICE: Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance 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.

APPLICATIONS MAY NOT BE SUBMITTED IN PAPER FORMAT.

This FOA must be read in conjunction with the application guidelines included in this announcement 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 system problems.

A compatible version of Adobe Reader is required for download. For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at http://grants.gov/CustomerSupport.

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

6. **Key Dates:** Release/Posted Date: October 1, 2010
   Opening Date: October 1, 2010
   Closing Date: September 30, 2011

Note: This is a continuously open announcement; preproposals and full proposals may be submitted and will be evaluated at any time throughout the year, unless otherwise noted or stated in a separate announcement.

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 Warfighter at home and abroad. 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 Command. General information on USAMRMC can be obtained from the USAMRMC website (https://mrmc.detrick.army.mil/).

This Broad Agency Announcement (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(a)(2). This Announcement provides a general description of the Command's research programs, including

specific areas of interest; general information; the evaluation and selection criteria; and proposal preparation instructions.

The USAMRMC's supporting contracting office, the U.S. Army Medical Research Acquisition Activity (USAMRAA), will process proposals selected for funding. The Grants/Contracting Officers at USAMRAA are the only individuals authorized to commit funds and bind the Government for awards to be funded under this Announcement.

CONFERENCE OR SYMPOSIUM SUPPORT: The USAMRMC may provide financial support (if funds are available) for conferences or symposia that benefit the Command's research program. The BAA Instructions for submitting a conference or symposium proposal can be found at www.usamraa.army.mil under the BAA link. The BAA Conference or Symposium Support electronic form can be found at www.usamraa.army.mil/pages/BAA_Forms/User/login.cfm. All conference or symposium proposals will be assigned a proposal log number and an e-mail or postcard will acknowledge receipt of a proposal. Usually, the PI should receive a decision letter or e-mail regarding the proposal within 60 - 90 days of submission.

PREPROPOSALS: Organizations are strongly encouraged to explore USAMRMC interest by submitting a preliminary research proposal (preproposal). Preproposals may be submitted at any time describing a specific idea or project that pertains to any of the research areas of interest outlined in the BAA. Brochures or other descriptions of general organizational or individual capabilities will not be accepted as a preproposal. The Preproposal electronic form is located at www.usamraa.army.mil/pages/BAA_Forms/User/login.cfm. Usually, the PI should receive a decision letter or e-mail regarding the preproposal within 60 - 90 days of submission.

FULL PROPOSALS: Full Proposals should be submitted within 90 days after being requested. Receipt of full proposals will be acknowledged by e-mail or postcard. The proposal log number for the full proposal will be the same number used for the preproposal (if one was submitted).

PLEASE NOTE: Individuals requesting to speak to USAMRMC personnel about whether there is interest in a specific research idea will be directed to submit a preproposal.

II. Detailed Information about the Funding Opportunity

A. RESEARCH AREAS OF INTEREST

1. MILITARY INFECTIOUS DISEASES RESEARCH PROGRAM

The Military Infectious Diseases Research Program (MIDRP) focuses on vaccines, antiparasitic drugs, deployable field clinical diagnostics, 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, diarrheal disease caused by bacteria, and norovirus. The MIDRP also has smaller research programs focused on cutaneous leishmaniasis, meningococcal disease, scrub typhus, and hemorrhagic diseases not on the Defense Threat Reduction Agency (DTRA) biothreat list and is in the process of developing a wound infection program (previously managed by the Combat Casualty Care Research Program). Proposals involving viral and bacterial biothreats, chemical threats, influenza, and cancer research cannot be supported by the MIDRP.

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

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

(2) Antiparasitic 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, and genomics directed at identification of potential 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.

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 1b, above]. However, proposals 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. Given that business issues make it difficult to get a vaccine on the market to provide protection against unusual diseases, U.S. FDA-licensable, broadly active therapeutics, effective against multiple endemic disease threats, (i.e., proposals and products incorporating a systems biology approach to treating infectious diseases) are of interest.

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. 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 first responders, 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 following paragraphs describe objectives of particular interest:

a. The principal causes of death among soldiers who die within the first hour of wounding are hemorrhage and traumatic brain injury. As a consequence, the CCCRP strongly supports:

(1) 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.

(2) 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 over stimulation, inflammation, cell loss, and neurologic dysfunction.

(3) 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. Battlefield and en-route pain management is also of

interest. Devices and therapies that can relieve pain with minimal effects on physical and cognitive performance and that have minimal or no potential for addiction are of interest. 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.

(4) 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; medical techniques and materiel to replace or regenerate lost tissues; 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), United States Army Medical Research and Materiel Command (USAMRMC), conducts biomedical research to deliver products and solutions to the Warrior that address health and fitness throughout the Deployment Cycle. The MOMRP is centered on cutting-edge scientific research and bringing science to the Soldier on the battlefield in a relevant, timely manner. The MOMRP depends on a phenomenal cadre of dedicated scientists and engineers who continuously and tirelessly work to protect the Nation's most valuable asset – the Warrior. 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 Soldier 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 Warrior injury and decrease attrition, medical cost, and minimize personal impact to the Warrior; provide enhanced protection capabilities from injury hazards in the operational environment; prevent vision and hearing loss along with blast-related injuries and training injuries; identify validated "return-to-duty" standards following injury; develop biomedically valid performance standards for individual and crew protection systems; develop injury risk criteria and tools for health hazard and Soldier survivability assessors; and Soldier monitoring/sensor technologies and decision support tools.

b. **Psychological Health and Resilience**: This research area focuses on the development and validation of effective evidence-based screening and assessment strategies and interventions that reduce the negative impact of behavioral health disorders and concussion/mild traumatic brain injury. Research also aims to develop psychological resilience among Warriors and Families. 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 posttraumatic stress disorder [PTSD], concussion, alcohol and other drug abuse, sleep disturbance, and mood disorder); and studies focused on enhancing implementation of evidence-based prevention, screening, assessment, and treatment techniques.

c. **Physiological Health**: This area of research develops biomedical countermeasures to sustain Warrior health and operational effectiveness, including: state-of-the-art policy, training, and materiel solutions to establish, sustain, optimize, and monitor Warrior health, physiological resilience, cognitive abilities throughout training, deployment, reset, and recovery cycles. This research aims to prevent or mitigate the effects of physiological stressors on the performance and fitness of Warriors. Studies include nutritional health surveillance, use of dietary supplements, and interventions to mitigate threats to operational health and performance. Research also aims to develop advanced biomedical modeling and networked physiological status monitoring capabilities, sleep and fatigue management of chronic sleep restriction, total sleep deprivation, and individual differences in sleep loss resilience.

d. **Environmental Health and Protection**: This area of research area includes assessment and sustainment of health and the operational effectiveness of Warriors 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 Warrior 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. The MOMRP uses an independent, external scientific peer review process to ensure high quality, reliability, and validity of its research.

