

I. OVERVIEW OF THE FUNDING OPPORTUNITY

United States Army Medical Research and Materiel Command



DEPARTMENT OF DEFENSE

**BROAD AGENCY ANNOUNCEMENT
for Extramural Medical Research**

Funding Opportunity Number: W81XWH18SBAA1

Announcement Type: Modified

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

KEY DATES

Release/Posted Date: October 1, 2017

Closing Date: September 30, 2022, 11:59 p.m. Eastern Time

This Funding Opportunity Announcement is a Broad Agency Announcement (BAA). It is continuously open for a 5-year period, from October 1, 2017 through September 30, 2022, 11:59 p.m. Eastern Time.

This Broad Agency Announcement must be read in conjunction with the General Submission Instructions, which are available for downloading from Grants.gov. The General Submission Instructions are located under the “package tab” and can be downloaded by selecting the “Download Instructions” icon when previewing the submission package.

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I.A. New for Fiscal Year 2018

The Fiscal Year 2018 – Fiscal Year 2022 (FY18-FY22) U.S. Army Medical Research and Materiel Command’s (USAMRMC) Broad Agency Announcement (BAA) for Extramural Medical Research contains several changes from previous USAMRMC BAAs. Read each section carefully. Note the following:

- The open period of the BAA has been extended to 5 years and will be amended annually with any updates.
- The format of the BAA has been revised to conform to Chapter II of Title 2, Code of Federal Regulations (CFR), Section 200.203 “Notices of funding opportunities.”
- The “Research Areas of Interest” can be found in [Appendix I](#).
- For assistance agreements:
 - The total period of performance may be proposed for up to 4 years in length; additional periods may be considered.
 - Any assistance agreement (grant or cooperative agreement) awarded under this BAA will be governed by the award terms and conditions that conform to the Department of Defense’s (DoD) implementation of Office of Management and Budget guidance in 2 CFR part 200, “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.” DoD implementation is located in Chapter XI of Title 2, CFR.
- For contract awards:
 - The total period of performance may be proposed for up to 5 years in length.
 - The total period of performance for conference or symposium support contracts may be proposed for up to 2 years in length.

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

The USAMRMC mission is to provide solutions to medical problems of importance to the American Service member at home and abroad, as well as to the general public at large. The scope of this effort and the priorities attached to specific projects are influenced by changes in military and civilian medical science and technology, operational requirements, military threat assessments, and national defense strategies. Extramural research and development programs play a vital role in the fulfillment of the objectives established by the USAMRMC. General information on USAMRMC can be obtained at <http://mrmc.amedd.army.mil/index.cfm>.

This BAA is intended to solicit extramural research and development ideas using the authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). The BAA is issued under the provisions of the Competition in Contracting Act (CICA) of 1984 (Public Law 98-369), as implemented in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016 and in DoD Grant and Agreement Regulations (DoDGARs) 22.315. In accordance with FAR 35.016, projects funded under this BAA must be for basic and applied research to support scientific study and experimentation directed toward advancing the state of the art or increasing knowledge or understanding rather than focusing on development of a specific system or hardware solution. Research and development funded through this BAA are intended and expected to benefit and inform both military and civilian medical practice and knowledge.

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

This BAA provides a general description of USAMRMC's research and development programs, including Research Areas of Interest, evaluation and selection criteria, pre-proposal/pre-application and full proposal/application preparation instructions, and general administrative information. Specific submission information and additional administrative requirements can be found in the document titled "General Submission Instructions" available in Grants.gov along with this BAA.

New for 2018: Proposal/Application submission by extramural organizations through Grants.gov requires use of the Workspace interface, which separates the proposal/application package into individual forms. Applicants must create a Workspace in Grants.gov, complete the required forms, and submit their proposal/application Workspace package.

The execution management agent for this BAA will be the Congressionally Directed Medical Research Programs (CDMRP). The CDMRP manages the electronic Biomedical Research Application Portal (eBRAP) system and retrieval and processing of full proposal/application submissions from Grants.gov. Refer to [Section II.G, Agency Contacts](#), for additional information.

The USAMRMC's supporting acquisition office, the U.S. Army Medical Research Acquisition Activity (USAMRAA), will be the awarding and administering office for proposals/applications

selected for funding, unless approval is obtained from the USAMRAA Principal Assistant Responsible for Contracting to allow another Federal acquisition office to execute and administer an award.

II.A. Program Descriptions

II.A.1. Military Infectious Diseases Research Program

The Military Infectious Diseases Research Program (MIDRP) focuses on vaccines, drugs, vector detection assays, and novel prevention strategies and therapeutics to treat microbial infections, including multidrug-resistant organisms in combat wound infections, as well as vector control measures for insect vectors that transmit naturally occurring endemic diseases with demonstrated or potential capability to decrease military operational effectiveness. Malaria, bacterial diarrhea, and dengue and lethal viruses are the main areas of interest for the MIDRP. The MIDRP also has programs in multidrug-resistant bacteria and fungi, Rickettsial diseases, emerging infectious diseases (e.g., chikungunya virus, Zika virus) not found on the Defense Threat Reduction Agency (DTRA) biothreat list. The MIDRP does not support proposals/applications for funding research on any select agent biologicals or chemical warfare threats or cancer.

Research efforts that focus on novel technologies and/or Investigational New Drug (IND)-enabling preclinical and clinical studies to facilitate the development of preventive and treatment therapies for the above-mentioned research areas are of interest to the MIDRP.

The MIDRP is also interested in proposals/applications incorporating a systems biology approach. Systems biology is the study of systems of biological components, which may be molecules, cells, organisms, or entire species. For more information, refer to Section II.D.2.a.iv, [Attachment 7, Data- and Research Resource-Sharing Plan](#).

Research Areas of Interest to the MIDRP are found in [Appendix I.I](#). Applicants are urged to read and consider these before preparing their proposals/applications.

II.A.2. Combat Casualty Care Research Program

The Combat Casualty Care Research Program (CCCRP) provides integrated capabilities for current and future operations to reduce the mortality and morbidity associated with major combat-related trauma across the spectrum of combat casualty care including point-of-injury and pre- or out-of-hospital care, the spectrum of en route care, and facilities-based treatment. A primary emphasis of the CCCRP is to identify and develop medical techniques, knowledge products, and materiel¹ (medical devices, drugs, and biologics) for early intervention in life-threatening battle injuries and prolonged field care² (PFC). Because battlefield conditions

¹ Materiel is defined as equipment and supplies of a military force.

² Prolonged field care is defined as field medical care, applied beyond “doctrinal planning timelines” by a North Atlantic Treaty Organization (NATO) Special Operations Combat Medic (NSOCM) or higher, in order to decrease patient mortality and morbidity. PFC utilizes limited resources and is sustained until the patient arrives at an appropriate level of care. Rasmussen TE, Baer DG, Cap AP, et al. 2015. Ahead of the Curve. *J Trauma Acute Care Surg* 79: S61-64.

impose severe constraints on available manpower, equipment, and medical supplies available for casualty care, the CCCRP places a premium on medical interventions that can be used within the battle area or as close to it as possible, before or during medical evacuation. Preferred medical techniques and materiel that can be used by combat medics must be easily transportable (i.e., small, lightweight, and durable in extreme environments and handling); devices must be easy to use and require low maintenance, with self-contained power sources as necessary. The CCCRP is interested in existing materiel for which concept and/or patient care efficacy have already been demonstrated, but that require improvement to meet military requirements. The CCCRP is also interested in proposals/applications incorporating a systems biology approach. For more information, refer to Section II.D.2.a.iv, [Attachment 7, Data- and Research Resource-Sharing Plan](#).

Research efforts are needed in principles and technologies to enhance self- and buddy-aid, also referred to as tactical care; techniques, methods, or materiel to improve basic and advanced life support for all injured persons; monitoring, sustainment, and management of all injured casualties during episodes of delayed care or PFC; and enhanced capability for triage of large numbers of casualties and staged treatment in the field. The principal causes of death among Service members who die within the first hour of wounding are hemorrhage and traumatic brain injury (TBI).

The CCCRP supports additional aspects of casualty care. These include drugs, devices, and/or novel surgical techniques to decontaminate, debride, protect, monitor, repair, and/or stabilize hard and soft tissue wounds to mitigate secondary tissue damage; orthopaedic and maxillofacial trauma repair strategies; and the prevention and/or mitigation of wound infection and disease in austere environments. The CCCRP is also interested in the development of sensors; diagnostic and prognostic algorithms; data gathering or capture modalities; processors to improve our capability for remote triage, monitoring, and management of casualties; and products to maintain casualties during prolonged evacuation.

The CCCRP also supports the conduct of military-relevant clinical research aimed at translating knowledge or materiel from basic and preclinical trauma research into clinical practice. This includes, but is not limited to, single- and multi-center clinical trials performed in the civilian setting to clarify the safety, efficacy, and optimal use of products stemming from the previously mentioned research areas.

The CCCRP supports the conduct of military-relevant, large data research projects including the use of large databases of common elements from trauma research projects (preclinical, translational, and clinical). Such studies should directly contribute to or effectively enable the data-driven conduct of combat casualty care. Examples include, but are not limited to, post-hoc analysis of data from completed trauma research projects, meta-analyses of a number of otherwise separate but completed studies, and the ability to harmonize data from planned or ongoing but otherwise separate research studies.

The Research Areas of Interest to the CCCRP are found in [Appendix I.II](#). Applicants are urged to read and consider these before preparing their proposals/applications.

II.A.3. Military Operational Medicine Research Program

The mission of the Military Operational Medicine Research Program (MOMRP) is to preserve and enhance the performance of Service members; to develop effective biomedical countermeasures against operational stressors; and to prevent and mitigate physical and psychological injuries and threats during training and operations in order to maximize, optimize and enhance health, medical readiness of Service members and their families, in support of the Army Biomedical Performance Enhancement (BPE), Human Dimension, Multi-Domain Operations (MDO), Soldier Lethality, Dense Urban Environment/Subterranean Operations, Army Big 6 Modernization Priorities (see below), and the DoD Total Force Fitness (TFF) concepts.

The highest priorities of the MOMRP are the support of the Army's six modernization priorities:

1. Long-Range Precision Fires
2. Next-Generation Combat Vehicle
3. Future Vertical Lift Platforms
4. Army Network
5. Air and Missile Defense
6. Soldier Lethality

The MOMRP provides the planning, programming, and budgeting of biomedical research to deliver products and solutions to Service members and their families that address readiness, health, and performance throughout the Service member lifecycle, to include their time in garrison and the deployed environments. The MOMRP is centered on cutting-edge scientific research and providing "Science to the Service member" on the battlefield and at home in a relevant, timely manner.

The MOMRP supports research focused on addressing and delivering actionable solutions for critical biomedical problems facing the military today and in the future. Service- and platform-specific issues are addressed through close coordination with all Services to prevent unnecessary duplication of effort.

The MOMRP is divided into four Research Areas of Interest (with examples of types of research efforts shown in parentheses): (1) *Environmental Health and Protection* (performance optimization and biomarker validation during extreme environmental [heat/cold/altitude] and contaminant/toxicological exposures; validated exposure assessment metrics and tools for critical military environmental chemical threats influencing performance readiness); (2) *Injury Prevention and Reduction* (validated military performance assessment tools and metrics, physiological mechanisms of musculoskeletal injury, countermeasures against aviation stressors; blast, blunt trauma, and accelerative injury prevention strategies; and musculoskeletal injury return-to-duty standards and strategies); (3) *Physiological Health and Performance* (biomedical performance enhancement, performance and recovery nutrition, weight balance optimization,

cognitive health and performance sustainment in the face of operational challenges, restorative sleep, and resilience to operational and environmental stressors, and the medical aspects of manned-unmanned teaming [MUM-T]); and (4) *Psychological Health and Resilience* (post-traumatic stress disorder [PTSD], suicide prevention and risk reduction, resilience [including military families], substance abuse prevention, and violence prevention within the military).

More information on these Research Areas of Interest can be found in [Appendix I.III](#).

Applicants are urged to read and consider these before preparing their proposals/applications.

The MOMRP is particularly interested in proposals/applications and products that incorporate integrated biomedical approaches (e.g., systems biology). Proposals/Applications are encouraged to leverage existing resources and infrastructure to support lifecycle logistics and sustainability. For more information, refer to Section II.D.2.a.iv, [Attachment 7, Data- and Research Resource-Sharing Plan](#).

Guidance for research studies targeting military families and children: (1) In accordance with Department of Defense Instruction (DoDI) 1402.5 and Army Directive 2014-23, Child Care National Agency Check and Inquiries (CNACI), background investigations are required for all individuals who have regular contact with military dependents under 18 years of age. All individuals who regularly interact with children under 18 years of age in Army-sponsored and -sanctioned programs are required to undergo specific initial background checks and periodic re-verifications. Investigators who propose work involving contact with military dependents under 18 years of age should plan for the additional time and funds required for such investigations. (2) Per Department of Defense Education Activity (DoDEA) Administrative Instruction 2071.3, DoDEA approval is required for research studies involving DoDEA school personnel, school facilities, students, sponsors, and/or data. Investigators proposing to conduct any research activities involving DoDEA schools should plan for the additional time (~3-6 months) and effort required to obtain approval from DoDEA to conduct such activities. Procedures and requirements for the review and approval of a research study request can be found at <http://www.dodea.edu/datacenter/research/requests.cfm>.

Guidance for research studies targeting DoD personnel for survey research: Protocols that target DoD personnel for research in which the primary data collection tool is a survey require additional administrative review per DoDI 1100.13. Investigators will need to coordinate with the USAMRMC, Human Research Protection Office (HRPO), to identify current submission requirements.

II.A.4. Clinical and Rehabilitative Medicine Research Program

The Clinical and Rehabilitative Medicine Research Program (CRM RP) focuses on the innovations required to reset our wounded Service members, both in terms of duty performance and quality of life. Innovations developed from CRM RP-supported research efforts are expected to improve restorative treatments and rehabilitative care to maximize function for return to duty (RTD) or civilian life. Medical technologies (drugs, biologics, and devices) and treatment /rehabilitation strategies (methods, guidelines, standards, and information) that will significantly improve the medical care our wounded Service members receive within the DoD healthcare system are of particular interest. Implementation of these technologies and strategies should

improve the rate of RTD of Service members, the time to RTD, clinical outcome measures, and quality of life, as well as 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 military-relevant conditions in wounded Service members, as well as those that incorporate a systems biology approach, are of interest to the CRMRP when they can be used to identify and describe, in a predictable manner, the safety and efficacy of novel technologies in patients. For more information, refer to Section II.D.2.a.iv, [Attachment 7, Data- and Research Resource-Sharing Plan](#).

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

All projects should adhere to a core set of reporting standards for rigorous study design. The CRMRP strongly encourages award recipients to follow the Animal Research: Reporting *In Vivo* Experiments (ARRIVE) guidelines (http://www.elsevier.com/_data/promis_misc/622936arrive_guidelines.pdf). While these standards are written for animal studies, the basic principles of randomization, blinding, sample size estimation, and data handling derive from well-established best practices in clinical studies and should be applied to those projects as well.

The Research Areas of Interest to the CRMRP are found in [Appendix I.IV](#). Applicants are urged to read and consider these before preparing their proposals/applications.

II.A.5. Medical Biological Defense Research Program

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

The Medical Biological Defense Research Program (MBDRP) 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. The MBDRP is interested in

applications and products incorporating a systems biology approach. For more information, refer to Section II.D.2.a.iv, [Attachment 7, Data- and Research Resource-Sharing Plan](#).

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

The Research Areas of Interest to the MBDRP are found in [Appendix I.V](#). Applicants are urged to read and consider these before preparing their proposals/applications.

II.A.6. Medical Chemical Defense Research Program

The DTRA JSTO-CBD manages research directed toward medical chemical defense; the program has limited funding for proposals/applications submitted through the USAMRMC BAA. DTRA also seeks proposals/applications for its requirements through FedBizOpps and DoD SBIR program solicitations. For information on DTRA business opportunities, visit its website at <http://www.dtra.mil/Contracts/BusinessOpportunities.aspx>.

