United
States
Army
Medical
Research and
Materiel
Command



# DEPARTMENT OF DEFENSE BROAD AGENCY ANNOUNCEMENT AREAS OF INTEREST

BAA 10-1

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FORT DETRICK, MARYLAND

# U.S. Army Medical Research and Materiel Command BAA 10-1

#### **PREFACE**

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 research ideas, and is issued under the provisions of the Competition in Contracting Act of 1984 (Public Law 98-369), as implemented in the 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. All Attachments that are required with the submission of a full proposal are described in the Mandatory Proposal Forms section of the BAA 10-01 General Information and Proposal Preparation document. Research proposals are sought from educational institutions, nonprofit organizations, private industry, and domestic and foreign government agencies. 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.

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is continuing the process of preparing this BAA for electronic commerce. The BAA will be revised as other electronic processes are developed. Amendments of this brochure will be advertised on the USAMRAA website (<a href="www.usamraa.army.mil">www.usamraa.army.mil</a>), at Grants.gov (<a href="www.grants.gov">www.grants.gov</a>), and in Fedbizopps (<a href="www.fedbizopps.gov">www.fedbizopps.gov</a>). Many of the programs and areas of interest may not have funding readily available, but the status of funds will be part of the advice elicited from a proposal. From time to time separate announcements or calls for proposals may supplement this BAA. These supplements will be featured on our homepage and announced at <a href="www.grants.gov">www.grants.gov</a>.

Questions concerning the preparation of preproposals or proposals can be emailed to (QA.BAA@amedd.army.mil) or faxed to 301-619-3002, ATTN: BAA 10-1 at USAMRAA or by calling Pam Nevels at 301-619-8802.

Mail: U.S. Army Medical Research Acquisition Activity ATTN: BAA 10-1

820 Chandler Street

Fort Detrick, MD 21702-5014

BAA Preproposal Forms (http://www.usamraa.army.mil/pages/BAA Forms/User/login.cfm)

# U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND BAA 10-1

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## I. RESEARCH AREAS OF INTEREST

#### A. 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.

- 1. Research and Development of Preventive Measures for Infectious Diseases includes:
- a. 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.
- b. 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.
- c. 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).
- d. 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.
- 2. 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.

#### B. COMBAT CASUALTY CARE RESEARCH PROGRAM

The Combat Casualty Care Research Program (CCCRP) provides integrated capabilities for farforward 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 lifethreatening 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. Medical techniques and materiel that can be used by first responders, which means that medical materiel 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, are preferred. Drugs and biologics, ideally, should not require refrigeration or other special handling. 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 available to enhance self- and buddyaid; 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:

- 1) 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:
  - a. Research and development of technologies to stop blood loss, to resuscitate the casualty, and to limit the immediate, short- and long-term deleterious consequences of severe hemorrhage. Included in this area of interest are noninvasive or minimally invasive sensors to detect and warn of impending vascular collapse and/or significant tissue damage due to perfusion deficits. Examples of specific products include: local and systemic hemostatic agents for the control of compressible and non-compressible hemorrhage, treatments to enhance oxygen delivery and perfusion of tissue, equipment and procedures for effective fluid resuscitation of casualties, and enhanced resuscitation fluids. Also of interest is the improved preservation, storage, transportability, and processing of red blood cells, platelets, and plasma.
  - b. Research and development of technologies to diagnose and to limit the immediate, shortand long-term impairments that follow traumatic brain injury and spinal cord injury. Included in this area of interest are non- or minimally-invasive sensors or assays to rapidly diagnose the severity of brain and spinal cord injury within the battle area or as close to it as possible, and drugs, biologics, or other agents to mitigate post-injury neural and immune cell overstimulation, inflammation, cell loss, and neurologic dysfunction.
- 2) 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. Management of pain after trauma 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.

3) The CCCRP supports additional aspects of casualty care. These include drugs or devices 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, processors, and simulation and modeling to improve our capability for remote triage, monitoring, and management of casualties; and in products to maintain casualties during prolonged evacuation.

#### C. MILITARY OPERATIONAL MEDICINE RESEARCH PROGRAM

The Military Operational Medicine Research Program (MOMRP) provides biomedical solutions that protect Soldiers and enhance their performance in operational and training environments that include multiple stressors. It is a unique biomedical research program with relevant Program Areas, a problem-solving orientation, and a human physiology research focus.