4. CLINICAL AND REHABILITATIVE MEDICINE RESEARCH PROGRAM

The Clinical and Rehabilitative Medicine Research Program (CRMRP) focuses on the innovations required to reset our wounded warriors, 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 warriors within the DoD healthcare system. Implementation of these technologies and strategies should improve the RTD of warriors, 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 warriors 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 six research areas: neuromusculoskeletal injury (including amputees), ocular and visual system injury (acute and chronic), hearing and vestibular systems injury, acute and chronic pain, regenerative medicine, and cognitive rehabilitation. While research topics of highest priority interest are listed below for each of these areas, proposals for topics that align within an overall research area will also be considered except as

specifically noted. Traumatic brain injury (TBI) research proposals will only be considered if the focus is related to one of these six areas (for example, TBI-associated visual dysfunction, or rehabilitation in the context of TBI or cognition). Novel manufacturing technologies necessary to translate innovative therapies or devices into clinical development are a focus.

a. **Rehabilitation of Neuromusculoskeletal Injuries:** Research directed toward strategies for rehabilitation in patients with complicating factors as a result of traumatic injuries and war related injuries (e.g., TBI, post-traumatic stress disorder (PTSD), and other comorbidities), comprehensive rehabilitative approaches focusing on polytrauma and its associated complications, functional outcome assessments focusing on return-to-duty and/or community reintegration, rehabilitative strategies for neuromusculoskeletal injury (including limb salvage patients), novel and evidence-based strategies to support rehabilitative approaches following regenerative medicine therapies to restore tissue and function, amputee-specific technologies and rehabilitative strategies that address/assess residual limb health, exercise and fitness systems and strategies for rehabilitation and sustainment of fitness in amputees, the prevention of heterotopic ossification, and minimizing the deleterious effects of contracture on function and mobility. Proposals for research to develop advanced prosthetics “hardware” (including complete systems, components, interfaces, control mechanisms, etc) will not be funded under this area of interest. However, proposals focusing on aspects of the rehabilitative care of amputees with prosthetics will be considered.

b. **Vision Restoration and Rehabilitation:** Research towards treatments for traumatic injuries and war-related injuries to ocular structures and the visual system, including blast and burn injuries; lid, adnexal, ocular, and orbital injuries; treatments to slow/stop loss of vision following injury; and ocular drug delivery. Also, research supporting diagnosis, treatment, and mitigation of visual dysfunction associated with TBI and war-related injuries and the restoration of the visual system (including regeneration and tissue repair following traumatic injury).

c. **Hearing and Balance Restoration and Rehabilitation:** Research to support the development of strategies and technologies that restore hearing loss and balance disorders due to trauma (including traumatic brain injury) with the end goal of achieving full return to duty capability. Areas of opportunity include, but are not limited to: acoustic trauma, tinnitus, central auditory processing disorders, vestibular dysfunction, pharmaceutical or regenerative medicine based technologies, and advanced medical devices. Future products based on these technologies should support returning to duty without maintenance, continued dosing or other logistical and medical support requirements.

d. **Pain Management:** Primary interest is in management of pain associated with traumatic or war-related injuries. Research to support the development of best practices for assessing and managing acute pain episodes in the context of chronic pain, strategies for the management of acute pain to prevent the development of chronic pain, strategies to identify and treat pain generators (including the pathophysiology of pain and improved objective diagnostic tools for pain), improved strategies for management of chronic pain (including novel pain control methods, complementary and alternative medicine techniques, and epidemiology of incidents of chronic pain and functional outcomes), and addressing psychosocial aspects of managing pain (including patient empowerment, family and other support systems, resilience and risk factors, and sleep management). Of high interest is the management of acute pain due to trauma. Devices and therapies that can relieve pain with minimal effects on physical and cognitive performance and that have minimal or no potential for addiction are of interest.

e. **Regenerative Medicine and Composite Tissue Engineering:** Regenerative medicine involves the use of innovative technologies such as scaffolds and tissue engineering, growth factors, and stem cell treatments to treat Warfighters who have suffered blast injuries, burns, lost limbs, or other tissue injuries. Research topics of particular interest include those directed toward the use of regenerative medicine-based techniques to repair functional nerve deficits (other than central nervous system or spinal cord), repair/replace neuromuscular tissue units of the face and composite facial features (including eyelids, lips, and nares), regenerate bone defects, tendon/muscle unit regeneration, ligament regeneration, vascular repair/revascularization, cartilage/joint regeneration, muscle protection/regeneration and wound management and tissue preservation (not to include infection control). Regenerative and tissue engineering systems that enable return of form and function to composite tissues (i.e., containing nerve, bone, vascular, muscle and associated connective tissue, and full thickness skin) concurrently are of high interest. Immune system control and modulation technologies that provide safer and more effective alternatives to current standards of practice and enable broader application of allogeneic and/or xenogeneic transplants are of interest.

f. **Cognitive Rehabilitation:** Research to support the development of strategies for the diagnosis, treatment, and mitigation of cognitive dysfunction associated with TBI and war-related 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.

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 is funding limited proposals through the USAMRMC BAA. DTRA also solicits proposals for its requirements through the Federal Business Opportunities (FedBizOpps) and the DoD Small Business Innovative Research (SBIR) Program solicitations. For information regarding DTRA business opportunities, please visit their website at the following link: http://www.dtra.mil/Business/DoingBusiness/BusinessHome.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), 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 for 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 (a) acute diseases due to agents of potential biological threat, (b) 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.

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 is funding limited proposals through the USAMRMC BAA. DTRA also solicits proposals for its requirements through the Federal Business Opportunities (FedBizOpps) and the DoD Small Business Innovative Research (SBIR) Program solicitations. For information regarding DTRA business opportunities, please visit their website at the following link: http://www.dtra.mil/Business/DoingBusiness/BusinessHome.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 soldier 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 soldiers' 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 soldier 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, 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 soldier 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. TELEMEDICINE AND ADVANCED TECHNOLOGY PROGRAM

The mission of the USAMRMC's telemedicine and advanced technology program is to explore medical science and engineering technologies ahead of programmed research, and to leverage programs to maximize benefits to military medicine. To accomplish this, research is centered around a number of scientific domains: Medical Robotics, Health Information Technologies, Medical Imaging Technologies, Advanced Prosthetics and Human Performance, Computational Biology, Biomonitoring Technologies, Simulation and Training Technology, Genomics and Proteomics, Integrative Disease Management, Infectious Disease, Neuroscience, Regenerative Medicine, Nanomedicine and Biomaterials, Trauma, Medical Logistics, and Telemedicine.

a. Medical Robotics. Objectives aimed at adapting, integrating or developing robotic technologies for medical indications. This includes but is not limited to location, assessment, treatment and rescue of battlefield casualties.

b. Health Information Technologies. Focus areas include:

(1) Establishment of a common development environment to allow rapid prototyping for standard military health care systems.

(2) Establish a research data cube and clinical data mart dataset to support the research community.

(3) Natural language processing.

(4) Voice recognition.

(5) Scanning paper based records.

(6) Interoperability.

(7) Usability testing of electronic health records.

(8) Terminology services/ontologies.

c. Medical Imaging Technologies. There are four research areas:

(1) Portable imaging and image guided therapeutics.

(2) Advanced high performance imaging.

(3) Computational methods and decision support.

(4) Advanced surgical cameras.

d. Advanced Prosthetics and Human Performance. Focus areas are:

(1) Advanced prosthetics, orthotics and other assistive devices. (Includes neuroprostheses, biomaterials, nano-materials, and robotics).

(2) Treatments and interventions for patients with limb amputations, fractures and other orthopedic related injuries. (May include use of regenerative medicine technologies).