The Medical Chemical Defense Research Program (MCDRP) seeks to preserve combat effectiveness through timely provision of medical countermeasures in response to Joint Service Chemical Warfare Defense Requirements. The fundamental orientation of the program is to protect U.S. Forces from the effects of chemical warfare agents by developing protective, pretreatment, and prophylactic products, providing products usable by the individual Service member for immediate treatment of chemical warfare agent exposures, developing antidotes/therapeutics to chemical warfare agents, defining care procedures for chemical warfare agent casualties, and advancing management of these casualties. The medical countermeasures are intended to preserve and sustain the Service members' combat effectiveness in the face of combined threats from chemical and conventional munitions on the integrated battlefield. The MCDRP is interested in applications and products incorporating a systems biology approach. For more information, refer to Section II.D.2.a.iv, [Attachment 7, Data- and Research Resource-Sharing Plan](#).

The broad goals of this program are described below.

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

exploiting molecular modeling and quantitative structure-activity relationships in support of drug discovery and design.

b. Provide medical countermeasures for the individual Service member to maintain combat effectiveness and prevent or reduce injury from chemical warfare agents: This goal encompasses research supporting development of new concepts for prophylaxes, pretreatments, antidotes, and therapeutic countermeasures; development of skin protectants and decontaminants; identification of factors that 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 RTD 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 U.S. have not materially reduced the threat that chemical weapons present to American Forces in the field. Many 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 U.S.

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).

The Research Areas of Interest to the MCDRP are found in [Appendix I.VI](#). Applicants are urged to read and consider these before preparing their proposals/applications.

II.A.7. Medical Simulation and Information Sciences Research Program

The mission of the Medical Simulation and Information Sciences Research Program (MSISRP) is to explore the implications of models and technology for medical education and for the provision, management, and support of health services in the military. The MSISRP plans, coordinates, and oversees a responsive world-class, tri-Service science and technology program focused on three areas of research. The first area is focused on improving military medical training through medical modeling, simulation, educational gaming, assessment systems, interoperable training platforms, and objective training metrics. The second area is focused on developing, researching, and/or improving technologies and informatics that support Theater and Operational Medicine, such as the capture, movement, storage, usability, use, and sharing of health-related data for better clinical care, strategic planning, process development, and software applications. The third area is focused on the Multi-Domain Operations, an operational environment involving greater dispersion and near isolation over great distances, which is likely to cause severe restrictions on mobility for medical missions and shortfalls in both human and materiel human resources due to area denial challenges. Combat units will need to be more self-sufficient and less dependent on logistical support. Combatant commanders with increased sick

or wounded Soldiers will face degradation of medical resources and encumbered combat effectiveness without new combat casualty management and Force multiplication strategies.

MSISRP is organized into three portfolios, one for each of the three focus areas.

The sub-focus areas and Research Areas of Interest to the MSISRP are found in [Appendix I.VII](#). Applicants are urged to read and consider these before preparing their proposals/applications.

II.A.8. Radiation Health Effects Research Program

The Radiation Health Effects Research Program (RHERP) focuses on developing medical countermeasures for acute ionizing radiation injury. The program has interest in the following research focus areas: post-exposure mitigation of radiation injury; protection and prevention of injury from ionizing radiation exposure (prophylaxis); mechanism of radiation injury; and development of novel biodosimetry tools. Research Areas of Interest to the RHERP are found in [Appendix I.VIII](#). The RHERP is interested in applications and products incorporating a systems biology approach. For more information, refer to Section II.D.2.a.iv, [Attachment 7, Data- and Research Resource-Sharing Plan](#).

II.A.9. Other Information

II.A.9.i. Clinical Trial Support

Investigator(s) proposing a clinical trial should refer to [Appendix II](#) for a detailed description of the requirements for such a proposal/application. The pre-proposal/pre-application submission process should be performed as described in [Section II.D.2.a.i](#). Full proposal/application submission is described in [Appendix II.B](#). Refer to the [Clinical Trial Submission Checklist](#) in preparing the full proposal/application.

A clinical trial is defined as a prospective accrual of human subjects where one or more intervention(s) (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. The term “human subjects” is used in this BAA to refer to individuals who will be recruited for or who will participate in the proposed clinical trial. For more information, a Human Subject Resource Document is provided at <https://ebrap.org/eBRAP/public/Program.htm>.

If the proposed clinical trial involves the use of a drug that has not been approved by the U.S. Food and Drug Administration (FDA) for the proposed investigational use, then an IND application to the FDA that meets all requirements under the Code of Federal Regulations, Title 21, part 312 (21 CFR 312) may be required. *If invited to submit a full proposal/application, the investigator(s) must submit an IND application to the FDA on or before the date of proposal/application submission. If the investigational product is a device, evidence that an Investigational Device Exemption (IDE) application that meets all requirements under 21 CFR 812 has been submitted to the FDA by the application submission deadline, or that the device is exempt or qualifies for an abbreviated IDE, is required.* The Government reserves the right to withdraw funding if an IND or IDE is necessary but has not been submitted to the FDA

prior to the grant submission deadline, or if documented status of the IND or IDE has not been obtained within 6 months of the award date.

II.A.9.ii. Conference or Symposium Support

The USAMRMC may, on a very limited basis, provide financial support for the management and execution of conferences or symposia that are critical to USAMRMC's mission. Funding for conference or symposium support may require approval outside of the USAMRMC and will only be considered if the event significantly furthers the mission of the DoD and has a quantifiable benefit or return on investment. If a conference or symposium proposal/application is selected for funding, the award will be issued as a contract.

II.A.9.iii. Use of Military and Department of Veterans Affairs (VA) Populations or Resources

Principal Investigators (PIs) are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs, and existing clinical trial networks. Collaboration with the DoD or VA is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DoD and VA areas of research interest or potential opportunities for collaboration can be found in [Appendix III](#).

If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the PI is responsible for demonstrating such access at the time of proposal/application submission and should develop a plan for maintaining access as needed throughout the proposed research. Access to target active duty military patient population(s) and/or DoD resource(s) or database(s) should be confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief. If appropriate, the proposal/application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the proposal/application should include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

Access to certain DoD or VA patient populations, resources, or databases may only be obtained by collaboration with a DoD or VA investigator who has a substantial role in the research and may not be available to a non-DoD or non-VA investigator if the resource is restricted to DoD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DoD or non-VA investigator collaborating with the DoD and/or VA. If access cannot be confirmed at the time of proposal/application submission, the

Government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s).

Use [Attachment 2, Supporting Documentation](#), to provide this documentation.

II.a.9.iv Technology Requirements and Standards

Any technology-based research products/prototypes (such as devices, mobile apps, software, information technology [IT] infrastructure, etc.) that expect to interact with military health IT systems should conform with accepted industry and DoD Information Management/IT standards for interoperability, cybersecurity, as well as the DoD Architecture Framework (DoDAF) and viewpoints. Additionally:

- a. Any products expected to provide data to Military Health System (MHS) Genesis, the new DoD Military Electronic Health Record system (which is the military version of Cerner Millennium commercial-off-the-shelf electronic health record), should be aimed toward meeting the Health Level 7 (HL7) and Fast Healthcare Interoperability Resources (FHIR) standards in order to ultimately provide integration with MHS Genesis.
- b. All software-based research products including computer code, software code, data and meta-data should be provided as deliverables, and electronic versions need to be able to be uploaded to standards-based electronic repositories.
- c. The approved DoD Mobile Solution is Samsung's Android mobile phone and tablet.

II.a.9.v. Data Sharing

The USAMRMC intends that information, data, and research resources generated under awards funded by this BAA be made available to the research community and to the public at large. The Government reserves the right to identify repositories for submission of data for archive. For additional guidance, refer to the General Submission Instructions, Appendix 2, Section K.

A number of research areas utilize Common Data Elements (CDEs) to facilitate the sharing of data to promote collaboration, accelerate research, and advance knowledge in specific topic areas. In accordance with the White House Office of Science and Technology Policy memorandum "Increasing Access to the Results of Federally Funded Research" and Executive Order (EO) 13625 and the National Research Action Plan (NRAP) responding to the EO "Improving Access to Mental Health Services for Veterans, Service Members, and Families (August 31, 2012)," Federally funded research is required to be conducted in a manner that promotes public access to scientific data. In cases of psychological health and TBI, use of CDEs is required under the NRAP. The USAMRMC strongly encourages applicants to incorporate CDE measures appropriate to each field of study, such as:

- PhenX Core and Specialty collections, which are available in the Mental Health Research, Substance Abuse and Addiction, and Research Domains Collections of the PhenX Toolkit, <https://www.phenxtoolkit.org/index.php>, in all studies involving human subjects, as applicable.

- TBI CDEs related to Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system data sharing requirements, which can be found at <http://fitbir.nih.gov>.
- Spinal cord injury research CDEs developed through the collaboration of the International Spinal Cord Society, the American Spinal Injury Association, and the National Institute of Neurological Disorders and Stroke CDE team, as referenced at <http://www.commondataelements.ninds.nih.gov/SCI.aspx>.

If the project includes the collection of bio-fluids, such as blood, saliva, urine, etc., the PI may be required to include a set of collection variables and patient phenotypic data in order to standardize the quality of bio-fluid studies. The suggested procedures for acquisition, processing, storage, and shipment of bio-fluids can be found in [Appendix IV](#).

II.B. Award Information

II.B.1. Funds Available and Anticipated Number of Awards

The funding amount for this BAA is unspecified, and the number of awards is indeterminate and contingent upon funding availability. Selection of research projects is a highly competitive process and is based on the evaluation of the proposal/application's technical merit, programmatic considerations, and the availability of funds. The quantity of meaningful submissions received normally exceeds the number of awards that the available funding can support. Any funding that is received by the USAMRMC and is appropriate for a research area described within this BAA may be utilized to fund proposals/applications.

II.B.2. Award Amounts and Periods of Performance

There are no specified funding limitations identified for a proposal/application submitted under this BAA. A budget should be commensurate with the nature and complexity of the proposed research. Researchers should submit budgets that include the entire period of performance of the research project. Budgets should include all direct and indirect costs, based on supportable, verifiable estimates. The budget for the full proposal/application should not differ significantly from the Pre-Application Budget Summary Form provided in the pre-proposal/pre-application submission.

Period of performance may differ depending upon the type of funding mechanism awarded under this BAA. For an assistance agreement, the total period of performance may be proposed for up to 4 years in length; additional periods may be considered. For research support contract awards, the total period of performance may be proposed for up to 5 years in length. For conference or symposium support contract awards, the total period of performance may be proposed for up to 2 years in length. Because the nature and scope of each proposed research project will vary, it is anticipated that the size and duration of each award will vary. Start dates will vary, depending on when proposals/applications were submitted and reviewed and the negotiation process. However, no proposal/application submitted under this BAA will be considered for funding after 24 months from the date of submission.

PIs seeking additional or continuation funding must submit new pre-proposals/ pre-applications and be invited to submit full proposals/applications.

Refer to the General Submission Instructions, Section III.A.5, for additional information regarding the research and related budget.

II.B.3. Mechanisms of Support

The USAMRMC executes its extramural research program primarily through the awarding of contracts and assistance agreements (grants and cooperative agreements). The type of instrument used to reflect the business relationship between the organization and the Government is at the discretion of the Government, in accordance with the Federal Grant and Cooperative Agreement Act of 1977, as amended, 31 USC³ 6301-6308, which provides the legal criteria to select a procurement contract or an assistance agreement. Refer to the General Submission Instructions, Appendix 2, for additional information.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organizations

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

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

The 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/ applications submitted through this BAA.

Government Agencies Within the United States: Local, state, and Federal Government agencies are eligible to the extent that proposals/applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their proposals/ applications do not overlap with their internal programs.

³ United States Code

II.C.1.b. Investigator(s)

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

Investigators are cautioned that awards are made to organizations only, not individuals.

II.C.2. Cost Sharing

Cost sharing or matching is not required under this BAA.

II.C.3. Other

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

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

Conflicts of Interest: All awards must be free of conflicts of interest (COIs) that could bias the research results. Prior to award of an assistance agreement or contract, applicants will be required to disclose all potential or actual COIs along with a plan to manage them. An award may not be made if it is determined by the Grants Officer or Contracting Officer that COIs cannot be adequately managed. Refer to the General Submission Instructions, Appendix 3, for additional information.

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

Subcontracting Plan: If the resultant award is a contract that exceeds \$700,000 and the offeror is other than a small business, the contractor will be required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.704 and AFARS 5119.704. A mutually agreeable plan will be incorporated as part of the resultant contract.

I.I.D. Proposal/Application Submission Information

I.I.D.1. Where to Obtain the Proposal/Application Submission Package

To obtain the complete Grants.gov proposal/application package (hereinafter, submission package), including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number **W81XWH18SBAA1**.

Submission is a two-step process requiring both (1) pre-proposal/pre-application submission through eBRAP (<https://eBRAP.org/>) and (2) full proposal/application submission through Grants.gov or eBRAP, depending on the type of proposal/application being submitted.

I.I.D.2. Content and Form of the Proposal/Application Submission for Research Awards Not Including a Clinical Trial

NOTE: Investigator(s) proposing a clinical trial should refer to [Appendix II](#) for a detailed description of the requirements for such a proposal/application. For the content and form of proposal/application submissions requesting conference or symposium support, see [Section I.I.D.2.b](#).

Submission of a pre-proposal/pre-application is required and must be submitted through eBRAP (<https://eBRAP.org/>). If the USAMRMC is interested in receiving a full proposal/application, the PI will be sent an invitation via eBRAP to submit. eBRAP is a multifunctional web-based system that allows PIs to submit their pre-proposals/pre-applications electronically through a secure connection, to view and edit the content of their pre-proposals/pre-applications and full proposals/applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

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

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

Because the invitation to submit a proposal/application is based on the contents of the pre-proposal/pre-application, a PI should not change the title or research objectives after the pre-proposal/pre-application is submitted. The PI and organization identified in the pre-proposal/pre-application should be the same as those intended for the full proposal/

application submission. If any changes are necessary after submission of the pre-proposal/pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507. A change in PI or organization after submission of the pre-proposal/pre-application will be allowed only at the discretion of the USAMRAA Contracting or Grants Officer.

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

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

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

During the pre-proposal/pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the full proposal/application submission process.

All pre-proposal/pre-application components must be submitted through eBRAP (<https://eBRAP.org>). Because the invitation to submit a proposal/application is based on the contents of the pre-proposal/pre-application, investigators should not change the title or research objectives after the pre-proposal/pre-application is submitted.

PIs and organizations identified in the pre-proposal/pre-application should be the same as those intended for the subsequent proposal/application submission. If any changes are necessary after submission of the pre-proposal/pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

The pre-proposal/pre-application consists of the following components, which are organized in eBRAP by separate tabs for each proposal/application type. Select "Research," "Research Including Clinical Trial," or "Conference/Symposium" when initiating the proposal/application. Refer to the General Submission Instructions, Section II, for additional information on pre-proposal/pre-application submission.

- **Tab 1 – Application Information**

Enter the information as described in eBRAP before continuing the pre-proposal/pre-application.

- **Tab 2 – Application Contact**

Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 Form). The Business Official must either be selected from the eBRAP list or invited for the pre-proposal/pre-application to be submitted.

Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on “Add Organizations to this Pre-application.” The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-proposal/pre-application to be submitted.

It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-proposal/pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

Enter the name, organization, and role of all collaborators and key personnel associated with the pre-proposal/pre-application.

- **Tab 4 – Conflicts of Interest**

List all individuals other than collaborators and key personnel who may have a conflict of interest (COI) in the review of the pre-proposal/pre-application (including those with whom the PI has a personal or professional relationship).

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

Refer to the General Submission Instructions, Appendix 3.D, for additional information. For questions related to COI, contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 5 – Required Files**

NOTE: No figures, charts, graphs, or other additional material will be accepted during the pre-proposal/pre-application process.

Provide responses in the appropriate data fields for the following in eBRAP. **EVERY DATA FIELD MUST CONTAIN COMPLETE INFORMATION.** eBRAP will truncate characters exceeding the limit specified for each data field. Enter “none” if there is no information to be included.