The MOMRP represents unique expertise in both health and performance effects of multiple interacting operational hazards and stressors. The focus is on multistressor interactions involving human tolerances, metabolic physiology, and brain functioning. The core biomedical research capabilities are organized into thirteen areas ranging from environmental medicine and bioenergetics, injury sciences and systems hazards, to neuropsychological stress and performance. These thirteen research areas have been consolidated into four spheres of research emphasis.

The four spheres of research emphasis include the following:

- 1. 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 of the military 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 develop Soldier monitoring/sensor technologies and decision support tools.
- 2. Psychological Health and Resilience This research addresses: development of effective strategies and interventions that reduce the impact of mental disorders and mild traumatic brain injury, while developing psychological resilience among Warriors and Families; development of strategies/policies to enhance/sustain mental health and well-being throughout service members' career; validation of early interventions and treatments and enhanced screening and identification of mental health and mTBI related health

concerns; and investigation of effective risk communications and provision of improved clinical guidelines for health care providers.

- 3. Environmental Health and Protection This research area includes: assessment and sustainment of health and the operational effectiveness of Warriors exposed to altitude, cold, heat, and toxic industrial chemicals; development of policy, training, planning/management tools and materiel solutions to sustain Warrior resilience, health and operational effectiveness when exposed to environmental stressors of altitude, cold, and heat; development of diagnostic, treatment, and reset solutions for Warriors suffering illness/injury from environmental stressors of altitude, cold, and heat; identification of biomarkers of exposure for environmental health hazards (toxic industrial chemicals and materials and key stressor interactions) in support of operational needs; and development of hand-held, fieldable devices for rapid identification of (1) exposure/effect biomarkers in body fluids and (2) industrial chemical-associated toxicity in environmental media.
- 4. Physiological Health This area of research involves the development of biomedical countermeasures to sustain Warrior health and operational effectiveness, e.g.: the development of state-of-the-art policy, training, and materiel solutions to establish, sustain, optimize, and monitor Warrior health, physiological resilience, cognitive effectiveness throughout training, deployment, reset, and recovery cycles; and the development of mission support and mission planning tools that minimize injury/illness and optimize health and performance in all operational environments.

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 and validity of its research..

Link to the Force Health Protection and Readiness Non-Government Medical Technology Website: If you represent a non-DoD organization and would like to provide information regarding your products or services, please read the procedures for submitting such information: Guidelines on Posting Your Organization's Research on the New FHP&R Non-Government Medical Technology Website

**D. 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: <a href="http://www.dtra.mil/be/business\_opp/procurement/acq\_procopp.cfm">http://www.dtra.mil/be/business\_opp/procurement/acq\_procopp.cfm</a>.

The Medical Biological Defense Research Program provides medical countermeasures for biological warfare agents. These countermeasures include specialized medical material 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:

- 1. Viral, Toxin and Bacterial Studies.
- a. 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.
- b. 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.
- c. 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.
- d. Preparation of research quantities of highly purified and characterized toxins as well as studies on basic chemistry, mechanisms of action, metabolism and excretion.
- 2. 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.
- a. Discovery of novel or unique biochemical elements or compounds with antiviral, antibacterial or antitoxin activity against the listed organisms.
- b. 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.

c. 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.

- 3. 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.
- **E. 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: <a href="http://www.dtra.mil/be/business\_opp/procurement/acq\_procopp.cfm">http://www.dtra.mil/be/business\_opp/procurement/acq\_procopp.cfm</a>.

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:

- 1. 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.
- 2. 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.

3. 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:

- a. Characterizing the mechanisms of vesicant agent pathophysiology to identify medical countermeasures against vesicant agents.
  - b. Developing innovative models of the pathophysiology of vesicant agent injury.
- c. Identifying and/or evaluating innovative candidate medical countermeasures against vesicant agents.
- d. Identifying, exploring, and developing innovative clinical diagnostic, prognostic, and management approaches to vesicant agent casualties.
- e. Characterizing the ocular lesions associated with vesicant agent exposures; developing treatments to ameliorate these injuries.
- f. Characterizing the mechanisms of nerve agent-induced seizures and resulting pathophysiology; to identify medical countermeasures against nerve agent-induced seizures.
- g. Identifying, synthesizing, and/or evaluating innovative candidate medical countermeasures against nerve agent-induced seizures.
  - h. Developing innovative models of the pathophysiology of nerve agent induced seizures.
- i. 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.
  - j. Developing innovative models for evaluation of chemical warfare agent scavengers.
- k. Identifying, expressing, synthesizing, and/or evaluating biotechnologically-derived or pharmaceutically-based scavengers as candidate medical countermeasures against chemical warfare agents.
- l. 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.
- m. Developing catalytic and/or stoichiometric additives for use in skin protectants, or decontaminants, to protect against chemical warfare agents, especially vesicant and nerve agents.