(3) Orthopedic injury prevention.

(4) Human performance optimization (to include but not limited to: diet, exercise, sleep)

(5) Polytrauma.

e. Computational Biology. Research focus is in 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.

f. 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.

g. Simulation and Training Technology. This area is focused on meeting the growing demands for continuing training for health care personnel, the reduction of medical errors, and the potential uses of these technologies in the practice of health care and treatment. This includes:

(1) Individual medical skills and proficiency.

(2) Unit medical skills.

(3) Use of simulation and virtual reality in patient therapies.

(4) Modeling of human biology/systems to aid/assist in any of the above.

h. Genomics and Proteomics. Research in these areas focuses on the use of genomics and proteomics to identify signatures and markers that can aid in early detection and in determining effective therapeutic agents across a wide array of disease states. New proteomics and genomics methodologies, instrumentation, and resources are all of interest

i. Chronic Disease and Integrative Medicine. Research in this area focuses on the use of a wide variety of advanced medical technologies to diagnose, treat, and manage patients with ongoing health problems. 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.

j. Infectious Disease. Research in this area focuses on vaccines, therapeutic agents, diagnosis, vector control, wound infections, and sepsis.

k. Neuroscience. Research in this area includes training, treatment, prevention, protection, assessment, and diagnosis, using a variety of methodologies, techniques, materials, and technologies. Current efforts in this area fall in the following categories:

(1) Traumatic Brain Injury and Spinal Cord Injury.

(2) Neuroprostheses and brain-machine interface

(3) Post-Traumatic Stress Disorder (and other behavioral pathologies of war).

(4) Neurodegenerative conditions.

(5) Neuro-imaging.

l. Regenerative Medicine. Research focuses on the development of treatments for damaged/non-functional tissues and organs using regenerative medicine technologies. This includes using gene- or cell-based therapies that prompt the body to autonomously regenerate and implanting engineered tissue/organs using modified (autologous) cells seeded onto biodegradable scaffolds. Basic and advanced research ranging from cell biology (i.e. differentiation, development, signaling, organization), technologies (i.e. bioreactors, tissue preservation and storage, cell harvesting and multiplication, fabrication), and enabling tools (i.e. microarrays, scaffolds, recombinant DNA technologies, etc) are needed.

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

n. Trauma. Research in this area covers a wide spectrum of scientific domains. The objective is to develop materials, therapies, treatments, and diagnostics that will improve trauma treatment.

o. 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, automated identification technologies to permit precise management of the medical supply chain, and technologies to support improved storage and delivery of critical medical supplies to the battlefield. This includes blood, oxygen, and other biologics that have specific operational handling requirements and limitations, as well as medical assemblages, optical fabrication, hospital services, facilities and repair. 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.

In addition to the above specified areas of interest, the Telemedicine and Advanced Technology Research Center manages Congressional Special Interest projects that cut across all areas of medical research and transition of such research and which impinge on or may be leveraged for the advancement of military medical interests. These projects are managed to optimize the stated military and medical uses stated in submitted proposals and, where possible, will be developed in conjunction with military subject matter experts to enhance required deliverables.

8. SPECIAL PROGRAMS

The USAMRMC is frequently directed by Congress to manage funding of research programs with specific goals and end-points for health related issues relevant to military personnel, military dependents, veterans, and the health of the American public. These research programs are generally concerned with topics relating to health-care delivery; to detection, diagnosis, control or eradication of specified diseases, conditions, or syndromes; or to other initiatives relevant to health needs. Funding of these areas is dependent upon Congressional direction and availability of funds.

Additional information on the USAMRMC's core military research and development programs organized under four Research Area Directorates (RADs) can be found at the following web site: https://mrmc.detrick.army.mil/index.cfm?pageid=medical_r_and_d.overview.

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 recipient and the Government will be a matter of negotiation prior to award. USAMRMC's supporting contracting office, USAMRAA, will process proposals selected for funding.

2. Funds Available and Anticipated Number of Awards: Funding has not been set aside specifically for this announcement and the number of awards is indeterminate. Selection of research projects is based on the evaluation of the proposal, programmatic review and the availability of funds.

3. Budget and Period of performance: Researchers are encouraged to submit proposals that span their entire research program, up to five years. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will vary. There are no specified funding limitations identified for the proposals submitted under the USAMRMC BAA, however, the budget should be commensurate with the nature and complexity of the proposed research, using supportable and verifiable estimates.

C. Eligibility Information

1. Eligible Applicants:

a. Private/Public/State Controlled Institutions of Higher Education

b. Hispanic-serving Institutions

c. Historically Black Colleges and Universities/Minority Institutions (HBCU/MI)

d. Tribally Controlled Colleges and Universities (TCCUs)

e. Alaska Native and Native Hawaiian Serving Institutions

f. Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)

g. Small Businesses

h. For-Profit Organizations (Other than Small Businesses)

i. Indian/Native American Tribal Governments

j. Indian/Native American Tribally Designated Organizations

k. Non-domestic (non-U.S.) Entities (Foreign Organizations)

l: Federal, State & Local Government Agencies

NOTE 1: Federally Funded Research and Development Centers are not eligible for awards in accordance with FAR 35.017**.**

NOTE 2: Investigators are cautioned that awards are made to organizations, not individuals. A principal investigator (PI) must submit a proposal through, and be employed by an organization in order to receive support.

2. Cost Sharing or Matching is not required for this announcement.

3. Dun & Bradstreet Universal Numbering System (DUNS) Number and Central Contractor Registration (CCR)

a. **Applicant Organization 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 be Registered with the Central Contractor Registry (CCR)** before submitting a grant application through Grants.gov or receiving an award from the Federal Government. The CCR 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 CCR registrations have an annual expiration – please verify the status of your organization's CCR registration well in advance of the proposal submission deadline. An organization can register by calling the CCR Assistance Center at 888-227-2423 or by registering online at www.ccr.gov. Collecting the information (Employer Identification Number [EIN] or Tax Identification Number [TIN]) can take 1-3 days. If you have the necessary information, online registration will take about 30 minutes to complete, depending upon the size and complexity of your organization. Allow a minimum of 5 business days to complete the entire CCR registration. 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).

Foreign organizations must obtain a CAGE code prior to registering with the CCR. A CAGE code can be obtained by calling 269-961-7766 or online at www.dlis.dla.mil/Forms/Form_AC135.asp.

4. Other Eligibility Information

a. To protect the public interest, the Federal Government ensures the integrity of Federal programs by striving to conduct business only with responsible recipients. The USAMRMC uses the Federal Awardee Performance and Integrity Information System (FAPIIS) to verify that a recipient is not ineligible to receive Federal awards. The FAPIIS is online at http://www.cpars.csd.disa.mil/FAPIISmain.htm.

b. **Administrative Requirements**: A recipient organization must meet certain minimum standards pertaining to institutional support, financial resources, prior record of performance, integrity, organization, experience, operational controls, facilities and conformance with safety and environmental statutes and regulations (OMB Circulars at www.whitehouse.gov/omb).

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 Grants.gov/Apply.