- Problem To Be Studied (4,000 character limit, including spaces).
- Theoretical Rationale, Scientific Methods, and Design (4,000 character limit, including spaces).
- Significance and/or Uniqueness of the Proposed Effort (4,000 character limit, including spaces).
- Military Relevance and Impact (4,000 character limit, including spaces).
- Brief Description of Research Involving Animals, Human Anatomical Substances and/or Human Subjects (4,000 character limit, including spaces).
- Plans and Strategy for Translation, Implementation, and/or Commercialization (4,000 character limit, including spaces).

Upload document(s) as individual PDF file(s). eBRAP will not allow a document to be uploaded in the Required Files tab if the number of pages exceeds the limits specified below.

- Budget Summary: Upload as “BudgetSummary.pdf.” Complete the two-page Budget Summary Form (available for download in eBRAP) as instructed.
- PI and Key Personnel Biographical Sketches (five-page limit per individual): Use boldfaced type or highlight titles of publications relevant to the proposed project. All biographical sketches should be uploaded as a single combined file.

Refer to the General Submission Instructions, Section II.C, for detailed information.

- **Tab 6 – Submit Pre-Application**

This tab must be completed for the pre-proposal/pre-application to be accepted and processed.

Pre-Proposal/Pre-Application Screening

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

Notification of Pre-Proposal/Pre-Application Screening Results

Following the pre-proposal/pre-application screening, PIs will be notified as to whether or not they are invited to submit full proposals/applications; however, they will not receive feedback

(e.g., a critique of strengths and weaknesses) on their pre-proposals/pre-applications. Within 120 days of submission, PIs should receive email notification via eBRAP regarding disposition of their pre-proposals/pre-applications.

II.D.2.a.ii. Step 2: Full Proposal/Application Submission Content

Proposals/Applications will not be accepted unless the PI has received notification of invitation.

All contributors and administrators to the proposal/application must use matching compatible versions of Adobe software when editing and preparing proposal/application components. The use of different software versions will result in corruption of the submitted file. Refer to the General Submission Instructions, Section III, for details on compatible Adobe software.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each proposal/application submission must include the completed full submission package for this BAA. The full submission package is submitted by the Authorized Organizational Representative through Grants.gov (<http://www.grants.gov/>).

II.D.2.a.iii. Full Proposal/Application Submission Guidelines

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

To submit the proposal/application package, create a Grants.gov Workspace. Add participants (investigators and Business Officials) to the Workspace, complete all required forms, and check for errors before submission. A proposal/application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the proposal/application package **at least 24-48 hours prior to the BAA closing date** to allow time to correct any potential technical issues that may disrupt the proposal/application submission.

NOTE: If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the proposal/application submission deadline.

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

The full proposal/application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the 5-day proposal/application verification period. During the proposal/application verification period, the full application package, *with the exception of the Project Narrative and Budget Form*, may be modified.

The organization’s Business Official or Authorized Organizational Representative (or Resource Manager/Comptroller) should approve/verify the full proposal/application submission prior to the end of the 5-day proposal/application verification period.

After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission. Refer to the General Submission Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.2.a.iv. Full Proposal/Application Submission Components

The Grants.gov Workspace submission package includes the following components (refer to the General Submission Instructions, Section III, for additional information on proposal/application submission). Note that components for a proposal/application including a clinical trial are provided in [Appendix II](#).

- **SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Submission Instructions, Section III.A.1, for detailed information.

Attachments

Each attachment to the full proposal/application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Submission Instructions, Appendix 4.

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or if they have incorrect file names, i.e., containing characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire full submission package may not exceed 200 MB.

- **Attachment 1: Project Narrative (20-page limit):** Upload as “ProjectNarrative.pdf.” There is no form for this information. The attachments must be PDF files in accordance with the formatting guidelines specified for full proposal/application preparation.

A detailed description of the research to be undertaken should be submitted. This should include the areas provided below and address their relationship to the state of knowledge

in the field and to comparable work in progress elsewhere. Evaluation of the proposed research will be influenced by the adequacy of this information.

Literature references and curriculum vitae will be shown in separate addenda entries. The following general outline should be followed:

- **Background:** Provide a brief statement of ideas and theoretical reasoning behind the proposed study. Describe previous experience most pertinent to this proposal/application. Cite relevant literature references. Include discussion of any findings (if available) from relevant pilot or preliminary work or any related work underway. For development of devices and technologies, provide an intellectual property plan as part of the [supporting documentation](#).
- **Hypothesis:** State the hypothesis to be tested and the expected results. For development of devices and technologies, discuss the technical feasibility of the proposed project including background of the problem, previous and current solutions, similar projects previously undertaken, and related development activities.
- **Technical Objectives:** State concisely the question to be answered by each research objective.
- **Project Milestones:** Identify timelines for critical events that must be accomplished in order for the project to be successful in terms of cost, schedule, and performance. For development of devices and technologies, discuss the timelines and provide a commercialization strategy/plan for the technology being developed.
- **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.
- **Public Purpose:** If appropriate, provide a concise, detailed description of how this research project will benefit the general public.
- **Methods:** Give details about the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation. For synthetic chemistry applications, include a clear statement of the rationale for the proposed syntheses. Outline and document the routes to the syntheses. For development of devices and technologies, discuss the engineering/technical design to achieve the project goals demonstrating the feasibility of the proposed product development. Discuss the perceived engineering/design strengths and flaws and recommendations for overcoming/preventing them. For studies involving human subjects, describe the recruitment plan and access to populations. The proposal/application should describe a plan for data access and sharing. (Access to subjects and data is the sole responsibility of the investigator.) As relevant, describe plans for addressing issues unique to working with military populations. For studies involving human and animal research, provide a statistical and data analysis plan. Describe the statistical model and data analysis plan with respect to the study objectives as appropriate to the type of study. For clinical studies and applied research involving

human subjects, specify the approximate number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. When possible, investigators should write protocols for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted proposal/application. Submission to HRPO of protocols covering more than the scope of work in the DoD-funded proposal/application will require HRPO review of the entire protocol as DoD-supported research and may include extensive modifications to meet DoD human subjects protection requirements.

- Additional Information: If human subjects, animals, or cadavers are involved in the research, proposals/applications may be submitted prior to obtaining human, animal, or cadaver protocol institutional approvals. However, protocols with required institutional approvals must be submitted no later than 60 days after award to demonstrate continued progress and ensure continuation of payment. The Contracting or Grants Officer may make exceptions in situations where human and/or animal use is not expected to begin until after the first year of the research project. In such cases, a timeframe for submission of the appropriate protocols and institutional approvals will be established prior to award.

PIs and collaborating organizations may not use, employ, or subcontract for the use of any human participants, including the use of human anatomical substances, human data, and/or human cadavers, or laboratory animals until applicable regulatory documents are reviewed and approved by the USAMRMC Office of Research Protections (ORP) to ensure that DoD regulations have been met.

- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
- For use of human anatomical substances, identify the commercial or organizational source(s) of the material. For cell lines, identify cell line(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.
- If applicable, indicate time required for submission and/or approval of documents (e.g., IND and IDE) to the FDA or appropriate Government regulatory agency.
- For studies involving human subjects, allow at least 2 to 3 months for regulatory review and approval by the USAMRMC HRPO; this does not include the additional time required for local Institutional Review Board (IRB) review and approval, as stated above.
- For animal studies, allow at least 2 to 3 months for regulatory review and approval by the USAMRMC Animal Care and Use Review Office; this does not include the additional time required for local Institutional Animal Care and Use Committee review and approval, as stated above.

- Refer to the General Submission Instructions, Appendix 1, for additional regulatory information.
- **Attachment 2: Supporting Documentation:** The attachment should be in PDF in accordance with the formatting guidelines specified for full proposal/application preparation. Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *There are no page limits for any of these components unless otherwise noted.*
 - Bibliography and References Cited: List the references in the order they appear in the proposal/application narrative. Use a reference format that gives the title of the citation. Do not send or attach copies of articles in print. There is no form for this information.
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
 - Facilities and Other Resources: Describe the facilities available for performance of the proposed research project and any additional resources proposed for acquisition at no cost to the award. Indicate if a Government-owned facility is proposed for use. Reference should be made to the original or present award under which the facilities or resources are now accountable. There is no form for this information.
 - Equipment: Include a description of existing equipment to be used for the proposed research project.
 - Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be attached.
 - Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. A letter from each organization involved in the project should be provided.
 - Collaboration: Provide letter(s) supporting stated collaborative efforts necessary for the project’s success, even if the collaboration is offered at no cost.
 - Use of DoD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military patient populations and/or DoD resources or databases.
 - Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the ACOS/R&D or Clinical Service Chief confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA NPC is not identified as the applicant institution for administering the funds, include a letter from the VA

ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

- *If the project involves collaboration with a Military Facility, special requirements apply.* A DoD researcher, to include collaborating DoD PIs, must obtain a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the research project. This letter must be included with the proposal/application.
- **Joint Sponsorship:** Describe present or prospective joint sponsorship of any portion of the program outlined in the proposal/application. In the absence of agreements among sponsors for joint support, the proposal/application should be structured so that the research can be carried out without the resources of any other sponsor. If, however, it is desirable to request partial support from another agency, the proposed plan should be stated and the reasons documented. If the plan cannot be formulated at the time the proposal/application is submitted, information should be sent later as an addendum to the proposal/application. Prior approval from both agencies must be secured for research to be undertaken under joint sponsorship. Provide letters of support related to recruitment, subject access, and data access plans.
- **Intellectual Property (if applicable):**
 - **Background and Proprietary Information:** All software and data first produced under the award are subject to a Federal purpose license. A term of the award requires the recipient to grant the Government all necessary and appropriate licenses, which could include licenses to background and proprietary information that have been developed at private expense.

Therefore, it is important to disclose/list any intellectual property (software, data, patents, etc.) that will be used in performance of the project or provide a statement that none will be used. If applicable, all proprietary information to be provided to the Government should be stated and identified; the applicant should indicate whether a waiver of the Federal purpose license will be required.
 - **Intellectual and Material Property Plan:** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.” The abstract is vitally important to both the scientific peer and programmatic review processes. In accordance with Section 8123 of the Consolidated and Further Continuing Appropriations Act, 2015 (Public Law 113-235), the PI is required to submit a technical abstract that fully describes the proposed work. The abstract must contain the title of the project and the name of the PI. Do not include figures or tables in the abstract. Use only characters available on a standard QWERTY keyboard. Spell out all Greek or other non-English letters. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.***

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

- Background: Provide a brief statement of the ideas and theoretical reasoning behind the proposed work.
 - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
 - Specific Aims: State concisely the specific aims of the study.
 - Study Design: Briefly describe the study design.
 - Relevance: Provide a brief statement explaining the potential relevance of the proposed work to the specific topic area being addressed and its impact on health outcomes.
- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.” The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. *Do not include proprietary or confidential information.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the outline below. Do not duplicate the technical abstract.

- Clearly describe the objectives and theoretical reasoning behind the proposed work in a manner readily understood by readers without a background in science or medicine.
 - Clearly describe the problem or question to be addressed and the ultimate applicability and impact of the research.
 - What types of patients will it help, and how will it help them? Include the current available statistics to the related injury/condition.
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected timeline it may take to achieve the expected patient-related outcome?
 - Describe how the proposed project will benefit Service members, Veterans, and/or their family members.
- **Attachment 5: Statement of Work (SOW) (two-page limit):** Upload as “SOW.pdf.” The SOW outlines and establishes the performance expectations and milestones for which the USAMRMC may provide funding. The SOW will be incorporated into the award document and, as such, is subject to release under the Freedom of Information Act. The SOW should identify all collaborating research sites involved in the performance of

the research. Suggested SOW formats and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>).

A series of relatively short statements should be included that comprise the approach to each of the major goals or objectives of the proposed research. The statements should outline the specific tasks, systems, key assessments/techniques, and materials that are reasonable estimates for testing the proposed hypotheses of the study. A timeline should be included that shows the work statements to be accomplished in each year of the award. Any animal use and/or human subjects recruitment should be included. Allow at least 2 to 3 months for the USAMRMC ORP regulatory review and approval processes for studies involving human subjects and 2 to 3 months for studies involving animal subjects.

- **Attachment 6: Impact/Outcomes Statement (one-page limit):** Upload as “Impact.pdf.” Explain the potential impact of the research in the field, the significance of this impact, and when it can be anticipated. Explain how the results of this research are expected to impact the intended beneficiaries. Expand upon the dual (military and public) purpose for the research, as appropriate.
- **Attachment 7: Data- and Research Resource-Sharing Plan (one-page limit):** *All data must be shared while ensuring appropriate protection of information.* Upload as “Sharing.pdf.” Describe how unique and/or final research data will be shared with the research community, along with any resulting research resources. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the proposed project. If there are limitations associated with a pre-existing agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data- and/or research resource-sharing plan. For projects involving clinical trials, PIs may be required to register their clinical trials on Clinicaltrials.gov (<https://clinicaltrials.gov/>). For projects involving TBI, PIs may be required to report data to the FITBIR informatics system (<http://fitbir.nih.gov/>). If the project includes systems biology-related research, the PI may be required to make the systems biology data, generated via an award, available to the research community by depositing research data into the SysBioCube system (<https://sysbiocube-abcc.ncifcrf.gov>). For studies that will enroll subjects with psychological health disorders, awardees may be requested to submit data to the National Institute of Mental Health Data Archive (NDA) <https://data-archive.nimh.nih.gov>. The NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share de-identified information with each other. Such studies may require the inclusion of specific language in the informed consent form which references the NDA (see [Appendix V](#)).

Refer to the General Submission Instructions, Appendix 2.K, for additional information.

- **Attachment 8: Transition Plan and Regulatory Strategy:** Upload as “Transition.pdf.” Provide information on the methods and strategies proposed to move the anticipated research outcomes (e.g., knowledge, models, devices, technologies, interventions) from this project to the next level (e.g., additional research, clinical trials,

delivery to the military or civilian market, incorporation into clinical practice) after successful completion of the award. Applicants are encouraged to work with their organization's Technology Transfer Office to develop the transition plan. The transition plan should include the components listed below, as applicable.

- Details of the funding strategy that will be used to bring the outcomes to the next level (e.g., specific potential industry partners, specific funding opportunities to be pursued).
- Description of collaborations and other resources that will be used to provide continuity of development.
- Brief schedule/timeline and milestones for bringing the outcome(s) to the next level.
- For knowledge outcomes, a description of what will be further developed and how it will be disseminated, and incorporated into clinical care.
- Identification of the anticipated regulatory strategy (e.g., additional non-clinical or clinical studies anticipated/required, FDA or regulatory authority meetings desired, industry partnerships) for movement of the research into later phases of development and to support a potential marketing application (e.g., New Drug Application, Biologics License Application).
- Outline of ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the Government's ability to access such products or technologies in the future.
- Evidence for involvement of appropriate intellectual property, licensing, and/or business professionals.
- A risk analysis for cost, schedule, manufacturability, and sustainability.
- A commercialization strategy including intellectual property, market size, financial analysis, strengths and weaknesses, barriers to market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- **Attachment 9: Collaborating DoD Military Facility Budget Form(s), if applicable:** Upload as "MFBudget.pdf." If a Military Facility will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form (available for download on eBRAP "Funding Opportunities and Forms" web page), including a budget justification for each year. If more than one Military Facility is proposed, submit a separate budget form for each site. Refer to the General Submission Instructions, Section III.A.5, for detailed information.

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 et seq.), the DoD is collecting certain demographic and career information to be able to assess

the success rates of women who are proposed for key roles in applications in science, technology, engineering, or mathematics (STEM) disciplines. To enable this assessment, each proposal/application must include the following forms completed as indicated.

Research & Related Personal Data: Refer to the General Submission Instructions, Section III.A.3, for detailed information.

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

- PI Biographical Sketch (five-page limit): Upload as “Biosketch_LastName.pdf.”
- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch_LastName.pdf.”
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”

Research & Related Budget: Refer to the General Submission Instructions, Section III.A.5, for detailed information.

Budget Justification (no page limit): Upload as “BudgetJustification.pdf.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

Project/Performance Site Location(s) Form: Refer to the General Submission Instructions, Section III.A.6, for detailed information.

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

NOTE: Proposals/Applications from **Federal agencies** must include in their budget justifications a **Federal Financial Plan**. Proposals/Applications from organizations that include **collaborations with DoD Military Facilities** must comply with special requirements. Refer to the General Submission Instructions, Section III.A.5, Research & Related Budget, for detailed information.