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

- o. Developing candidate formulations for skin protectants or decontaminants containing catalytic and/or stoichiometric additives and evaluating these formulations against chemical warfare agents.
- p. Characterizing the pathophysiology and natural progression of chemical warfare agent-induced damage to human tissues.
- q. Developing and validating innovative techniques for rapid and accurate analysis of human tissues and body fluids for detection of chemical warfare agent exposures.
- r. Characterizing the effects of long-term or chronic exposures to chemical warfare agents and/or medical countermeasures to these agents.
- s. Identifying, exploring, and developing innovative clinical diagnostic, prognostic and management approaches to nerve agent casualties.
- t. Developing and validating field usable procedures for diagnosis, prognosis, and treatment of chemical warfare agent casualties under both field and laboratory conditions.

#### F. 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.

- 1. 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.
- 2. Health Information Technologies. Focus areas include:
  - a. Establishment of a common development environment to allow rapid prototyping for standard military health care systems.
  - b. Establish a research data cube and clinical data mart dataset to support the research community.
  - c. Natural language processing.
  - d. Voice recognition.
  - e. Scanning paper based records.
  - f. Interoperability.
  - g. Usability testing of electronic health records.
  - h. Terminology services/ontologies.
- 3. Medical Imaging Technologies. There are four research areas:
  - a. Portable imaging and image guided therapeutics.

- b. Advanced high performance imaging.
- c. Computational methods and decision support.
- d. Advanced surgical cameras.
- 4. Advanced Prosthetics and Human Performance. Focus areas are:
  - a. Advanced prosthetics, orthotics and other assistive devices. (Includes neuroprostheses, biomaterials, nano-materials, and robotics).
  - b. Treatments and interventions for patients with limb amputations, fractures and other orthopedic related injuries. (May include use of regenerative medicine technologies).
  - c. Orthopedic injury prevention.
  - d. Human performance optimization (to include but not limited to: diet, exercise, sleep)
  - e. Polytrauma.
- 5. 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.
- 6. 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.
- 7. 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:
  - a. Individual medical skills and proficiency.
  - b. Unit medical skills.
  - c. Use of simulation and virtual reality in patient therapies.
  - d. Modeling of human biology/systems to aid/assist in any of the above.
- 8. 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
- 9. 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.

- 10. Infectious Disease. Research in this area focuses on vaccines, therapeutic agents, diagnosis, vector control, wound infections, and sepsis.
- 11. 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:
  - a. Traumatic Brain Injury and Spinal Cord Injury.
  - b. Neuroprostheses and brain-machine interface
  - c. Post-Traumatic Stress Disorder (and other behavioral pathologies of war).
  - d. Neurodegenerative conditions.
  - e. Neuro-imaging.
- 12. 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.
- 13. 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.
- 14. 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.
- 15. 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.

#### G. 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 care.

The CRMRP focuses its efforts on the following five research areas: neuromusculoskeletal injury (including amputees), ocular and visual system injury, hearing and vestibular systems injury, chronic pain, and regenerative medicine. 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 five areas (for example, TBI-associated visual dysfunction, or rehabilitation in the context of TBI).

#### 1. Rehabilitation of Neuromusculoskeletal Injuries

Research directed toward strategies for rehabilitation in patients with complicating factors (e.g., TBI, post-traumatic stress disorder (PTSD), and other comorbidities), 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.

#### 2. 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).

### 3. Hearing and Balance Restoration and Rehabilitation

Research to support the development of strategies for the diagnosis, treatment, and mitigation of dysfunction associated with TBI and war-related injuries and the restoration of sensory systems for hearing and balance (including regeneration and tissue repair following traumatic injury).

#### 4. Chronic Pain Management

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). The interest is in management of pain associated with traumatic or war-related injuries.

#### 5. Regenerative Medicine

Regenerative medicine involves the use of innovative technologies such as scaffolds and tissue engineering, growth factors, and stem cell treatments to restore Warfighters who have suffered severe blast injuries or burns or lost limbs. 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).

#### H. 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: <a href="https://mrmc.amedd.army.mil/mrdindex.asp">https://mrmc.amedd.army.mil/mrdindex.asp</a>.