Note: Only the forms package directly attached to a specific 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 assistance must be submitted electronically through Grants.gov (http://www.grants.gov). An Authorized Organizational Representative (AOR) must be registered with Grants.gov. In order to safeguard the security of your electronic information, Grants.gov requires an organization representative to register for a username and password. Your **CCR 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 CCR registration, must authorize someone to become an AOR. This safeguards the organization from individuals who may attempt to submit proposals 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 Point of Contact listed on your organization's CCR registration will receive a notification stating that you have registered by email and requesting assignment of user privileges. The AOR will also receive a copy of this email. The E-Business Point of Contact will need to login to Grants.gov at https://apply07.grants.gov/apply/loginhome.jsp and confirm you as an Authorized Organization Representative (AOR).

Please 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 provide financial support (if funds are available) for conferences or symposia that benefit the Command's research program. The BAA Instructions for submitting a conference or symposium proposal can be found at www.usamraa.army.mil under the BAA link. The BAA Conference or Symposium Support electronic form can be found at www.usamraa.army.mil/pages/BAA_Forms/User/login.cfm. All conference or symposium proposals will be assigned a proposal log number and an e-mail or postcard will acknowledge receipt of a proposal. Usually, the PI should receive a decision letter or e-mail regarding the proposal within 60 - 90 days of submission.

b. **Preproposals:** Organizations are strongly encouraged to explore USAMRMC interest by submitting a preliminary research proposal (preproposal). Preproposals may be submitted at any time describing a specific idea or project that pertains to any of the research areas of interest outlined in the BAA. Brochures or other descriptions of general organizational or individual capabilities will not be accepted as a preproposal. The Preproposal electronic form is located at www.usamraa.army.mil/pages/BAA_Forms/User/login.cfm. All preproposals will be assigned a proposal log number and an e-mail or postcard will acknowledge receipt of a

preproposal. Usually, the PI should receive a decision letter or e-mail regarding the preproposal within 60 - 90 days of submission.

PLEASE NOTE: Individuals requesting to speak to USAMRMC personnel about whether there is interest in a specific research idea will be directed to submit a preproposal.

c. **Full Proposals:** Full Proposals should be submitted within 90 days after being requested. Receipt of full proposals will be acknowledged by e-mail or postcard. The proposal log number for the full proposal will be the same number used for the preproposal (if one was submitted).

The forms identified in www.grants.gov for the USAMRMC BAA Funding Opportunity must be completed and included as part of the submission for a full proposal. Full proposals may be submitted without protocols for human and animal use. However, protocols with required institutional approvals must be submitted not later than 60 days after award to demonstrate continued progress and ensure continuation of payment. The Contracting/Grants 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 time frame 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, reviewed, and approved by USAMRMC to ensure that DoD regulations are met.

Each submission must include the completed package of forms identified in www.grants.gov for the Funding Opportunity W81XWH-BAA 11-1. 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. The R&R Subaward Budget Attachment(s) Form is optional (to be used as needed). **NOTE: Attachments are located under the Full Announcement tab of the funding opportunity. All Attachments that require signatures must be filled out electronically, printed, signed, scanned and then uploaded as an Attachment to the proposal as a .PDF file.**

d. **Formatting Guidelines:** Full Proposals should be submitted within 90 days after being requested and an award decision should be rendered by the Government within 180 days after submission. Forms and information supporting the submission of a full proposal are located at www.grants.gov.

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

1. **Type Font:** 12 point, 10 pitch (Times New Roman is strongly recommended).

2. **Type Density:** No more than 15 characters per inch (including spaces). (For proportional spacing, the average for any representative section of text should not exceed either 15 characters per inch or 114 characters per line.)

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

4. **Margins:** Minimum of 0.5 on all sides.

5. **Color, Resolution and Multimedia Objects:** Proposals 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 directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white. Photographs and illustrations, etc. must be submitted in JPEG format only (no bitmaps or TIFF).

6. **Acronyms:** Spell out all acronyms the first time they are used. One page following the proposal body is allocated to spell out acronyms, abbreviations and symbols.

7. **Language:** English

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

e. **Mandatory Proposal Forms**: Each submission must include the completed package of forms identified in www.grants.gov for the Funding Opportunity W81XWH-BAA-11-1. 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. The R&R Subaward Budget Attachment(s) Form is optional (to be used as needed). **NOTE: Attachments are located under the Full Announcement tab of the funding opportunity. All Attachments that require signatures must be filled out electronically, printed, signed, scanned and then uploaded as an Attachment to the proposal as a .PDF file.**

1. **The SF 424 (R&R), Application for Federal Assistanc**e is required for each application. All appropriate information must be entered into this form to allow for auto-population of all subsequent forms in this application package. The form is self-explanatory, with the following exceptions:

- **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 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** is not applicable
- **State Application Identifier** is not applicable.
- **Block 4a – Federal Identifier Box** will be populated by Grants.gov for an original application. The Grants.gov tracking number (i.e., the Federal Identifier Number assigned to the original application) must be manually entered for Changed/Corrected applications.
- **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 descriptive title of the project.
- **Block 12 – Proposed Project.** The actual start date will be determined during negotiations if the 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 this application. If outside the U.S., select the appropriate country from the dropdown menu.
- **Block 15 – Estimated Project Funding.** Enter the total funds (direct + indirect/facilities and administrative costs) requested for the entire performance period of the project.
- **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 pre-proposal file associated with this proposal. **Preproposal File name should be the eight digit log number assigned to the preproposal so the number will automatically populate to the pre-application box.**

2. **Research & Related Budget –** An estimate of the total research project cost, with a breakdown by category and year, must accompany each full proposal. 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 proposals are encouraged to cover the total estimated duration of the project. Incremental funds may be provided by USAMRMC for effort performed during each Federal fiscal year. Costs proposed must conform to the following regulations and principles:

Commercial Firms: Federal Acquisition Regulations (FAR) Part 31 and Defense FAR Supplement Part 31, (http://farsite.hill.af.mil) Contract Cost Principles and Procedures.

Educational Institutions: CFR, Title 2, Part 220, "Cost Principles for Educational Institutions." This was previously in OMB Circular A-21.

Nonprofit Organizations: CFR, Title 2, Part 230, "Cost Principles for Nonprofit Organizations." This was previously in OMB Circular A-122.

State, Local and Tribal Governments: CFR, Title 2, Part 225, "Cost Principles for State, Local and Indian Tribal Governments." This was previously in OMB Circular A-87.

The cost of preparing proposals in response to this BAA is not considered an allowable direct charge to any resultant contract, grant or cooperative agreement. It is, however, an allowable expense to the bid and proposal indirect cost specified in FAR 31.205-18, and CFR, Title 2, Parts 220 and 230.

Section A & B – Senior/Key Person: The basis for labor costs should be predicated upon actual labor rates or salaries. Budget estimates may be adjusted upward to forecast salary or wage cost-of-living increases that will occur during the period-of-performance. The proposal should separately identify and explain the ratio applied to base salary/wage for cost-of-living adjustments and merit increases in the budget justification (Section K)

The qualifications of the PI and the percentage of time that they and other professional personnel will devote to the research are important factors in selecting research proposals for funding. For each key staff member identified on the budget form, list the base salary and the percentage of each appointment to be spent on this project.

Section C – Equipment Description: It is the DoD policy that all commercial and non-profit recipients provide the equipment needed to support proposed research. In those rare cases where specific additional equipment is approved for commercial and non-profit organizations, such approved cost elements shall be separately negotiated.