II.D.2.b. Content and Form of the Proposal/Submission Information for Conference or Symposium Support

II.D.2.b.i. Where to Obtain the Proposal/Application Submission Package

To obtain the complete Grants.gov proposal package (hereinafter, submission package), including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number **W81XWH18SBAA1**.

Submission is a two-step process requiring both pre-proposal submission and full proposal submission through eBRAP (<https://eBRAP.org/>).

II.D.2.b.ii. Content and Form of the Proposal Submission

Refer to [instructions for research proposal submission](#) for details on the use of eBRAP.

II.D.2.b.iii. Step 1: Pre-Proposal Submission Content

During the pre-proposal process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the full proposal submission process.

All pre-proposal components must be submitted through eBRAP (<https://eBRAP.org/>). Because the invitation to submit a proposal is based on the contents of the pre-proposal, investigators should not change the title or research objectives after the pre-proposal is submitted.

PIs and organizations identified in the pre-proposal should be the same as those intended for the subsequent proposal submission. If any changes are necessary after submission of the pre-proposal, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

The pre-proposal consists of the following components, which are organized in eBRAP by separate tabs. Refer to the General Submission Instructions, Section II, for additional information on pre-proposal submission.

- **Tab 1 – Application Information**

- Enter the information as described in eBRAP before continuing the pre-proposal.

- **Tab 2 – Application Contact**

- Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration. The Business Official must either be selected from the eBRAP list or invited for the pre-proposal to be submitted.
- Select the performing organization (site at which the PI will perform the proposed work) and contracting organization (organization submitting on behalf of the PI), and click on “Add Organizations to this Pre-application.” The organization(s) must either be selected from the eBRAP drop-down list or invited for the pre-proposal to be submitted.
- It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-proposal submission is needed.

NOTE: The eBRAP system does not require approval of the pre-proposal by the PI’s organization.

- **Tab 3 – Collaborators and Key Personnel**

- To enable the USAMRMC to avoid COI during the screening and review processes, list the name, organization, and role of all participants in the proposed conference or symposium support, including collaborators, consultants, and subrecipients/subawardees.

- **Tab 4 – Conflicts of Interest**

- List all individuals other than collaborators and key personnel who may have a COI in the review of the pre-proposal (including those with whom the PI has a personal or professional relationship).

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

Refer to the General Submission Instructions, Appendix 3.D, for additional information. For questions related to COI, contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 5 – Required Files**

NOTE: Figures, charts, graphs, or other additional material will not be accepted during the pre-proposal process.

Provide responses in the appropriate data fields for the following in eBRAP. DO NOT LEAVE ANY FIELDS BLANK. eBRAP will truncate characters exceeding the limit specified for each data field. Enter “none” if there is no information to be included.

- Conference or Symposium Objectives: (4,000 character limit, including spaces).
- Impact and Outcomes of the Proposed Conference or Symposium: (2,000 character limit, including spaces).
- Proposed Budget to Include Direct and Indirect Costs: (1,000 character limit, including spaces).
- PI and Key Personnel Biographical Sketches (five-page limit per individual): Use boldfaced type or highlight titles of publications or specific expertise relevant to the proposed conference or symposium support. All biographical sketches should be uploaded in a single combined file.
- Refer to the General Submission Instructions, Section II, for detailed information.

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

Pre-Proposal Screening

USAMRMC scientists or outside experts will screen pre-proposals for technical merit and programmatic considerations. Based on the screening of the pre-proposal, a PI may be invited to submit a full proposal.

Notification of Pre-Proposal Screening Results

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

II.D.2.b.iv. Step 2: Full Proposal Submission Components for Conference or Symposium Support

eBRAP submission package components: For the FY18-FY22 BAA Conference or Symposium Support contract award, the eBRAP submission package includes the following components, which are organized in eBRAP by separate tabs. To access these tabs, go to “My Applications” and click on “Start Full Application” for the log number under which the pre-proposal was submitted.

- **Tab 1 – Summary:** Provides a summary of the proposal information.
- **Tab 2 – Application Contacts:** This tab will be populated by eBRAP. Add Authorized Organizational Representative.
- **Tab 3 – Full Application Files:** Under each Application Component in eBRAP, upload each as an individual PDF file. Refer to the General Submission Instructions, Appendix 4, for detailed formatting guidelines.

Proposal Component: Attachments: Each attachment must be uploaded as an individual PDF file unless otherwise stated.

- **Attachment 1: Conference or Symposium Objectives: (five-page limit):** Upload as “Objectives.pdf.” The page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the conference or symposium. Inclusion of URLs that provide additional information to expand the Conference or Symposium Objectives and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the proposal.

A detailed description of the conference or symposium to be undertaken should be submitted. This should include the areas listed below and address the relevance to the

USAMRMC mission. Evaluation of the proposed conference or symposium will be influenced by the adequacy of this information.

- Literature-relevant publications and curriculum vitae will be shown in separate addenda entries. The following general outline should be followed:
 - **Background:** Provide a brief statement of ideas and theoretical reasoning behind the proposed conference or symposium. Describe previous experience most pertinent to this proposal such as participation in professional societies and attendance at other relevant meetings. Cite relevant literature references.
 - **Technical Objectives:** State concisely the question(s) to be answered during the conference or symposium, and how the outcomes of the conference or symposium will benefit the USAMRMC mission.
 - **Project Milestones:** Identify timelines for critical events that must be accomplished in order for the conference or symposium to be successful in terms of cost, schedule, performance, and outcomes.
- **Attachment 2: Agenda (two-page limit):** Upload as “Agenda.pdf.” The proposed agenda should include potential topics and speakers and a schedule format that will meet the conference or symposium objectives.
- **Attachment 3: List of Relevant Publications (two-page limit):** Upload as “References.pdf.” Relevant publications should provide evidence for why the conference or symposium, with the proposed agenda and speakers, should be supported.
- **Attachment 4: Statement of Work (two-page limit):** Upload as “SOW.pdf.” The SOW outlines and establishes the performance expectations and milestones for which the USAMRMC may provide funding. The SOW will be incorporated into the award document and, as such, is subject to release under the Freedom of Information Act. A series of relatively short statements should be included that comprise the approach to each of the major goals or objectives of the proposed effort. The statements should outline the specific tasks, including but not limited to: planning committee meeting dates, speaker selection, meeting publication plan, invitation and Save-the-Date release dates, compilation of abstract submission guidelines, etc.
- **Attachment 5: Impact/Outcomes Statement (two-page limit):** Upload as “Impact.pdf.” Describe the potential impact of the conference or symposium content in the field and the significance of this impact. Describe the potential impact of the conference or symposium for individual attendees at various levels. Provide the milestones and methods for publication and/or peer review of the conference or symposium results and recommendations.
- **Attachment 6: Key Personnel Qualifications (two-page limit):** Upload as “Personnel.pdf.” Describe the qualifications, capabilities, and experience of the proposed key personnel to demonstrate that they will be able to achieve the proposed objectives.

- **Attachment 7: Key Personnel Biographical Sketches (five-page limit per biographical sketch):** Upload all biographical sketches as a single document as “Biosketch.pdf.”
- **Attachment 8: Budget (no page limit):** Upload as “Budget.pdf.” Prepare the budget using the Conference/Symposium Budget form and include a detailed budget justification.
- **Tab 4 – Application and Budget Data:** Review and edit Proposed Project Start Date, Proposed End Date, and Budget Data pre-populated from the Conference/Symposium Budget form.
- **Tab 5 – Submit/Request Approval Full Application:** Once all components have been uploaded and prior to the full proposal submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will validate files against the BAA requirements and discrepancies will be noted. If no discrepancies are noted, press the “Confirm Submission” button to complete the proposal submission. eBRAP will notify your Business Official by email to log into eBRAP to review and to approve the proposal prior to the Approval deadline.

The PI should receive disposition regarding the proposal via an email from eBRAP within 180 days of submission.

II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)

Applicant organizations and all subrecipient organizations must have a DUNS number to submit proposals/applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit proposals/applications through the Grants.gov portal. Verify the status of the applicant organization’s Entity registration in SAM well in advance of the proposal/applications submission deadline. Allow several weeks to complete the entire SAM registration process.

Applicants must maintain an “Active” SAM status to be qualified to receive Federal awards. If an applicant is not fully compliant with the requirements at the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

Refer to the General Submission Instructions, Section III, for further information regarding Grants.gov requirements.

New Requirement: In March 2018, the General Services Administration (GSA) implemented fraud prevention security measures in the SAM that require every *new* contractor registrant to provide a written (hard copy), notarized letter confirming the entity’s Administrator authorized to register the entity in the SAM database or to make changes to its registration. Effective April 29, 2018, the notarized letter process is now mandatory on all *current* registrants at SAM who have a requirement to update data on their SAM record. The notarized letter is mandatory

and is required before the GSA Federal Service Desk (FSD) will activate the entity's registration. The Office of the Secretary of Defense and GSA realize the length of time needed to transmit, receive, process, and approve the notarized letters presents a significant impact on the ability of the contracting activity to make timely awards, but these steps must be taken to mitigate fraud concern. ***Notarized letters are required for all new and existing SAM-registered entities.*** The notarized letters must be postal service mailed (not emailed or faxed) to the "Federal Service Desk" and must contain the information outlined in the SAM-posted Frequently Asked Questions (FAQs) at: <https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/sam-update>. Instructions for domestic entities and instructions for international entities with embedded templates for use are also provided within the SAM Update notice with frequently asked questions at <https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/sam-update>.

II.D.4. Submission Dates and Times

This is a continuously open announcement through September 30, 2022; therefore, reviews occur throughout the year. Pre-proposals/Pre-applications may be submitted at any time throughout the 5-year period from the BAA release date to the BAA closing date (noted in [Section I](#)). An invited full proposal/application should be submitted within 90 days of the PI's receipt of an invitation to submit. No pre-proposal/pre-application or full proposal/application may be submitted under this BAA after September 30, 2022, 11:59 p.m. Eastern Time. If an invited proposal/application is not submitted by September 30, 2022, 11:59 p.m. Eastern Time, the applicant must wait for the next available opportunity for submission, i.e., the release of the FY23 BAA (to be posted to Grants.gov October 1, 2022). No proposal/application received under this BAA will be considered for funding after 24 months from the date of submission.

II.D.5. Intergovernmental Review

This BAA is not subject to EO 12372, "Intergovernmental Review of Federal Programs." The EO provides for state and local government coordination and review of proposed Federal financial assistance and direct Federal development. The EO allows each state to designate an entity to perform this function. This coordination and review is not required under this BAA.

II.D.6. Funding Restrictions

There are no specified funding limitations identified for a proposal/application submitted under this BAA. Refer to the General Submission Instructions, Section III.A.5, "Research & Related Budget," for discussion of allowable costs, including pre-award costs and collaborations with Military Facilities.

II.D.7. Other Submission Requirements

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

II.E. Proposal/Application Review and Selection Information

II.E.1. Criteria for Research Proposals/Applications Not Including a Clinical Trial

II.E.1.a. Peer and Programmatic Review

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

- **Research Objectives:** The degree to which the stated objectives are clear, valid, and logical. For development of devices and technologies, the degree to which the performance objectives are plausible; the proposed effort demonstrates familiarity with the historical background of the problem and previous/current solutions; and the awareness of similar projects previously undertaken and related activities. The extent to which the proposed research project demonstrates an innovative approach and relates to the Research Areas of Interest identified in [Section II.A](#) and [Appendix I](#).
- **Scientific Design Excellence:** The degree to which proposed plans, methods, techniques, and procedures are feasible, clear, valid, adequately referenced, and state-of-the-art; the merit of the statistical features of the study; the extent to which literature searches were used to document the strengths of the proposed project. For development of devices and technologies, the feasibility of the proposed product/technology development plan; how well the engineering/technical design is likely to achieve the goals indicated; adequacy of the engineering/design solutions; and how well the perceived engineering/design strengths and flaws are addressed. To what degree the intellectual and material property plan is appropriate and demonstrates cooperating institutions' willingness and ability to resolve intellectual and material property issues.
- **Impact/Outcomes:** The potential impact of the research in the field, the significance of this impact, and when it can be anticipated. For development of devices and technologies, the potential translation, implementation, and/or commercial use for the product/technology being developed, including whether the funding strategy described to bring the product(s) to the next level of development (e.g., clinical trial, transition to industry, delivery to the market, progression toward incorporation into standard practice) is appropriate and proposed milestones are appropriate and feasible.
- **PI and Key Personnel Qualifications:** The qualifications, capabilities, and experience of the proposed PI and other key personnel to demonstrate that the proposed staff has the knowledge, technical expertise, and management skills to achieve the proposed objectives as well as the time available for the percentage of efforts indicated for the project.
- **Facilities and Resources:** The proposed facilities and equipment, population resources, or unique combinations of these, to demonstrate that the organization has the necessary facilities and resources required for accomplishing the proposed objectives.

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

2. Programmatic Review: To make funding recommendations, the following criteria will be used by programmatic reviewers:

- Scientific peer review results
- Adherence to the intent of the award mechanism
- Program portfolio balance and priorities
- Relative military benefit
- Relative innovation, impact, and translatability

NOTE: Military-relevant research must be responsive to the healthcare needs of the Armed Forces, family members of the Armed Forces, and the U.S. Veteran population. Proposals/Applications must address a military-relevant health problem responsive to one of the Research Areas of Interest identified in [Section II.A](#) and [Appendix I](#).

II.E.2. Criteria for Research Proposals/Applications Including a Clinical Trial

II.E.2.a. Peer and Programmatic Review

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

- **Clinical Impact**
 - How relevant the anticipated outcomes of the proposed clinical trial are to the targeted population.
 - How well the sample population represents the targeted patient population that might benefit from the proposed intervention.
 - How the potential outcomes of the proposed clinical trial will provide/improve short-term benefits for individuals.
 - How significantly the long-term benefits for implementation of the intervention may impact patient care and/or quality of life.

- **Research Strategy**

- How well the scientific rationale for testing the intervention is supported by the preliminary data, critical review and analysis of the literature, and/or laboratory/preclinical evidence.
- How well the study aims, hypotheses or objectives, experimental design, methods, data collection procedures, and analyses are designed to answer clearly the clinical objective.
- How well the inclusion and randomization criteria meet the needs of the proposed clinical trial.
- How well the exclusion criteria are justified.
- How well plans to collect specimens and conduct laboratory evaluations are addressed, if applicable.
- To what degree the data collection instruments (e.g., surveys, questionnaires), if applicable, are appropriate to the proposed study.

- **Statistical Plan**

- To what degree the statistical model and data analysis plan are suitable for the planned study.
- How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
- Whether the statistical plan compensates for the use of a subpopulation of a recruited sample population to ensure appropriate power can be achieved within the subpopulation study.

- **Intervention**

- Whether there is evidence of support, indicating availability of the intervention from its source, for the duration of the proposed clinical trial (if applicable).
- To what degree the intervention addresses the clinical need(s) described.
- How the intervention compares with currently available interventions and/or standards of care.
- To what degree preclinical and/or clinical evidence supporting the safety of the intervention is provided.
- Whether a member of the study team holds the IND/IDE for the indication proposed or whether the timeline proposed for obtaining the IND/IDE is appropriate (if applicable).

- For investigator-sponsored INDs, whether there is evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the FDA.
- Whether plans to comply with Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), and Good Clinical Practices (GCP) guidelines are appropriate.
- Whether measures are described to ensure the consistency of dosing of active ingredients for nutritional supplements (if applicable).
- **Recruitment, Accrual, and Feasibility**
 - How well the availability of human subjects for the clinical trial and the prospect of their participation is addressed.
 - Whether access to the proposed human subjects population is demonstrated.
 - The degree to which the recruitment, informed consent, screening, and retention processes for human subjects will meet the needs of the proposed clinical trial.
 - How well the proposal/application identifies possible delays (e.g., slow accrual, attrition) and presents adequate contingency plans to resolve them.
 - To what extent the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study (e.g., Will human subjects still be able to take their regular medications while participating in the clinical trial? Are human subjects required to stay overnight in a hospital?).
- **Ethical Considerations**
 - How the level of risk to human subjects is minimized and how the safety monitoring and reporting plan is appropriate for the level of risk.
 - Whether a research monitor with expertise consistent with the nature of the potential risk(s) is identified, if applicable.
 - How well the evidence shows that the procedures are consistent with sound research design and, when appropriate, that these procedures are already in use for diagnostic or treatment purposes.
 - To what degree privacy issues are appropriately considered.
 - To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.