An itemized list of permanent equipment is required, showing the cost for each item. Permanent equipment is any article of nonexpendable tangible property having a useful life of more than two years and an acquisition cost of $5,000 or more per unit. The justification for the cost of each item of equipment included in the budget must be disclosed to include:

(1) Vendor Quote: Show name of vendor and number of quotes received and justification if intended award is to other than the lowest bidder.

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

(3) Estimate: Include rationale for estimate and reasons for not soliciting current quotes.

(4) Special test equipment to be fabricated by the contractor for specific research purposes and its cost.

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

(6) 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 with contractor funds, would be capitalized for Federal income tax purposes.

(7) Title of equipment or other tangible property purchased with government funds may be vested in institutions of higher education or with nonprofit organizations, whose primary purpose is the conduct of scientific research. Normally the title will vest in the recipient if vesting will facilitate scientific research performed by the institution or organization for the Government.

(8) Commercial organizations are expected to possess the necessary plant and equipment to conduct the proposed research. Equipment purchases for commercial organizations will be supported only in exceptional circumstances.

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 meeting is limited. **Travel outside the United States, including between foreign countries, requires prior approval from USAMRAA at least 90 days before travel.**

NOTE: The PI shall budget for, prepare for, and participate in a 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 ninety (90) days prior to the meeting. The meetings will generally be held in the Ft Detrick, MD area but could occur elsewhere in the U.S.

Section E – Participant/Trainee Support Costs: This section is self-explanatory.

Section F - Other Direct Costs

Section F.1. – Materials and Supplies (Consumables): The justification supporting materials and supplies (consumable) costs should include a general description of expendable equipment and supplies. If animals are to be purchased, state the species, strain (if applicable) and the number to be used. If human cell lines are to be purchased, state the source and the description.

Section F.2. – Publication Costs: This section is self-explanatory.

Section F.3. – Consultant Services: Regardless of whether funds are requested, the justification should include the names and organizational affiliations of all consultants. State the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.

Section F.4. – ADP/Computer Services: This section is self-explanatory.

Section F.5. – Subaward/Consortium/Contractual Costs: The cost justification must include a description of services or materials that are to be awarded by subcontract or subgrant. The following information must be provided on sub awards totaling $10,000 or more:

a. Identification of the type of award to be used (e.g., cost reimbursement, fixed price);

b. Identification of the proposed subcontractor or subgrantee, if known, and an explanation of why and how the subcontractor or subgrantee was selected or will be selected;

c. Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition; and

d. The proposed acquisition price.

e. The offeror's cost or price analysis for the subgrant or subcontract proposed price.

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 proposals 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: This section is self-explanatory.

Section F.7. – Alterations and Renovations: This section is self-explanatory.

Section F (8 – 10) – Research-Related Subject Costs: Include Itemize 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) – Other Direct Cost (if applicable): Include other anticipated direct costs that are not specified elsewhere in the budget. Unusual or expensive items should be fully explained and justified.

Section G – Direct Costs: This section is self-explanatory.

Section H – Indirect Costs (fringe, overhead, general and administrative, and other): The most recent rates, dates of negotiation, base(s) and periods to which the rates apply should be disclosed along with a statement identifying whether the proposed rates are provisional or fixed. If negotiated forecast rates do not exist, provide sufficient detail regarding a determination that the costs included in the forecast rate are allocable according to applicable FAR/DFARS or OMB Circular provisions (see above). Commercial firms can also visit www.dcaa.mil for additional information on indirect rates. Disclosure should be sufficient to permit a full understanding of the content of the rate(s) and how it was established.

As a minimum, justification for indirect costs should identify:

a. All individual cost elements included in the forecast rate(s);

b. The basis used to prorate indirect expenses to cost pools, if any;

c. How the rate(s) was calculated; and

d. The distribution basis of the developed rate(s).

Payment of indirect costs for contracts, grants, cooperative agreements (or similar arrangements) using Basic Research (6.1) funds made available by the 2008 or later DoD Appropriations Acts will be limited to no more than 35% of the total costs negotiated.

Section I – Total Direct and Indirect Costs: This section is self-explanatory.

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 will be negotiated. Any fixed 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. The website for the form is:

(www.dtic.mil/whs/directives/infomgt/forms/forminfo/forminfopage2192.html)

Section K – Budget Justification: The Budget Justification must be included as an attachment at Research & Related Budget – Section K for each research period. Organizations must provide sufficient detail and justification so that the Government can determine the proposed costs to be allocable 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 (if applicable) must be attached as part of the budget justification if the proposal is submitted by a Federal agency. (No page limit.)

Proposals from Federal agencies must provide 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 institutions, and universities. It should be noted, however, that it is contrary to policy to allow for any Recipient to send funds back to a U.S. Government entity except under very limited circumstances provided for in USAMRAA policy, such as:

(1) The Recipient can show that such funds will not originate from the USAMRMC award, or

(2) There is separate statutory authority, aside from Cooperative Research and Development Agreement (CRADA) authority, that would allow for it, or

(3) The Recipient can show that exceptional or extraordinary circumstances exist that merit a waiver of this policy.

Such waiver must receive approval from the USAMRMC Resource Management Office and the Staff Judge Advocate before approval by USAMRAA. Examples of exceptional circumstances that could merit approval would be (i) if the research protocol involved numerous radiological studies, such as computer tomography scans, which needed to be performed and analyzed at a U.S. Government medical treatment facility (MTF) facility after the normal expiration of the Appropriation from which the award was made, and which studies would otherwise not be performed as part of the standard of medical care, and/or (ii) if the research calls for the purchase and use of chemical or biological materials that cannot legally be purchased and/or used by the Recipient, but can legally be purchased by the Government lab or MTF, then a CRADA can be employed for the Recipient to provide those funds to the lab or MTF to make such purchases.

Recipients under a cooperative agreement are allowed to provide non-fund resources to a Government lab or MTF, such as supplies, equipment, or personnel. This should be specifically provided for under the assistance document.

3. **Research & Related Project/Performance Site Location(s) –** Include the names and addresses for each location where research will be performed for the proposal. 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. Please note that each additional research site requesting funds will require a subcontract budget.

4. Research & Related Senior/Key Person Profile: Include the requested information for each senior/key person proposed on the project and attach 1) a current biographical sketch (**Attachment 1** - located at www.grants.gov) and 2) current & pending support on which this person is working or proposed. The list of Current/Pending Support should be attached in PDF format and should include the title, time commitments, supporting agency and level of funding for all existing and pending research projects involving the PI and key personnel. Provide justification for USAMRMC support and interest where the projects overlap or parallel.

5. Research & Related Other Project Information: This form is self-explanatory. The following information must be included as attachments to this form:

Blocks 1 - 5: This section is self-explanatory in addressing the use of human subjects, the use of animals, proprietary information and environmental impact of the research.

Block 6 – Project Summary/Abstract (Attachment 2 - located at www.grants.gov**):** The abstract is vitally important to both the peer and programmatic review process. The programmatic review includes an evaluation of the abstract as part of the peer review summary statement; therefore, it is paramount that the investigator submits an abstract that fully describes the proposed work. The abstract must contain the title of the proposal and the name of the PI. Do not include figures or tables in the abstract. Spell out all Greek or other non-English letters. Abstracts of all funded proposals may be posted; therefore, proprietary or confidential information should not be included in the abstract.

The structured technical abstract should provide a clear and concise overview of the proposed work, including the background, objective, or hypothesis and its supporting rationale, significance of the proposed work to the program's goals, specific aims of the study and the study design.

An outline is provided below for preparing the structured technical abstract.

a. Background: Provide a brief statement of the ideas and 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 – in that order. There is no form for this information. The attachments should be in PDF, in accordance with the formatting guidelines specified for full proposal preparation.

The Statement of Work (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, 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 may be incorporated into the award document and, as such, is subject to release under 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. The SOW for a three-year research effort should **not exceed one page** of single-spaced typing.

Body of Proposal - 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. This information **should not exceed 20 pages**. 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 reasoning behind the proposed study. Describe previous experience most pertinent to this proposal. Cite relevant literature references;

2. **Hypothesis**. State the hypothesis to be tested and the expected results;

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

4. **Project Milestones**: Identify time-lines for critical events that must be accomplished in order for the project to be successful in terms of cost, schedule and performance.

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 proposals include a clear statement of the rationale for the proposed syntheses. Outline and document the routes to the syntheses.

Block 8 – Bibliography & References Cited. List the references in the order they appear in the proposal 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 preparation.

Block 9 – Facilities & Other Resources. Describe the facilities available for performance of the proposed request and any additional facilities or equipment proposed for acquisition at no cost to USAMRMC. Indicate if Government-owned facility or equipment is proposed for use. Reference should be made to the original or present contract under which the facilities or equipment items are now accountable. There is no form for this information. The attachments should be in PDF, in accordance with the formatting guidelines outlined for full proposal 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 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, which might not be familiar to reviewers who are not current in the proposal, and research area.

- **Collaboration and Joint Sponsorship -** Provide letter(s) supporting stated collaborative efforts, which are provided at no cost, and are necessary for the project's success. Describe present or prospective joint sponsorship of any portion of the program outlined in the proposal. In the absence of agreements among sponsors for joint support, the proposal 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 is submitted, information should be sent later as an addendum to the proposal. Prior approval from both agencies must be secured for research to be undertaken under joint sponsorship.

- **Attachment 3: Certificate of Environmental Compliance -** Information regarding environmental compliance must be provided with the full proposal (located at www.grants.gov**).**

- **Attachment 4: Instructions for Facility Safety Plan** is located at https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.safety) and must be completed and included with the full proposal.

- **Attachment 5: Representations and Certifications** - The form for contracts is located at http://orca.bpn.gov. ORCA is an e-Government initiative that was designed by the Integrated Acquisition Environment (IAE) to replace the paper based Representations and Certifications process. The Representations for Assistance Agreements (Grants & Cooperative Agreements) (located at www.grants.gov**).**

- **Attachment 6: Certifications and Assurances for Assistance Agreements** - By signing and submitting a proposal or accepting an award, the recipient is concurring with the specified assurances and certifications, in compliance with the DoD 3210.6-R, Department of Defense Grants and Agreements Regulations, Part 22, Appendices A and B. (located at www.grants.gov**).**

- **Multimedia Objects, Photographs, Illustrations, Graphs, etc.** - Proposals 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 directing the reviewer to the electronic file for parts of the proposal 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.**

f. **Optional Forms**

1. **R&R Personal Data:** The Federal Government has a continuing commitment to monitor the operation of its review and award processes to identify and address any inequities

based on gender, race, ethnicity, or disability of its proposed PDs/PIs and co-PDs/PIs. To gather information needed for this important task, the applicant should submit the requested information for each identified PD/PI and co-PDs/PIs with each proposal. Submission of the requested information is voluntary and is not a precondition of award. However, information not submitted will seriously undermine the statistical validity, and therefore the usefulness, of information received from others. Any individual not wishing to submit some or all the information should check the box provided for this purpose. Upon receipt of the application, this form will be separated from the application. This form will not be duplicated, and it will not be a part of the review process. Data will be confidential.

2. **R&R Subaward Budget Attachment(s) Form:** On this form, you will attach the R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the R&R budget instructions. Please remember that any files you attach must be a PDF document. Important: Please attach your subawardee budget file(s) with the file name of the subawardee organization. Each file name must be unique.

You may use this form if applicable OR attach subcontractor budgets in PDF format as part of Budget Justification on tab K of Research and Related Budget forms. Regardless of the format used, the DUNS number for each subaward site should be included on this form.)

Please note that the files to be attached to the R&R Subaward Budget Attachment(s) Form must be PDF documents. 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) for this application 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 and reasonable for the proposed research effort. The following information must be provided on subawards totaling $10,000 or more:

- Identification of the type of award to be used (e.g., cost reimbursement, fixed price);
- Identification of the proposed subcontractor or subgrantee, if known, and an explanation of why and how the subcontractor or subgrantee was selected or will be selected;
- Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition; and
- The proposed acquisition price.
- The applicant's cost or price analysis for the subgrant or subcontract proposed price.

If the resultant award is a contract that exceeds $650,000 and the applicant is a large business or an educational institution (other than a Historically Black College or University/Minority Institution), the applicant 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: 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 under the assistance agreement. 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 assistance agreement take precedence over any term or condition included in supporting information.

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

Principal Investigators (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, reviewed, and approved by USAMRMC to ensure that DoD regulations are met.

Additionally, ***studies involving animals and studies that meet the definition of non-exempt human subjects research (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 IACUC or IRB **and** by the Office of Research Protections (ORP) at USAMRMC. The ORP office responsible for animal research is the Animal Care and Use Review Office (ACURO), and the ORP Human Research Protection Office (HRPO) is responsible for all research involving human subjects. Exempt ***human subjects research*** requires a determination from the PI's Institution **as well as** the ORP at USAMRMC. Protocols and required approvals must be submitted no later than 60 days after award to ensure continuation of payments. The Contracting/Grants Officer may grant exceptions in situations where human use is not expected to occur until after the first year of the research project. In such cases a timeframe for submission of the appropriate protocols should be established during discussion/negotiation.

1. Research involving Animal Use

Specific documents relating to the use of animals in the proposed research will be requested if the proposal is selected for funding (these documents should not be submitted with the proposal). The Animal Care and Use Review Office (ACURO), a component of the USAMRMC Office of Research Protections (ORP), must review and approve all animal use prior to the start of working with animals. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version the animal use appendix entitled "Research Involving Animals". For guidance on which version of the appendix to use as well as links to both, please visit ACURO's web page at: https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro_Animalappendix. Allow 2 to 4 months for regulatory review and approval processes for animal studies.

Contact ACURO for additional information via email to the central email box ACURO@amedd.army.mil.

2. Research Involving Human Subjects, Human Subjects Data, or Human Anatomical Substances

All USAMRMC -funded research involving human subjects and human biological substances must receive a headquarters-level administrative review (HLAR) and be approved by the USAMRMC Office of Research Protections (ORP) in addition to local Institutional Review Boards (IRBs). The ORP is mandated to ensure that all research complies with specific laws and directives governing research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed, and may require information in addition to that supplied to the local IRB.