- **Personnel and Communication**

- Whether the composition of the study team (e.g., study coordinator, statistician) is appropriate.
- To what degree the study team's background and expertise are appropriate to accomplish the proposed work (e.g., statistical expertise, expertise in the disease, and clinical studies).
- How the levels of effort of the study team members are appropriate for successful conduct of the proposed trial.
- How well the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, standardization of procedures) meet the needs of the proposed clinical trial.

- **Transition Plan and Regulatory Strategy**

- Whether the identified next level of development and/or commercialization is realistic.
- Whether the funding strategy described to bring the intervention to the next level of development (e.g., specific industry partners, specific funding opportunities to be applied for) is reasonable and realistic.
- How the regulatory strategy and development plan to support a product label change, if applicable, is appropriate and well described.
- Whether the proposed collaborations and other resources for providing continuity of development, including proposed development or modification of clinical practice guidelines (CPG) and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications are established and/or achievable.
- Whether the schedule and milestones for bringing the intervention to the next level of development (next-phase clinical trials, transition to industry, delivery to the market, incorporation into standard practice, and/or approval by the FDA) are achievable.
- Whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
- How well the proposal/application identifies intellectual property ownership, describes any appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent Government access to products supported by this BAA/Funding Opportunity.

- Whether the applicant has demonstrated that they have access to all intellectual property rights necessary for development and commercialization and evidence that the Government has the ability to access such products or technologies.

- **Budget**

- Whether the budget is appropriate for the proposed research.

- **Environment**

- To what degree the scientific environment, clinical setting, and accessibility of institutional resources support the clinical trial at each participating center or institution (including collaborative arrangements).
- Whether there is evidence for appropriate institutional commitment from each participating institution.
- If applicable, to what degree the intellectual and material property plan is appropriate.

2. Programmatic Review: To make funding recommendations, the following criteria will be used by programmatic reviewers:

- Scientific peer review results
- Adherence to the intent of the award mechanism
- Program portfolio balance and priorities
- Relative military benefit
- Relative innovation, impact, and translatability

NOTE: Military-relevant research must be responsive to the healthcare needs of the Armed Forces, family members of the Armed Forces, and the U.S. Veteran population. Proposals/Proposals/Applications must address a military-relevant health problem responsive to one of the Research Areas of Interest identified in [Section II.A](#) and [Appendix I](#).

II.E.3. Criteria for Conference or Symposium Support Proposals

II.E.3.a. Peer and Programmatic Review

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

- **Conference or Symposium Objectives and Plan:** The degree to which the stated objectives are clear, valid, and logical. The degree to which the performance objectives are plausible and the proposed effort demonstrates familiarity with the historical background of the problem and previous/current solutions (such as professional society meetings). The degree of quality and completeness of the overall management and

execution plan. The extent to which the conference or symposium relates to the Research Areas of Interest identified in [Section II.A](#) and [Appendix I](#). The extent to which the conference or symposium circumstances do not create the appearance of Government impropriety.

- **Scientific Excellence:** The degree to which proposed conference or symposium procedures are state of the art and the degree to which the conference or symposium includes expert peer review in rating and selection of presentation through methods such as abstract submission and established processes for invitation of appropriate participants.
- **Impact/Outcomes:** The potential impact of the conference or symposium content in the field and for individual attendees, the significance of this impact, and when it can be anticipated, as well as methods for publication and peer review of conference or symposium results and recommendations.
- **Key Personnel Qualifications:** The qualifications, capabilities, and experience of the proposed key personnel to demonstrate that the proposed staff has the knowledge, technical expertise, and management skills to achieve the proposed objectives.
- **Budget:** The degree to which the budget reflects the actual needs of the proposed work and is thoroughly detailed and fully justified so that the Government can evaluate and determine the costs to be allocable, allowable and reasonable, and commensurate with the complexity and nature of the meeting proposed. The extent to which the costs reflect common sense and good judgment as to appropriate and necessary conference or symposium expenses and do not include expenses that are prohibited (including, but not limited to, entertainment-related expenses including hiring musicians or other entertainers, procurement of extraneous promotional items, decorations or other goods and services for participants that are unrelated to the purpose of the conference or symposium, procuring tickets to recreational activities outside of the conference setting, or using DoD funds to produce non-substantive audio/visual materials).

2. Programmatic Review: The following criteria will be used by programmatic reviewers:

- Programmatic relevance
- Scientific merit and relative impact
- Relevance to the DoD mission

II.E.4. Proposal/Application Selection Process

All invited proposals/applications are evaluated by USAMRMC scientists, other Federal agency representatives, outside scientists with diverse expertise, clinicians, consumers, or combinations thereof, using a two-tier review process. The first tier is peer review of proposals/applications against established criteria for determining technical merit. The second tier is programmatic review based on established criteria for determining relevance to the mission of the USAMRMC and its programs.

All USAMRMC review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign agreements to (1) protect the confidentiality of the information in the proposal/application and (2) not disclose evaluation information outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's proposal/application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party by military personnel or employee of the Federal Government is a crime in accordance with 18 USC 1905.

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

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

II.E.5. Integrity and Performance Information

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

An applicant, at its option, may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about itself that a Federal awarding agency previously entered and is currently available in FAPIIS.

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

II.E.6. Notification of Proposal/Application Review Results

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

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

II.F. Award Administration Information

II.F.1. Award Notices

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

The awarding agency will be the USAMRAA. The USAMRAA Contracting and Grants Officers are the only individuals authorized to obligate funds and bind the Federal Government.

Authorization to begin performance will be received via an award document (contract, grant, or cooperative agreement, as applicable) signed by the USAMRAA Contracting or Grants Officer. No commitment on the part of the Government should be inferred from discussions with any other individual.

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

Refer to the General Submission Instructions, Appendix 2, Section D, Award Notices, for additional information. Applicable requirements in the DoDGARs are found in 32 CFR, Chapter I, subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this BAA. Refer to the full text of the USAMRAA General Research Terms and Conditions for Institutions of Higher Education, Hospitals, and Non-Profit Organizations and the USAMRAA General Research Terms and Conditions for For-Profit Organizations available at <http://www.usamraa.army.mil/Pages/Resources.aspx> for further information.

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

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

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs apply to grants and cooperative agreements resulting from this BAA. See 2 CFR, Chapter XI, and 32 CFR, Chapter I.

Applicable requirements in the FAR, found in 48 CFR, Chapter 1, DFARS, found in 48 CFR Chapter 2, and Army Federal Acquisition Regulation Supplement (AFARS), found in 48 CFR Chapter 51, apply to contracts resulting from this BAA.

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

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

II.F.3. Reporting Requirements

Refer to the General Submission Instructions, Appendix 2, Section A, for general information on reporting requirements.

Technical/Scientific reporting requirements may include:

- Monthly, quarterly, and/or annual progress reports
- Final progress report
- In-progress reviews
- Quad charts: The Quad Chart template is a one-page Word document or PowerPoint file that must be downloaded from eBRAP at https://cdmrp.org/Program_Announcements_and_Forms/ and completed for submission and application.

The Government may request additional reports, which will be identified prior to award.

II.G. Agency Contacts

II.G.1. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

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

Phone: 800-518-4726 (International: 1-606-545-5035)

Email: support@grants.gov

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

II.H. Other Information

II.H.1. Contractor/Recipient Qualification

Refer to the General Submission Instructions, Appendix 3, for general information on required qualifications.

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

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

II.H.2. Proprietary Information

Do not include any proprietary information in the pre-proposal/pre-application. Proprietary information should ***only be included*** in the full proposal/application ***if necessary for evaluation purposes***. Abstracts of all funded proposals/applications will be posted publicly. ***Therefore, do not include proprietary information in the abstracts.***

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

II.H.3. Administrative Actions

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

II.H.3.a. Rejection

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

- Project Narrative exceeds the page limit.
- Project Narrative is missing.
- Budget form contains only zeros.
- Full proposal/application submission in the absence of an invitation.
- For proposals/applications including a clinical trial, the following may result in administrative rejection:
 - Human Subject Recruitment and Safety Procedures ([Attachment 6](#)) is missing.
 - Intervention ([Attachment 7](#)) is missing.
 - Data Management ([Attachment 8](#)) is missing

II.H.3.b. Modification

- Pages exceeding the specific limits may be removed prior to review for all documents other than the Project Narrative.
- Documents not requested may be removed.
- Following proposal/application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the proposal/application submitted to Grants.gov. During this verification period, the PI may upload missing documents (excluding those listed above, [Section II.H.3.a, Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the 5-day proposal/application verification period; otherwise, the proposal/application will be reviewed as submitted. If either the Project Narrative exceeds the page limit or the Budget form contains only zeros, an updated Grants.gov submission package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID.

II.H.3.c. Withdrawal

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

- Federal agency personnel involved in the review process and/or with making funding recommendations are named as being involved in the research proposed or found to have assisted in the pre-proposal/pre-application or proposal/application processes, including, but not limited to, concept design, proposal/application development, budget preparation, and the development of any supporting documentation. *If formal collaboration with Military Facility personnel is planned (i.e., included in the proposal/application in performance of*

the research), this prohibition is not applicable. However, these Military Facility personnel are prohibited from being involved in the review process and/or with making funding recommendations.

- Inclusion of any employee of USAMRMC review contractors in pre-proposal/pre-applications or full proposals/applications for funding without adequate plans to manage COIs. Refer to General Submission Instructions, Appendix 3.D, for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The full proposal/application does not propose the same research project as described in the pre-proposal/pre-application.
- The full proposal/application budget differs significantly from the budget included in the pre-proposal/pre-application.
- Proposed research of work that was or is currently funded may result in withdrawal.
- For studies requiring an IND or IDE, documentation of IND/IDE submission and/or approval is not provided.
- Applications may be administratively withdrawn from further consideration if the applicant cannot demonstrate access to the relevant study population and resources.

II.H.3.d. Withhold

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

II.H.4. Common Submission Problems

- Failure to enter an email address for change notifications under the BAA in Grants.gov for notifications on any modification made to the initial posting.
- Attachments are uploaded into the incorrect form on Grants.gov forms. (See the appropriate Proposal/Application Submission Checklist in [Section II.I.](#))
- Failure to contact the Grants.gov Help Desk when needed.
- Failure to include attachments.
- Inability to locate attachment forms. (Select “Search Grants” at <http://www.grants.gov> and enter W81XWH18SBAA1 in the “Opportunity Number” block; or in the “CFDA” block,

enter 12.420, and perform a “Search.” Under the “Opportunity Number” column, look for number W81XWH18SBAA1 in the list.)

- Use of “illegal” characters in attachment titles.
- Attachments exceed size limits.
- Upload attempts of unacceptable attachments: bitmap, TIFF, etc.
- Duplicate upload of documents.

II.I. Research Proposal/Application Not Including a Clinical Trial Submission Checklist

Grants.gov Application Components	Upload Order	Action	Completed
SF424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Impact/Outcomes Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	7	Data- and Research Resource-Sharing Plan: Upload as Attachment 7 with file name "Sharing.pdf."	
	8	Transition Plan and Regulatory Strategy: Upload as Attachment 8 with file name "Transition.pdf."	
	9	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 9 with file name "MFBudget.pdf," if applicable.	
Research & Related Personal Data		Complete form as instructed.	
Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
		Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget		Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form		Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.	

II.J. Research Proposal/Application Including a Clinical Trial Submission Checklist

Application Components	Action	Completed
SF424 (R&R) Application for Federal Assistance	Complete form as instructed.	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Human Subject Recruitment and Safety Procedures: Upload as Attachment 6 with file name "HumSubProc.pdf."	
	Intervention: Upload as Attachment 7 with file name "Intervention.pdf."	
	Data Management: Upload as Attachment 8 with file name "Data Manage.pdf."	
	Study Personnel and Organization: Upload as Attachment 9 with file name "Personnel.pdf."	
	Surveys, Questionnaires, and Other Data Collection Instruments: Upload as Attachment 10 with file name "Surveys.pdf," if applicable.	
	Impact Statement: Upload as Attachment 11 with file name "Impact.pdf."	
	Transition Plan and Regulatory Strategy: Upload as Attachment 12 with file name "Transition.pdf."	
	IND/IDE Documentation: Upload as Attachment 13 with file name "IND-IDE.pdf."	
	Military Relevance Statement: Upload as Attachment 14 with file name "MilRel.pdf."	
	DoD Military Budget Form(s): Upload as Attachment 15 with file name "MFBudget.pdf," if applicable.	

Application Components	Action	Completed
Research & Related Personal Data	Complete form as instructed.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed.	

II.K. Conference and Symposium Support Proposal Checklist

eBRAP Application Components	Upload Order	Action	Completed
Attachments Form	1	Conference or Symposium Objectives: Upload as Attachment 1 with file name "Objectives.pdf."	
	2	Agenda: Upload as Attachment 2 with file name "Agenda.pdf."	
	3	List of Relevant Publications: Upload as Attachment 3 with file name "References.pdf."	
	4	Statement of Work: Upload as Attachment 4 with file name "SOW.pdf."	
	5	Impact/Outcomes Statement: Upload as Attachment 5 with file name "Impact.pdf."	
	6	Key Personnel Qualifications: Upload as Attachment 6 with file name "Personnel.pdf."	
	7	Key Personnel Biographical Sketches: Upload as Attachment 7 with file name "Biosketch.pdf."	
	8	Budget: Upload as Attachment 8 with file name "Budget.pdf."	

APPENDIX I: RESEARCH AREAS OF INTEREST

I. Military Infectious Diseases Research Program

A. Research and Development Toward Preventive Measures for Infectious Diseases

- **Vaccines:** The development of vaccines to protect the Warfighter is a priority for the MIDRP. Vaccines can be administered prior to deployment, thereby protecting the Warfighter by preventing disease, obviating the need for prophylactic medication, and reducing the medical logistic burden. The MIDRP supports studies to characterize infectious disease agents and their mechanisms of pathogenesis, utilizing various approaches to identify and evaluate vaccine candidates in animal models and humans, as well as studies of protective immune responses to these agents.
- **Anti-Parasitic Drugs:** The MIDRP supports research efforts for discovery, design, and development of drugs to prevent and treat malarial infections. This includes drug synthesis, characterization of modes of action, screening for antimalarial activity, in vitro and in vivo research using animal models, and drug resistance mechanisms. Investigations into parasite metabolism, structural biology, genomics, proteomics, and metabolomics focused on identification of potential novel targets for drug intervention are also relevant to the MIDRP.
- **Vector Control Products:** The MIDRP supports investigations focusing on arthropod vectors and arthropod vector-borne diseases (primarily malaria, dengue, and scrub typhus). Current studies target vector-pathogen-human interactions, vector control measures (including personal protective equipment), and risk assessment (including identification and classification of vectors, improved surveillance techniques, and field-deployable assays for detecting pathogens in their vectors).
- **Combat Wound Infections:** The MIDRP supports research to inform and/or facilitate product development to detect, prevent, treat, and manage combat wound infections. Investigations in this area include characterization of the mechanisms of biofilm formation in wounds, the mitigation of biofilm formation in wounds, novel therapies for wound infection treatment, and methods to understand the dynamics of microbial communities in infected and healing wounds. In addition, novel chemical classes and/or biologics to prevent or treat combat wound infection and/or biofilm formation are of interest.

B. Research and Development of Therapeutic Measures for Infectious Diseases

Therapeutic drug development (including studies to screen, synthesize, and develop therapeutic drugs for malaria and other military-relevant infectious agents) is secondary to prophylactic drug development within the MIDRP (see Section I.A above). However, efforts to advance novel drug delivery systems (i.e., sustained-release, reduce toxicity, or targeted drug delivery) would be considered. In addition, MIDRP supports investigations into the development of novel medical countermeasures and innovative treatment approaches (e.g., chelators, phage, antimicrobial peptides, quorum-sensing inhibitors, and host immune augmentation) against multidrug-resistant organisms in combat wound infections and against pathogenic bacterial biofilm formation. Given modest pharmaceutical industry interest in developing and marketing

vaccines for orphan diseases, the MIDRP is also interested in applications for the development of products leading to FDA-licensed treatment options and broadly active therapeutics against multiple endemic disease threats.