During the regulatory review process for research involving human subjects, the ORP requirements must be addressed and any changes to the already approved protocol must approved as an amendment by the local Institutional Review Board (IRB). It is strongly recommended that investigators carefully read the "Guidelines for Investigators" found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo The time to approval depends greatly on adherence to these guidelines in a clear and comprehensive manner. 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 is selected for funding. ***Allow at least 4 months for regulatory review and approval processes for studies involving human subjects.***

Requirements: 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 (DHHS) Office for Human Research Protection (OHRP) Federalwide Assurance (FWA) or a DOD Assurance. ***All awardees (institution listed on proposal, contract, assistance agreement) receiving funds that will support non-exempt human subjects research are considered to be "engaged" in the research and responsible for oversight, even if the research is sub-contracted to other institutions.***

Training. Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming that this instruction has been completed will be required during the regulatory review process.

Informed Consent Form:

The following must appear in the consent form:

1. A statement that the DOD or a DOD organization is funding the study.

2. A statement that representatives of the U. S. Army Medical Research and Materiel Command (or the DOD) are authorized to review research records.

3. In the event that a separate Health Insurance Portability and Accountability Act (HIPAA) () authorization is required, representatives of the USAMRMC must be listed as one of the parties to whom private health information may be disclosed.

Intent to Benefit: Investigators must consider the requirements of Title 10 United States Code Section 980 (10 USC 980) applicable to DOD-sponsored research before writing a research protocol. 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."

Furthermore, and consistent with the Common Federal Rule for the Protection of Human Subjects, if an individual cannot give his or her own consent to participate in a research study, consent of the individual's legally authorized representative must be obtained before the individual's participation in the research. Moreover, an individual not legally competent to consent (e.g., incapacitated individuals, cognitively impaired, minors) may not be enrolled in a DOD-supported experiment unless the research is intended to benefit each subject enrolled in the study. For example, a subject may benefit directly from medical treatment or surveillance beyond the standard of care. PIs should be aware that this law makes phase I and placebo-controlled clinical trials problematic because of the "intent to benefit" requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative.

Note: *This statute is only applicable to certain intervention studies. The 10 USC 980 does not apply to retrospective studies, observational studies, blood draws and tissue collections. Contact HRPO for further clarifications regarding applicability of 10 USC 980 to your project.*

Medical Monitor Requirement. An independent medical monitor must be identified in the protocol for all greater than minimal risk protocols. A CV or biosketch and human subjects protection training is provided. The medical monitor must have no apparent conflict of interest. The medical monitor must not be under the supervision of the principal investigator or other investigators or research staff. It is acceptable to provide appropriate compensation to the medical monitor for his or her services.

The role of the medical monitor must be described in the protocol and be consistent with DoD guidance. Medical monitors should be physicians, dentists, psychologists, nurses, or other healthcare providers capable of overseeing the progress of research protocols, especially issues of individual volunteer management and safety. Medical monitors must be independent of the investigative team and possess sufficient educational and professional experience to serve as the volunteer advocate. Depending on the nature of the study, the medical monitor may be assigned to assess one or more of the following phases of research project: volunteer recruitment, volunteer enrollment, data collection, or data storage and analysis. The medical monitor provides an independent evaluation of serious adverse events and unanticipated problems involving risk to subjects or others to the IRB and the ORP. The medical monitor may be assigned to discuss research progress with the principal investigator, interview volunteers, consult on individual cases, or evaluate adverse event reports. Medical monitors must promptly report discrepancies or problems to the IRB and the ORP. They shall have the authority to stop a research study in progress, remove individual volunteers from a study, and take whatever steps are necessary to protect the safety and well-being of research volunteers until the IRB can assess the medical monitors report

Research with no physical or psychological risks may be determined to be greater than minimal risk for other reasons (e.g. sensitivity of identifiable data). In these cases it may be acceptable to employ a "research monitor" to fulfill this role. For example, someone with an Information Technology background may be appropriate to monitor security of data stored in electronic systems.

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 the Commander of military facilities or units in which recruitment will occur or the study will be conducted will be requested. Some sites may also require that each volunteer seek written permission from their supervisor prior to participation in research studies.

Special consideration must be given to the recruitment process for military personnel. The Chain of Command should not be involved in the recruitment of military personnel and should not 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 and may be recommended in other situations as well, especially when young enlisted service members are recruited who are trained to follow orders. Service members are trained to act as a unit, so peer pressure should also be considered and minimized if possible.

Payment to Military Personnel. Under 24 USC 30, payment to Active Duty military personnel for participation in research is limited to blood donation and may not exceed $50 per blood draw. Active Duty research volunteers may not receive any other payment 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 or discharge. Information regarding alcohol or drug abuse, drunk driving, sexual or spousal abuse and sexual orientation can lead to actions under the Uniform Code of Military Justice including incarceration and dishonorable discharge. For aviators, loosing flight status due to a physical or psychological concern is an issue.

Please Note: The USAMRMC ORP HRPO conducts random 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

The ORP accepts protocol submissions in the format required by the local IRB. To avoid delays in the approval process, PIs should take the ORP guidelines into account when developing protocols for submission to the local IRB.

If you have difficulty accessing any of the https://mrmc web sites related to Research Protection, please go to **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.

h. **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 offerors whose proposals 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 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.htm.

Location of Attachmemts 1-6: Perform a Basic Search at www.grants.gov for Funding Opportunity number W81XWH-BAA-11-1. When you reach the main screen for the funding opportunity, attachments are located under the middle tab entitled "Full Announcement."

3. **Submission Dates and Times:** This is a continuously open announcement; preproposals may be submitted and will be evaluated at any time throughout the year, unless otherwise noted or stated in a separate announcement.

4. **Intergovernmental Review:** This announcement is not subject to intergovernmental review.

5. **Funding Restrictions:** All USAMRMC assistance awards are subject to the terms and conditions, cost principles, and other considerations described in the U. S. Army Medical Research Acquisition Activity General Terms And Conditions For Assistance Awards.

Pre-award costs are allowable as follows:

Assistance Agreements: An institution 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 grantee must obtain the Contracting/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.

Contracts: An institution may request and negotiate precontract cost prior to contract award. The Precontract cost agreement must be executed by the Contracting Officer prior to incurring any cost. The cost 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/precontract costs in anticipation of a competing or non-competing 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/precontract costs result in borrowing against future support and that such borrowing must not impair the institution'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: The US Army Medical Research and Materiel Command (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.

6. Other Submission Requirements: None

E. 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:** The USAMRMC scientists or outside experts will evaluate preproposals for scientific merit and programmatic/military relevance. PIs whose preproposals meet preliminary qualifications may be invited to submit full proposals. Full proposals will be evaluated using a two-tier review process.

Note: Full proposals may be rejected if they do not reflect the stated timeline and budget noted in the preproposal.

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

a. **Military and Program Relevance:** Military-relevant research must be responsive to the health care needs of the Armed Forces, family members of the Armed Forces, and the U.S. Veteran population. Proposals must address a military-relevant health problem responsive to one of the areas of interest outlined in the BAA.

b. **Research Objectives:** The stated objectives must be clear, valid, and logical. Research projects that demonstrate an innovative approach are desired.

c. **Scientific Excellence:** The proposed plans, methods, techniques and procedures must be feasible, clear, valid, adequately referenced, and state-of-the-art. Literature searches are recommended for documenting the strengths of the proposed project.

d. **Impact/Outcomes:** Explain how the results of this research are expected to impact the intended beneficiaries. Expound upon the dual (military and commercial) purpose for the research, as appropriate.

e. **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 and skills to achieve the proposed objectives as well as the time available for the percentage of effort indicated for the project.

f. **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.

g. **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 fair and reasonable and commensurate with the complexity and nature of the research proposed.

h. **Commercialization Strategy**: Describe the commercialization plan. Commercialization plan must include: Intellectual Property, Market Size, Financial Analysis, Strengths and Weaknesses, Barriers to Market, Competitors and Management Team.

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. The programmatic review is primarily concerned with three criteria: peer review recommendations, programmatic priorities, and portfolio balance. Other programmatic priorities that may be considered include:

a. Congressional guidance
b. Military mission, relevance, health, medicine, beneficiaries
c. DoD Priorities
d. VA Priorities
e. Collaborations with federal researchers

Selection Process: After the two-tiered evaluation, proposals 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 they have adequately addressed the following requirements:

1. Research involving Human Subjects/Anatomical Substances (if proposed),
2. Research involving Animals (if proposed),
3. Facility Safety Plan (FSP),
4. Certificate of Environmental Compliance, and
5. Representations for Assistance Agreements & Certifications and Assurances for Assistance Agreements or Representations & Certification for a Contract, as appropriate.

Special Programs: Evaluation and selection of proposals is based upon scientific merit, programmatic relevance, and Congressional intent for awarded funds. Military relevance, collaborative efforts with DOD and/or VA scientists and clinicians, or other priorities may be evaluation criteria or requirements. Criteria and requirements for submission and evaluation of proposals may differ from those of other USAMRMC solicitation instruments, as well as other requirements stated in this BAA. Such differences will be noted in the specific BAA Supplement or solicitation instrument. For example, these special programs usually specify a submission closing date, and a specific submission process. Other areas where differences may apply are:

1. Submission of Pre-Proposals of one page or longer may be required;

2. Submission of Letters of Intent may be required;

3. Full Proposal submission requirements may be sent to applicant with invitation to submit full proposal;

4. Progress reporting requirements may differ and will be detailed in award document;

5. Points of contact for Principal Investigator (PI) inquiries may be identified;

6. Travel Cost guidelines may differ; and,

7. PI notification of proposal receipt may differ.

3. **Recipient Qualifications:** In addition to other information provided herein, by submitting a proposal and accepting an award, the recipient 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 must meet the specific Funding Opportunity requirements.

Investigators are cautioned that awards are made to organizations, not individuals. A principal investigator (PI) must submit a proposal through, and be employed by an organization in order to receive support. (Federally Funded Research and Development Centers are not eligible for awards in accordance with FAR 35.017)**. Should the PI of a funded project leave the recipient institution, both the PI and institution 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 institution.**

F. Award Administration Information

1. **Award Notices:** The PI should receive a decision letter or e-mail regarding the preproposal within 60 - 90 days of submission. The Government should forward an award for a selected proposal within 180 days after submission of a complete proposal package.

2. **Administrative and National Policy Requirements**

a. **Information Release:** Award recipients are required to agree to the release of information pertaining to the research and development supported by the USAMRMC. Statement 1 shall be included in all such releases; Statements 2-5 shall be included if relevant to the research being conducted:

1. "This work was supported by the US Army Medical Research and Materiel Command under Award No. _____. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army."

2. In conducting research using humans 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

3. "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.

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

5. "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." (www.cdc.gov/od/ohs/biosfty/biosfty.htm)

6. "Information" includes but is not limited to news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings, and symposia.

Failure to include Statement 1 on all information releases and Statements 2-5 when required can 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 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 funding and should be coordinated through the USAMRAA Contracting/Grants 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 their award efforts. The visits must all be coordinated with the Contracting/Grants 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. Under cost-reimbursement type awards, payments are made in response to monthly vouchers or invoices submitted by the awardee. Under grants and cooperative agreements, advance payments are normally made periodically, in accordance with the negotiated payment schedule included in the award document.

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 grantee or its collaborator, but the US 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 contract or grant.

h. **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 301-619-2065) prior to expending time and effort in preparation of a proposal.

i. **Disclosure of Information Outside the Government:** Proposals will only be disclosed outside of the Government for the sole purpose of technical evaluation. The USAMRMC obtains a written agreement from the evaluators that information in the proposal will only be used for evaluation purposes and will not be further disclosed. Proposals for funded projects will be subject to public release under the Freedom of Information Act to the extent that they are incorporated into an award document; proposals that are not selected for funding will not be subject to public release.

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

k. **Information Service:** Submitters 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.

l. **2 CFR Part 170 - Requirements for Federal Funding Accountability and Transparency Act Implementation** - 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, 2010, the obligation must be reported by no later than December 31, 2010.)

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

m. **2 CFR Part 25 - Financial Assistance Use of Universal Identifier and Central Contractor Registration** - Appendix A to Part 25--Award Term)

I. Central Contractor Registration and Universal Identifier Requirements

A. Requirement for Central Contractor Registration (CCR). 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 CCR 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) 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 CCR Internet site (currently at

http://www.ccr.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.

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 reports that outline the accomplishments and progress for that period.

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

c. 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) and approval for continuation must be submitted directly to the Office of Research Protections.

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

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

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

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

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

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

G. Agency Contact: Questions concerning the preparation of preproposals or proposals can be emailed to (QA.BAA@amedd.army.mil), ATTN: BAA 11-1 at USAMRAA or by contacting Pam Nevels at pamela.nevels@amedd.army.mil.

Mail: U.S. Army Medical Research Acquisition Activity
ATTN: BAA 11-1
820 Chandler Street
Fort Detrick, MD 21702-5014

Issues in submitting applications through the Grants.gov portal should be directed to the Grants.gov help desk at 1-800-518-4726 or email support@grants.gov. The Contact Center hours of operation are Monday-Friday, 7 AM to 9 PM Eastern Standard Time.

H. Other Information: Common Problems And Proposal Submission Guide

1. Failure to sign up for updates 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 helpdesk.
5. Failure to send attachments.
6. Inability to locate Attachments. (Perform a Basic Search at www.grants.gov for Funding Opportunity number W81XWH-BAA-11-1. When you reach the main screen for the funding opportunity, attachments are located under the middle tab entitled “Full Announcement”.)

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	Attachment 1 PI Biographical Sketch	Attach to Biographical Sketch field
	PI Current/Pending Support In PDF format	Attach to Current & Pending Support field
	Attachment 1 Key Personnel Biographical Sketches	Attach to Biographical Sketch field for each senior/key person
	Key Personnel Current/Pending Support	Attach to Current & Pending Support field for each senior/key person
Research & Related Other Project Information	Attachment 2 Proposal Abstract	Attach to Block 6 Project Summary/Abstract
	Project Narrative and Body of Proposal in PDF format	Attach to Block 7 Project Narrative
	Attachment 3 Certificate of Environmental Compliance	Attach to Block 11 Other Attachments
	Attachment 4 All applicable Facility Safety Plan documents	Attach to Block 11 Other Attachments
	Attachment 5 Representations for Assistance Agreements	Attach to Block 11 Other Attachments
	Attachment 6 Certifications and Assurances for Assistance Agreements	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