II. Combat Casualty Care Research Program

- A. Research and development of technologies to stop blood loss, resuscitate the casualty, and limit the immediate, short-, and long-term deleterious consequences of severe hemorrhage:** Research focused on the pre-hospital setting including point of injury, the initial “Golden Hour” after injury, and scenarios in which a casualty cannot be transported through traditional levels of care (i.e., PFC) are of high interest. Included in this area of interest are diagnostics and therapeutics to predict, diagnose, prevent, and treat coagulopathy of trauma and non-invasive 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 or devices (exovascular or endovascular) for control of vascular disruption and subsequent compressible and non-compressible hemorrhage, treatments to sustain or enhance oxygen delivery and perfusion of vital tissues and organs, and equipment and procedures for effective fluid resuscitation and enhanced resuscitation fluids. Also of interest are the improved preservation, storage, transportability, and processing of red blood cells, platelets and plasma, and other blood or blood-like substitutes.
- B. Research and development of technologies to diagnose and to limit the immediate, short-, and long-term impairments that follow TBI and spinal cord injury:** Research specializing in “polytrauma” accounting for the impact of hemorrhagic shock and failure to oxygenate and/or ventilate as brain injury progresses is of interest to provide insight leading to improvements in CPG. Included in this area of interest are non-invasive or minimally invasive sensors or assays to rapidly diagnose the severity of brain and neurological injury within the battle area (or as close to it as possible) and drugs, biologics, or other agents to mitigate the progression of neurotrauma/secondary brain injury such as post-injury neural and immune cell overstimulation, inflammation, cell loss, and/or neurologic dysfunction.
- C. Research and development of technologies to diagnose and reduce acute secondary organ damage:** Secondary damage to organs frequently occurs after severe trauma and resuscitation. The CCCRP is interested in materiel and/or devices that can reduce acute secondary organ damage such as ischemia/reperfusion injury, cell death, general organ failure, and secondary brain/spinal cord damage. Technologies to sustain or support single- and multiple-organ injury and failure are also of interest to the CCCRP. These objectives include methods to reduce cellular demand for oxygen and metabolic substrates and therapeutics to modulate the immune response to traumatic injury as well as single- and multiple-organ support or replacement technologies (extracorporeal). In addition, the utilities of these modalities during (and the effects of longer distance) en route care on the critically injured casualty are also of interest.
- D. Research and development into the impacts of transport:** An important element of combat casualty care is the transport of patients from the initial point of injury and throughout the continuum of care. Accordingly, the CCCRP is interested in improving and

maintaining optimal clinical outcomes for en route care including PFC. Identifying feasible ways to mitigate the stresses of flight and/or transport (such as hypobaria, hypoxia, vibration, and g-forces) in an austere/constrained environment and the impact on clinical outcomes (such as healing rates, pain, infection rates, etc.) are particularly important. Additionally, establishing either timeframes or ways to measure the appropriate time to transport patients with critical injuries (including neurotrauma, burns, lung injuries, and musculoskeletal injuries) are a critical element to improving outcomes.

III. Military Operational Medicine Research Program

- A. Injury Prevention and Reduction:** This area of research addresses the requirement to provide the biomedical basis for countermeasures that prevent and mitigate Service member injuries and performance decrements occurring in training and operational (including close combat) environments, decrease attrition and medical cost, minimize personal impact to the Service member, and promote, optimize, and enhance readiness. The primary needs of the Injury Prevention and Reduction portfolio are developing and validating RTD physical performance standards following musculoskeletal injury; understanding the physiological impact of exposure to repetitive low-level blast in order to validate military safety standards and health hazard assessment prediction tools to prevent brain, sensory, and lung injury; understanding the bioeffects from exposure to emerging directed energy threats (e.g., laser, microwave, and radiofrequency waves); understanding the physiology of injury and repair mechanisms and their interrelationships with both modifiable and non-modifiable factors (e.g., environment, nutrition, sleep, stress, situational and cognitive awareness, genetics, sex, age) to promote effective interventions; providing validated injury criteria with animal models and postmortem human subject against blunt and ballistic threats to inform helmet and body armor developments; developing injury thresholds against directed energy threats; developing interventions to mitigate musculoskeletal injury risk and optimize and enhance performance in complex military systems; and developing and validating assessment tools and strategies to promote Service member physical performance optimization (individual and group). Finally, “omics”-level efforts that identify individual strengths/vulnerabilities to injury and performance are important to guide training and operational strategies that maximize readiness and lethality. Coordination with medical DoD labs such as the U.S. Army Aeromedical Research Laboratory, Walter Reed Army Institute of Research, Uniformed Services University of the Health Sciences, U.S. Army Institute of Environmental Medicine, and Naval Health Research Center is highly encouraged.
- B. Psychological Health and Resilience:** The Psychological Health and Resilience research program area is interested in research aimed at maximizing resilience; enhancing readiness and psychological health; and decreasing PTSD, depression and anxiety disorders, suicide, and risk behaviors (e.g., substance abuse, anger/aggression, sexual harassment and assault, and interpersonal workplace and domestic violence within the military). Additional psychological health areas of interest include military-related grief, guilt, or loss issues; moral injury; interdisciplinary and universal prevention and life-skills training strategies to mitigate negative psychological health trajectories; and reduction of stigma and other barriers to psychological healthcare-seeking. MOMRP has interest in understanding and addressing psychosocial/psychological health challenges unique to military families, women Service members, Reserve and Guard, and lesbian, gay, bisexual, and transgender Service members.

This research area focuses on the development and validation of effective training and prevention interventions, screening and assessment strategies, and treatment and rehabilitation interventions that address the psychological health topic areas. In addition, this research area focus may include development and validation of effective evidence-based training and prevention interventions for concussion/mild TBI. Research areas of particular interest include studies to elucidate underlying mechanisms of PTSD risk and treatment response; studies addressing PTSD comorbidities (including, but not limited to, PTSD, concussion, alcohol and other drug abuse, sleep disturbance, mood disorders, suicidality, and interpersonal psychosocial factors); studies focused on enhancing translation, implementation, and uptake of evidence-based strategies and treatments; research focused on designing and testing far-forward interventions to mitigate risk of PTSD development immediately after exposure to trauma; establishing validated objective RTD standards following psychological injury; and research focused on community/systems-level health psychology approaches appropriate for military populations. Proposals/Applications that incorporate and evaluate leveraging of technology (e.g., telemedicine, remote monitoring, biosensors, advance immunologic testing, and health information technologies) and leverage existing resources (to including mining/use of medical record data) and infrastructure to support psychological risk prevention and management, lifecycle logistics, and sustainability are encouraged. Also of interest are rigorous studies on complementary and integrative health (CIH) approaches spanning mind/body, movement, natural products, non-Western medicine approaches and spiritual practices, along with validation studies of CIH therapies. Research topics of particular interest include those directed at evaluating efficacy of cognitive training approaches to promote resilience and prevent/mitigate acute negative responses to psychological trauma and promote readiness; and the development of a systematically applied set of therapeutic services designed to mitigate psychological disorders by changing unhelpful thought patterns and unhealthy behaviors, reducing emotional distress, and restoring function and quality of life.

- C. Physiological Health and Performance:** This area of research develops biomedical countermeasures to sustain Service member health and operational effectiveness. It informs military policy, training, CPG, and the development of materiel solutions to establish, sustain, optimize, and monitor Service member health, physiological factors of resilience, and cognitive and physical performance throughout the military lifecycle, including training, deployment, reset, and injury recovery cycles. This research area aims to prevent or mitigate the negative effects of operational and training stressors on the readiness, performance, and fitness of Service members, as well as safely enhance performance with evidence-based pharmacological and non-pharmacological personalized strategies based on a systems medicine approach. Studies may include, but are not limited to, those that investigate the use of dietary supplements and nutritional and behavioral interventions to mitigate threats to readiness, operational health, and performance. Research also aims to develop healthy sleep and fatigue management strategies, strategies that exploit individual differences in sleep loss resilience, and strategies that promote individualized resilience to various operational stressors and injuries. Physiological health and performance research also encompasses work focusing on overall brain and cognitive fitness. Basic, applied, and advanced research studies utilizing technologies and strategies to monitor and promote Service member and family readiness and health to support the Army Surgeon General's Performance Triad and U.S. Army Training and Doctrine Command Human Dimension Initiative are of interest.

D. Environmental Health and Protection: This area of research includes assessment and sustainment of health, Force readiness, and the operational effectiveness of Service members exposed to harsh operational environments including altitude, cold, heat, undersea, and exposure to environmental toxicant health hazards or a combination of environmental stressors. Studies may include, but are not limited to, methods for effective monitoring of environmental exposures in individuals and populations and assessment of health risks following exposures to environmental stressors. This research also includes development of policy, training, planning/management tools, decision aids, knowledge and materiel solutions, physiological status monitoring systems, interventions, and reset solutions to sustain Service member readiness, and health and operational effectiveness to environmental stressors encountered during training or operations. In addition, research identifies biomarkers of exposure, dosimetry, and risk management to environmental toxicant health hazards, neurological and physical assessment tools for optimizing performance of the Service member exposed to environmental toxicant hazards, and development of portable devices for rapid identification of biomarkers of complex exposures and health effects in support of military operational requirements. Research also focuses on developing wearable solutions that are small size, low weight, cube, and have minimal power requirements for real-time physiological status monitoring in harsh operational environments.

IV. Clinical and Rehabilitative Medicine Research Program

A. Neuromusculoskeletal (NMS) Injury Rehabilitation: The NMS Injury Rehabilitation program area seeks research efforts directed toward optimal treatment, rehabilitation, and reintegration following Service-related NMS injury including: Service-related acute and repetitive overuse injury management, limb loss rehabilitation and prosthetic management, and limb trauma rehabilitation and orthotic management. Areas of encouragement include: validation of therapeutic exercise dosage (frequency, intensity, timing, and/or type) and rehabilitation strategies to improve Warfighter function, performance, and quality of life; understanding confounders of optimal rehabilitation; research to develop and validate standardized metrics of function, performance, and quality of life across and beyond the continuum of rehabilitative care; validation of existing short- and long-term reintegration strategies; research to predict and mitigate secondary health deficits following NMS injury; and efforts to develop and validate rehabilitation technologies (rehabilitation tools, interoperability of devices, prosthetic sockets, orthotic devices, advanced prosthetic control, sensory/proprioception, etc.) for Warfighters with NMS injuries to restore function and quality of life.

B. Vision Restoration and Rehabilitation: The Sensory Systems program area is seeking research efforts aimed at understanding and treating traumatic and Service-related injuries (blast, burn, penetrating, chemical, etc.) to ocular structures and the visual system (optic neuropathy, corneal scarring, retinal injury, lids and adnexal injuries, and ocular polytrauma, etc.). Additional areas of interest include studies to improve or advance visual system diagnostic/assessment capabilities, and restoration/rehabilitation strategies (including, but not limited to, rehabilitation for multisensory dysfunctions, low vision and blindness, and oculomotor vision disorders) following traumatic injury.

- C. Hearing Loss/Dysfunction, Balance Disorders, and Tinnitus:** The Sensory Systems program area is seeking research efforts to support the development of strategies and technologies (including, but not limited to, medical devices, pharmaceuticals, rehabilitation strategies, and regenerative medicine-based approaches) to restore and/or rehabilitate patients with hearing loss/dysfunction, balance disorders, and/or tinnitus due to trauma (including TBI). This includes research focused on the etiology of injury including studies to support an understanding of the molecular, cellular, and physiological mechanisms underlying hearing loss/dysfunction, balance disorders, and tinnitus. Additional areas of interest include research supporting the development, advancement, and/or validation of objective diagnostics, and treatment/rehabilitative strategies for hearing loss/dysfunction, balance disorders, multisensory dysfunction, and tinnitus after traumatic or Service-related injuries.
- D. Pain Management:** The primary interest of the Pain Management program area is management of acute and chronic pain associated with traumatic or combat-related injuries. The CRMRP's specific needs include development of alternative interventions to current opioid analgesics for pain management by the medic/corpsman on the battlefield/remote locations; development of intervention strategies for acute pain management in deployed locations, including battlefield and resource-limited environments; development of strategies for management of acute pain under the care of a clinician in non-deployed settings; development of intervention strategies for chronic pain management in deployed locations, including battlefield and resource-limited environments; development of intervention strategies for management of chronic pain under the care of a clinician in non-deployed settings; identification of pain generators and etiology of pain; development of strategies for identifying and addressing biopsychosocial aspects of pain; and development of substance misuse and abuse assessments and treatments in pain management.
- E. Regenerative Medicine and Composite Tissue Engineering:** Regenerative medicine involves the use of innovative technologies such as scaffolds and tissue engineering, growth factors, and cell-based treatments to restore Service members who have suffered combat-related injuries. Research topics of particular interest include those directed toward the use of regenerative medicine-based technologies to repair functional neural deficits (to include all peripheral nerves, visual system, and auditory system but excluding other deficits associated with central nervous system or spinal cord), repair/replace neuromuscular tissue units of the extremities or face including composite facial features (eyelids, lips, and nares), regenerate bone defects (weight-bearing and alveolar), regenerate skin, address vascular repair/revascularization, regenerate cartilage/musculoskeletal connective tissues for the prevention of post-traumatic arthritis, muscle protection/regeneration, vascularized tissue allotransplantation, immunomodulation, and tolerization related to vascularized tissue allotransplantation and wound management and tissue preservation such as promotion of scarless wound healing (not to include infection control).
- F. TBI Rehabilitation:** The sensorimotor clinical rehabilitation line of effort within the TBI program seeks to develop, evaluate, and/or validate rehabilitation intervention strategies (e.g., multitask/dual-task) to address TBI-related sequelae. Interventions should remediate TBI-related deficits including, but not limited to, dizziness, cognitive dysfunction (e.g., attention, memory, or impaired executive function), or sensorimotor deficits (e.g., gaze or gait instability). Intervention strategies should aim to increase patient tolerance for

rehabilitation and result in clinically meaningful and measurable improvement in targeted impairments, functional deficits, and barriers to participation. Competitive proposals/applications will address theorized physiologic mechanisms underlying treatment strategy. Clinical research is needed to investigate the optimal delivery of rehabilitation interventions and prescription (i.e., frequency, intensity, timing, and type) and to investigate comparative effectiveness of standard of care and novel intervention strategies. Studies that characterize or investigate proposed neural mechanisms of recovery with rehabilitation will be favorably considered. Cognitive rehabilitation studies that utilize a practice-based evidence design to identify clinical best practices and optimal outcomes among active duty Service members and like-aged Veterans with persistent post-traumatic cognitive sequelae are encouraged.

G. Ecological Assessment: The Ecological Assessment line of effort within the TBI program aims to develop, evaluate, and/or validate RTD outcome measures following rehabilitation in patients with mild TBI. Outcome measures may integrate novel or commercially available assessment technologies to enhance sensitivity and/or specificity. Outcome measures should be both ecologically valid (i.e., focused on military-specific tasks) and clinically feasible, with an aim to inform RTD/participation decisions in either an operational or garrison-based environment. Outcome measures should quantify and characterize patient impairments, functional limitations, and barriers to participation and have a strong plan for validation in the Warfighter population.

V. Medical Biological Defense Research Program

A. Viral, Toxin, and Bacterial Studies

- Identification and characterization of organisms and toxins. Molecular antigenic analysis; development of diagnostic assays; studies on structure and function that are related to mechanisms of action, binding, internalization, and interaction with the immune system and neutralizing antibodies; investigation of pathogenesis and immunology that will inform and enable decisions 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.
- Vaccine development, with emphasis on protection from aerosolized agents, 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 de-speciated 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.
- 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 development of 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.

- 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, non-specific protection against viruses, bacteria, and toxins as described above. Studies of their pharmacokinetics and other measurements relevant to more effective drug use are also of interest, as is the 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.

Research areas of interest include:

- Discovery of novel or unique biochemical elements or compounds with antiviral, antibacterial, or antitoxin activity against biological organisms.
- Development of testing models for evaluation of compounds effective against toxins of several classes, including pre- and post-synaptic toxins, membrane-damaging toxins, and toxins that inhibit protein synthesis and others.
- 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.
- Development of novel treatments to reverse paralysis in nerve terminals exposed to botulinum neurotoxin (BoNT) serotypes A, B, E, or F, with emphasis on the following objectives: (a) development of clinically feasible treatments to block the catalytic activity of the BoNT light chain; (b) treatments to accelerate recovery from paralysis-induced atrophy by targeting skeletal muscle regenerative pathways; and (c) identification and development of novel chemical scaffolds for small molecule inhibitors of the catalytic activity of the light chain of BoNT serotype A. While there may be limited funds available for development of promising approaches, this effort is predominantly focused on the accelerated development of clinically viable treatments with existing efficacy data.

C. Identification and Diagnosis: The investigation and evaluation of sensitive and specific methods of identifying and diagnosing both antigens and antibodies of viruses, bacteria, and rickettsia in biological materials. Development of sensitive and specific immunologic, chemical, or biological assays for the rapid (within minutes) and reliable (1) diagnoses of acute diseases due to agents of potential biological threat and (2) identification of toxins or their metabolites in biological samples. Assay may include antigen, antibody, or metabolite

detection or the use of nucleic acid probes or synthetic antigens. In addition, there is interest in the development of rapid identification and diagnostic methods for the assay of toxins, metabolites, and analogs in clinical specimens.

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

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

In addition, two specific topics currently of interest are:

- Next-generation analytic capabilities for BSV: The objective is to develop next-generation methodologies to enhance analytic capabilities in the detect-identify-respond timeline for a bioevent. Research should be exploratory, with a low-technology readiness level, and should address long-term challenges in threat surveillance. Efforts should significantly contribute to the current body of knowledge and lead to new concepts for technology application that may have impact on future BSV analytic capabilities.
- Biosurveillance Ecosystem (BSVE) Analytics 2.0: The objective is to ensure state-of-the-art technologies are made rapidly accessible through the BSVE. This topic seeks to develop analytic applications to synthesize and interrogate multiple sources of data to provide high confidence in the prediction, early warning, and forecasting (inclusive of mitigation strategies) of disease events. Metrics shall be devised such that successful utilization of these analytic tools will result in a measurable impact on the bioevent timeline. Efforts in this area should result in flexible, extensible, and sustainable analytics and models that are designed to plug into the BSVE as à-la-carte services rather than as standalone capabilities.

VI. Medical Chemical Defense Research Program

- Characterizing the mechanisms of vesicant agent pathophysiology to identify medical countermeasures against vesicant agents.
- Developing innovative models of the pathophysiology of vesicant agent injury.

- Identifying and/or evaluating innovative candidate medical countermeasures against vesicant agents.
- Identifying, exploring, and developing innovative clinical diagnostic, prognostic, and management approaches to vesicant agent casualties.
- Characterizing the ocular lesions associated with vesicant agent exposures; developing treatments to ameliorate these injuries.
- Characterizing the mechanisms of nerve agent-induced seizures and resulting pathophysiology to identify medical countermeasures against nerve agent-induced seizures.
- Identifying, synthesizing, and/or evaluating innovative candidate medical countermeasures against nerve agent-induced seizures.
- Developing innovative models of the pathophysiology of nerve agent-induced seizures.
- Developing catalytic and/or stoichiometric chemical warfare agent scavengers from biological molecules (e.g., antibodies and enzymes) that provide protection against nerve agent incapacitation and lethality for extended periods following their administration.
- Developing innovative models for evaluation of chemical warfare agent scavengers.
- Identifying, expressing, synthesizing, and/or evaluating biotechnologically derived or pharmaceutically based scavengers as candidate medical countermeasures against chemical warfare agents.
- 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.
- Developing catalytic and/or stoichiometric additives for use in skin protectants, or decontaminants, to protect against chemical warfare agents, especially vesicant and nerve agents.
- Developing innovative models for evaluation of catalytic and/or stoichiometric additives in skin protectants or decontaminants.
- Developing candidate formulations for skin protectants or decontaminants containing catalytic and/or stoichiometric additives and evaluating these formulations against chemical warfare agents.
- Characterizing the pathophysiology and natural progression of chemical warfare agent-induced damage to human tissues.
- Developing and validating innovative techniques for rapid and accurate analysis of human tissues and body fluids for detection of chemical warfare agent exposures.

- Characterizing the effects of long-term or chronic exposures to chemical warfare agents and/or medical countermeasures to these agents.
- Identifying, exploring, and developing innovative clinical diagnostic, prognostic, and management approaches to nerve agent casualties.
- Developing and validating field-usable procedures for diagnosis, prognosis, and treatment of chemical warfare agent casualties under both field and laboratory conditions.

VII. Medical Simulation and Information Sciences Research Program

A. The Medical Simulation (MedSim) Portfolio

The Medical Simulation (MedSim) Portfolio is focused on three overarching initiatives: Combat Casualty Simulation Initiative, Medical Readiness Initiative, and Tools for Medical Education. These three science and technology initiatives feed into broader Defense Health Agency programs with programmatic goals in Joint Evacuation and Transport Simulation (JETS) and Point of Injury Training Simulation (POINTS). The JETS program seeks to standardize patient movement training within the MHS continuum of care while sustaining clinical standards of patient management. The POINTS program seeks to enable Point of Demand, mass-customizable training.

- **Combat Casualty Simulation Initiative (CCSI):** This initiative focuses on simulations that advance combat casualty care. Research in this area will examine the efficacy of modern simulation system technology versus current training models with emphasis on multi-trauma and mass casualty scenarios. The CCSI supports research to inform simulation development and acquisition in ways to develop appropriate fidelity material properties and characteristics that best mimic tissue and respond appropriately to users' actions; develop training assets for high state of combat medical readiness; provide resiliency training prior to deployment to better elicit higher performance under pressure; and to create and evaluate efficient and effective ways to deliver team (collective) training. Goals include:
 - Optimizing critical lifesaving skills and procedures through training and educational simulation systems.
 - Developing adaptable, flexible, and interoperable training assets to reflect the continuous changes and modifications in combat-related injuries for high state of combat casualty medical readiness.
 - Increasing psychological resilience into pre-deployment training and increasing emphasis on mastery of skills and procedures through simulation system training tools.
 - Creating and integrating more physiologically based algorithms and models into simulation systems (mannequins and/or virtual/augmented/immersive reality) to appropriately and accurately represent tissue behaviors and characteristics.
 - Increasing emphasis on PFC training and researching and integrating simulation systems to substantially improve communicating and connecting with each other to transfer and

accept information/data from one system to another to support a system of system training and education interactive environment.

- Developing system of systems interoperable architecture to allow all Services at all roles within the continuum of care to train collectively, either with a modular training system or a collection of training systems to better understand clinical outcomes from a holistic patient perspective instead of as individual skills or procedures.
- **Medical Readiness Initiative:** This initiative focuses on medical provider training systems and assessment of competence for sustained military and public medical readiness. Research efforts are aligned with maximizing healthcare professionals' training and investigating how existing medical cognitive and psychomotor skills might degrade. The initiative seeks to research improved intelligent automated assessment systems that will assist in directing and catering the type of training courses an individual needs as well as systems that connect medical training to real-world patient outcomes. This initiative invites research and development toward near-time, pre-intervention rehearsal. Goals include:
 - Identifying, researching, and developing predictive models that may accelerate cognitive, psychomotor, and healthcare behavioral skills (tasks) to a level of proficiency and develop reliable and predictable tools to accelerate development of clinical skills or to minimize skill decay (or degradation).
 - Identifying, researching, and developing simulation system tools that will improve (or allow) ethical, patient-focused, and more predictable pre-surgical/intervention models and pre-surgical/intervention training systems to optimize clinical outcomes.
 - Identifying and researching potential predictors (data, markers, classifiers, etc.) for how training or use of any type of simulation system transitions to the real-world and patient outcomes.
 - Improving assessment systems of users' cognition, psychomotor skills, and affective behavior before, during, and after (retention) training.
 - Leading the effort to develop a sustainable medical education lifecycle.
- **Tools for Medical Education:** Research and develop next-generation inter-professional, open-source platforms, toolkits, and models to deliver future training systems in combat casualty care and medical readiness to improve the overall health of the Force. Focus is on promoting deliberate practice, enhancing mastery learning, enabling instructors, and preventing skill decay. Outcomes will result in resource sharing, collaborative research, and wide dissemination of knowledge and products to the medical modeling, simulation, training, and education community at large. Goals include:
 - Ensuring that advanced medical simulation tools and system capabilities are ubiquitous and support a diverse set of skills as well as allowing an individual or team to learn more advanced skills on a single device.

- Creating medical models and repositories that can be openly shared for medical simulation system developers and for the medical simulation community at large.
- Researching effective, efficient, elegant, accurate, appropriate, and robust medical models (anatomical, physiological, and/or behavioral) for developing next-generation mannequin prototypes and virtual/augmented/immersive reality simulation systems.
- Democratizing of knowledge and products through training platforms and tools that deliver healthcare content and advocate open-source/open-architectures to allow limited resources to be shared.

B. The Health Information Technology and Informatics (HITI) Portfolio

- **Theater/Operational Medicine:** This is the main priority research domain for technologies and data management that improve and document clinical care and support services to the Armed Forces combat and deployment Warfighters. Focusing on providing high-quality healthcare services by improving information accessibility, data management, data movement, remote healthcare delivery, and decision support for Joint Casualty Management, Joint Patient Movement, Joint Performance Enhancement, Joint Medical Logistics and Infrastructure Support, and Joint Theater Medical Command and Control and research for the Armed Forces to promote, improve, conserve, or restore the mental or physical well-being of personnel.

The HITI Theater/Operational Medicine focus area provides technology solutions, software, decision support tools, algorithms, data management, knowledge, and HITI services to enhance the efficiency of healthcare operations in combat and operational environments. The objective of HITI Theater/Operational Medicine research is to ensure delivery of high-quality healthcare services through technologies for improved information accessibility and information management and use of emerging/advanced technologies by clinicians caring for injured Service members. The Government plans to use research outcomes to assess critical technology elements and technology maturity, system integration risk, future use feasibility, and, where necessary, technology maturation and demonstration to fulfill critical capability gaps in theater/operational medicine healthcare delivery and support. Particular focus is placed on advanced information management and use of emerging and next-generation technologies. The goal is to research technology and data tools/strategies to support Theater/Operation Medicine within the following categories:

- **Joint Casualty Management (JCM)** directly supports medical care in theater/operational environments and sustains a healthy and fit Force. JCM delivers five of the seven Joint Health Services Support capabilities outlined in the new Taxonomy Continuum of Health Care Capabilities developed in Joint Publication 4-02, Health Service Support. The capabilities delivered are expected to be technology and informatics solutions for first responders, forward resuscitative care, theater hospitalization, definitive care, and en route care.
- **Joint Medical Logistics Infrastructure Support (JMLIS)** must establish the principles and practices that will move medical logistics into focused logistics. To integrate into the

focused logistics system and to provide the highest quality of care, the medical logistics system must be able to accomplish two primary tasks. The first, accomplished in conjunction with Service Force management and Force design organizations, is to ensure that the medical supplies, materiel, and equipment with which U.S. medical forces deploy include the latest technologies and advances in the medical field. The second task is to ensure that medical supplies, materiel, and equipment are delivered to the right person, at the right place, and at the right time. JMLIS must incorporate new technologies and informatics solutions to provide real-time medical and operational capability and situational awareness of medical logistics operations within the joint area of operations. JMLIS technology and informatics will rapidly integrate advances in research, technology, and doctrine from science, medicine, engineering, information technology, and other areas into fielded capabilities.

- **Joint Patient Movement** supplies and develops solutions for interoperable device data to improve ground and air evacuation capabilities, standardization for device data to improve ability to evacuate the casualty to a treatment site and autonomous device interoperability to support reception/staging en route care operations, and prolonged care in place.
- **Joint Performance Enhancement** supplies and develops innovative data capture, storage, analytics, management, and movement solutions for real-time, non-invasive monitoring of vigilance, subject performance, and enhancement of cognitive abilities for optimal decision making in Warfighter readiness.
- **Joint Theater Medical Command and Control** will research and validate a Joint Medical Command and Control solution that will synchronize and integrate health and medical force-related information from disparate databases and systems into one efficient, effective command and control capability. The resulting medical decision-based application will utilize intelligence, algorithms, decision support, or other novel approaches to organize and synthesize planning information queried from existing databases. It is anticipated that the data will eventually be migrated to a cloud solution to enable real-time response to anticipated, emerging, or contingency (crisis) situations. The research will enable direction, management, and/or coordination of assigned medical forces, assets, and resources in the accomplishment of assigned missions.
- **Military Healthcare Services:** Research into how healthcare providers and patients can better use health services and population health-related data, information, and technologies to improve health. Efforts to directly impact the way healthcare is provided to the patient, improve medical providers' ability to treat patients, promote health through readiness-centric patient engagement, patient safety-driven medical device information, interoperability, and connected healthcare services. Focus areas are as follows:
 - **Readiness-Centric Patient Engagement Applied Solutions:** Improve readiness through patient-initiated healthcare activities. Provide a user view of information that is comprehensive of healthcare and patient-generated data that can apply analytic and trending algorithms to help providers and patients make better decisions. Provide large volumes of data from agnostic input and devices, from any environment, in real time, to

enable usable, actionable information. Develop and apply methods for analysis, interpretation, prediction, and modeling of health system and patient-generated data. The objective is to use mathematical and/or intelligent learning/machine learning tools to extract practical information, usable/actionable clinical knowledge, and/or predict disease or adverse events from health system and patient-generated data.

- **Patient Safety-Driven Medical Device Information and Interoperability:** Improve systems or applications that will enable medical devices to interact with each other for the purpose of improving patient care, and to integrate health system or patient-generated medical device information seamlessly with an Electronic Health Record system for the purpose of providing effective clinical decision support to assist healthcare professionals and patients in making better clinical and/or lifestyle decisions.
- **Connected Healthcare Services:** Promote “Healthcare Anywhere” through mobile and telehealth solutions that are usable, and facilitate point-of-injury care and documentation of care in theater/operational medicine environments for Roles 1, 2, and 3.

- Role 1

This includes the provision of primary care, emergency treatment (resuscitation and stabilization), and preparation for transfer, usually under the guidance of a medical officer. This capability is normally integral to a major land-based unit and also reflects the provision of medical support inherent to an afloat platform.

- Role 2

This includes the reception and sorting of patients as well as the ability to provide elements of damage control resuscitation and the treatment of casualties. This is bolstered by a wider range of medical and nursing interventions and enhanced laboratory and imaging facilities. In addition, this level of care will prepare patients for further transfer with a limited holding capacity to prepare casualties for onward evacuation or for RTD.

- Role 3

This incorporates reception from Role 2 Military Treatment Facilities as well as direct receipt from local incidents. Major specialist facilities are available at this level of care with intensive care, holding, and nursing capabilities. Final sorting of casualties for transfer to Role 4 or RTD will occur here.

- **Health Information Technology Infrastructure and Data Management:** Research to enhance health enterprise infrastructure by implementing superior information technology and communications infrastructure.
 - **Health Data Management:** Improvements to data availability, management, storage, and operational use of Enterprise Health Data. Proposed objectives will ensure the unique identification of each patient, as well as aggregated data strategies for population health and big data.

- **Health Informatics or Information Technology (HIT) Infrastructure:** Research into system interfaces that will ensure that products or systems work efficiently with other products or systems, present or future, without any unintended restrictions. Improve the ability of medical devices to securely and reliably exchange health system or patient-generated data/information with other devices and with medical documentation and management systems. Research to examine technology integration and clinical/business process integration to reduce implementation barriers with regard to remote health monitoring.
- **Medical Resourcing:** Research to improve financial and personnel management for better delivery of healthcare services. Distribution of healthcare resources around the globe through solutions for personnel management and personnel support functions, or interoperable Joint Force research outcomes with concentration on:
 - **Medical Personnel Resource Planning and Allocation:** Deliver technologies and solutions for personnel management functions. Research to harness potential novel HITI approaches to efficiently and effectively match incoming patients with a provider and efficiencies gained through HITI mobile technologies for budgetary planning and execution.
 - **Education and Training:** Explore technologies to streamline the access to, and management of, educational systems across the MHS. Conduct research to explore the use of HIT in the provision of training. Develop best approaches to leveraging HIT and discovering efficient training delivery across the enterprise. Research to harness potential efficiencies gained through e-textbook interoperability.
 - **Financial Planning and Budget Execution:** Research on efficiencies gained through HITI technologies and data management for budgetary planning and execution.

C. Medical Capabilities to Support Dispersed Operations Portfolio

The Multi-Domain Battle, an operational environment involving greater dispersion and near-isolation over great distances, is likely to cause severe restrictions on mobility for medical missions and shortfalls in both human and materiel human resources due to area denial challenges. Combat units will need to be more self-sufficient and less dependent on logistical support. Combatant commanders with an increased number of sick or wounded Soldiers will face degradation of medical resources and encumbered combat effectiveness without new combat casualty management and Force multiplication strategies.

- **Medical Robotics Research** focuses on man-machine teaming in the delivery of medical care and patient handling to include automated patient monitoring and assessment functions for patient hold capabilities, aid in patient extraction from contested areas, and autonomous closed-loop interventions. As robotic capabilities continue to evolve, autonomous and tele-operated semi-autonomous robotic patient support systems could serve as Force multipliers for medical operations for closed-loop patient monitoring and triage as for robotics intervention. In addition to what may be considered contemporary robotics, i.e., an integration of knowledge-based software with electrical and mechanical engineering

technologies, or so-called “hard robotics,” one approach to employing robotics for medical applications is the emerging field of so-called “soft robotics.” Soft robotics involves the use of soft and deformable structures in the robotics systems that deal with uncertain and dynamic task environments, e.g., grasping and manipulation of unknown objects, locomotion in rough terrains, and physical contacts with living cells and human bodies. Soft robotics faces a number of fundamental scientific challenges: the studies of unconventional materials are still in their exploration phase; it has not been fully clarified what materials are available and useful for robotics applications; tools and methods for fabrication and assembly are not established; the Government does not have broadly agreed upon methods of modeling and simulation of soft continuum bodies; it is not fully understood how to achieve sensing, actuation and control in soft bodied robots; and the Government is still exploring ways to test, evaluate, and communicate the soft robotics technologies.

- **Medical Autonomous and Unmanned Systems** focuses on delivering enhanced autonomous and unmanned medical capabilities such as the delivery of forward resuscitation treatment and emergency resupply of Class VIII products like whole blood as well as closed-loop en route care modules that could enable general purpose unmanned vehicles to perform casualty evacuation (CASEVAC) missions with some level of on-board medical capability and bi-directional interface with remote medical personnel. Focus areas include automating critical care procedures such as physical (pressure-controlled, palpable, tactile) diagnostics and automated therapeutics in the field and to integrate those capabilities into ground and air unmanned systems platforms to enable unmanned CASEVAC missions. Areas of basic research include:
 - Intelligent agent approaches to integration of intelligent algorithms from multiple critical care systems during PFC or extended evacuation. This effort focuses on new approaches for autonomous clustering of individual closed-loop medical systems and intelligent agent algorithms that interact with each other to enable future development of systems that provide care for multiple injuries (polytrauma) while maximizing patient outcomes through physiologic optimization and deconflicting multiple medical procedures.
 - Strategies for interfacing medical intelligent systems, closed-loop diagnostic, and critical care systems into autonomous unmanned ground and air platforms that allow for unmanned and expedited care of combat casualties and extended evacuations in the dispersed field environment.
 - Research in the area of artificial intelligence and perception systems for accurate detection, monitoring, and modeling of human physiology to enable future applied research in autonomous casualty extraction and en route care systems. Autonomous systems for these applications require high-fidelity mapping and identification of the human body, organs, and structures in near real-time for safe physical contact with casualties and interaction with Soldiers.
- **Virtual Health/Telehealth and Decision Support Tools for the Combat Medic** focuses on enabling greater field medical capabilities for the combat medic in the far-forward future battlefield in PFC and austere environments. The task is to research, design, and develop advanced telehealth capabilities and tools as well as automated decision support systems that

operate in a pre-hospital context capable of providing greater support for the combat medic in the diagnosis, triage, and treatment stages, as well as reachback, if available, either synchronously (real time) or asynchronously (store/forward) to specialty care providers and other expert medical consultants from remote locations (both in-garrison and in-theater).

VIII. Radiation Health Effects Research Program

- A. Medical Countermeasures (MCMs) for Acute Radiation Exposure:** Radiation MCMs include radioprotectants (pre-exposure) and mitigators and therapeutics (post-exposure). Both categories of MCMs are focused on preventing or treating the effects of acute radiation exposure, including the resultant development of acute radiation syndrome (ARS). The focus area examines ARS resulting from exposure to ionizing radiation from radioactive sources or a nuclear detonation, including low linear energy transfer (LET) sources (gamma and x-rays) and high LET sources (neutrons). Research objectives include, but are not limited to, identifying mechanisms of action, obtaining efficacy and safety data in animal models for MCMs for ARS, and demonstrating improved survivability following high doses of radiation with treatment either before exposure or within 24 hours after exposure. Research in biodosimetry in support of MCM development may also be considered.

APPENDIX II: CLINICAL TRIALS

A. Important Aspects of Clinical Trials

A clinical trial is defined as a prospective accrual of human subjects in which one or more intervention(s) (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. The term “human subjects” is used in this BAA to refer to individuals who will be recruited for or who will participate in the proposed clinical trial. For more information, a Human Subject Resource Document is provided at <https://ebrap.org/eBRAP/public/Program.htm>.

The following are important aspects of submissions proposing a clinical trial:

- The proposed clinical trial is expected to begin no later than 12 months after the award date.
- The proposed intervention to be tested should offer significant potential impact for the targeted population.
- Inclusion of preliminary data relevant to the proposed clinical trial is required.
- The proposed clinical trial must be based on sound scientific rationale that is established through logical reasoning and critical review and analysis of the literature.
- The proposal/application should describe the planned indication for the product label, if appropriate, and include an outline of the development plan required to support that indication.
- The proposal/application should demonstrate availability of, and access to, a suitable patient population that will support a meaningful outcome for the study. The PI should discuss how accrual goals will be achieved and how standards of care may impact the study population.
- The proposal/application should demonstrate documented availability of and access to the drug/compound, device, and/or other materials needed, as appropriate. The quality of the product should be commensurate with FDA manufacturing standards applicable to the type and phase of product being developed (i.e., Quality System Regulation, GMP).
- The proposed clinical trial design should include clearly defined and appropriate endpoints, and follow GCP guidelines.
- The proposal/application should include a clearly articulated statistical analysis plan, appropriate statistical expertise on the research team, and a power analysis reflecting sample size projections that will clearly answer the objectives of the study.
- The proposal/application should include a clearly articulated data management plan and use of an appropriate database to safeguard and maintain the integrity of the data.

- The proposal/application should include a clearly articulated safety management plan outlining how safety pharmacovigilance will be conducted, as applicable.
- The proposal/application should include a clearly articulated clinical monitoring plan outlining how the study will be monitored for GCP compliance.
- The proposal/application should include a study coordinator(s), who will guide the clinical protocol through the local IRB of record and other Federal agency regulatory approval processes, coordinate activities from all sites participating in the trial, and coordinate participant accrual.
- The proposal/application should include a Transition Plan and Research Strategy (including potential funding and resources) showing how the product will progress to the next clinical trial phase and/or delivery to the market after the successful completion of the award.
- The proposal/application should clearly demonstrate strong institutional support.

Funded studies are required to file the study in the National Institutes of Health clinical trials registry, www.clinicaltrials.gov. Refer to the General Submission Instructions, Appendix 1, Section C, for further details.

Multi-Institutional Clinical Trials: If the proposed clinical trial is multi-institutional, plans for the multi-institutional structure governing the research protocol(s) should be outlined in [Attachment 9: Study Personnel and Organization](#). The lead organization responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements. A single IRB or Ethics Committee (EC) pathway is strongly recommended whenever possible. The master protocol and consent form must be reviewed by the Human Research Protection Office prior to distribution to the additional sites for IRB/EC review. Communication and data transfer among the collaborating institutions, as well as how specimens and/or imaging products obtained during the study will be handled, should be included in the appropriate sections of the proposal/application. A separate intellectual and material property plan agreed upon by all participating institutions is also required for multi-institutional clinical trials. PIs are encouraged to integrate with existing DoD or other Government-funded clinical trial networks if appropriate.

If the IRB determines that a trial presents greater than minimal risk to human subjects, the DoD requires an independent research monitor with expertise consistent with the nature of risk(s) identified within the research protocol.

B. Full Proposal/Application Submission Components

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

- **SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Submission Instructions, Section III.A.1, for detailed information.

Attachments:

Each attachment to the full proposal/application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Submission Instructions, Appendix 4.

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire full submission package may not exceed 200 MB.

The Project Narrative is NOT the formal clinical trial protocol. Instead, all essential elements of the proposed clinical trial necessary for scientific review must be included as directed in Attachment 1 (the Project Narrative) and Attachments 6-8 described below. Failure to submit these attachments as part of the application package will result in rejection of the entire application.

- **Attachment 1: Project Narrative (20-page limit):** Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background:** Describe in detail the rationale for the study. Provide a literature review and describe the preliminary studies and/or preclinical data that led to the development of the proposed clinical trial. Provide a summary of other relevant ongoing, planned, or completed clinical trials and describe how the proposed study differs. Include a discussion of any current clinical use of the intervention under investigation and/or details of its study in clinical trials for other indications (as applicable). The Background section should clearly support the choice of study variables and should explain the basis for the study questions and/or study hypotheses. This section should establish the relevance of the study and explain the applicability of the proposed findings.

If the proposed clinical trial was initiated using other funding prior to this proposal/application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically, identify the portions of the study that will be supported with funds from this award.

- **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses. The aims should agree with the primary aims and associated tasks described in the SOW.

- **Study Design:** Describe the type of study to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.
 - Identify the intervention to be tested and describe the projected outcomes.
 - Define the study variables, outline why they were chosen, and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
 - Describe the study population and inclusion and exclusion criteria that will be used.
 - Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random).
 - Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
 - If using psychometric measures, describe their reliability and validity.
- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study.
- **Attachment 2: Supporting Documentation:** Combine and upload as a single file named “Support.pdf.” Start each document on a new page. If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application. *There are no page limits for any of these components unless otherwise noted.*
 - **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in this BAA, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at a Military Facility is named as a collaborator on a proposal/application, the proposal/application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.
- Letters of Commitment (if applicable): If the proposed study involves use of a commercially produced investigational drug, device, or biologic, provide a letter of commitment from the commercial entity indicating availability of the product for the duration of the study, support for the proposed phase of research, and support for the indication to be tested.
- Use of DoD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military patient populations and/or DoD resources or databases.
- Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the ACOS/R&D or Clinical Service Chief confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA NPC is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

- *If the project involves collaboration with a Military Facility, special requirements apply.* A DoD researcher, to include collaborating DoD PIs, must obtain a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the research project. This letter must be included with the proposal/application.
- **Joint Sponsorship:** Describe present or prospective joint sponsorship of any portion of the program outlined in the proposal/application. In the absence of agreements among sponsors for joint support, the proposal/application should be structured so that the research can be carried out without the resources of any other sponsor. If, however, it is desirable to request partial support from another agency, the proposed plan should be stated and the reasons documented. If the plan cannot be formulated at the time the proposal/application is submitted, information should be sent later as an addendum to the proposal/application. Prior approval from both agencies must be secured for research to be undertaken under joint sponsorship. Provide letters of support related to recruitment, subject access, and data access plans
- **Intellectual Property:** Information can be found in 2 CFR 200.315, “Intangible Property.”
 - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Data- and Research Resources-Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Submission Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.” The abstract is vitally important to both the scientific peer and programmatic review processes. In accordance with Section 8123 of the Consolidated and Further Continuing Appropriations Act, 2015 (Public Law 113-235), the PI is required to submit a technical abstract that fully describes the proposed work. The abstract must contain the title of the project and the name of the PI. Do not include figures or tables in the abstract. Use only characters available on a standard QWERTY keyboard. Spell out all Greek or other non-English letters. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.***

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

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

- Specific Aims: State concisely the specific aims of the study.
 - Study Design: Briefly describe the study design.
 - 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.
 - Clinical Impact: Briefly describe how the proposed project will have an impact on research and patient care.
- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.” The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. *Do not include proprietary or confidential information.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the outline below. Do not duplicate the technical abstract.

- Clearly describe the objectives and rationale for the proposed study in a manner readily understood by readers without a background in science or medicine.
 - Describe the ultimate applicability and impact of the research.
 - What types of patients will it help, and how will it help them? Include the current available statistics to the related injury/condition.
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected timeline it may take to achieve the expected patient-related outcome?
 - Describe how the proposed project will benefit Service members, Veterans, and/or their family members.
- **Attachment 5: Statement of Work (three-page limit):** Upload as “SOW.pdf.” The SOW outlines and establishes the performance expectations and milestones for which the USAMRMC may provide funding. The SOW will be incorporated into the award document and, as such, is subject to release under the Freedom of Information Act. The SOW should identify all collaborating research sites involved in the performance of the research. Suggested SOW formats and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>).

A series of relatively short statements should be included that comprise the approach to each of the major goals or objectives of the proposed research. The statements should outline the specific tasks, systems, key assessments/techniques, and materials that are

reasonable estimates for testing the proposed hypotheses of the study. A timeline should be included that shows the work statements to be accomplished in each year of the award. Any animal use and/or human subjects recruitment should be included. Allow at least 2 to 3 months for the USAMRMC ORP regulatory review and approval processes for studies involving human subjects and 2 to 3 months for studies involving animal subjects.

If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., IND and IDE applications) by the FDA or other Government agency.

- **Attachment 6: Human Subject Recruitment and Safety Procedures (no page limit):** Upload as “HumSubProc.pdf.” The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.
 - **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). Demonstrate that the research team has access to the proposed study population. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays. Include justification of any age, race, ethnicity, or sex limitations provided.
 - **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

Inclusion of Women and Minorities in Study: Consistent with the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects,” and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded from the clinical trial.
 - **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, healthcare provider identification).
 - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
 - If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan.

- Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.
- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.
 - *For the proposed clinical trial, provide a draft, in English, of the Informed Consent Form.*
 - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.
 - Include information regarding the timing and location of the consent process.
 - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
 - Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
 - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
 - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial to be in compliance with Title 10 United States Code Section 980 (10 USC 980) (<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf>). If applicable, please refer to the General Submission Instructions, Appendix 1, for more information.
 - **Assent:** If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.
- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine

eligibility/suitability for study participation and the diagnostic criteria for entry. Please note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.

– **Risks/Benefits Assessment:**

- **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Study risks include any risks that the human subject is subjected to as a result of participation in the clinical trial. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
- **Risk management and emergency response:**
 - ❖ Describe how safety surveillance and reporting to the IRB and FDA (if applicable) will be managed and conducted.
 - ❖ Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
 - ❖ Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.
 - ❖ Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).
 - ❖ Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
 - ❖ If the IRB determines that a trial presents greater than minimal risk to human subjects, the DoD requires an independent research monitor with expertise consistent with the nature of risk(s) identified within the research protocol. If applicable, please refer to the General Submission Instructions, Appendix 1, for more information on study reporting authorities and responsibilities of the research monitor.
- **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society.

- **Attachment 7: Intervention (no page limit):** Upload as “Intervention.pdf.” The Intervention attachment should include the components listed below.
 - **Description of the Intervention:** Identify the intervention to be tested and describe the particular outcomes. As applicable, the description of the intervention should include the following components: complete name and composition, storage and handling information, source, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed. Description of devices should include general concept of design, detailed operational instructions, any potential risks to users, and intended benefits. Other types of interventions should be fully described. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights for the conduct of the clinical trial.

Summarize key preclinical pharmacological findings, dosage studies, and other clinical studies (if applicable) that examine the safety of the intervention.

- **Study Procedures:** Describe the interaction with the human subject to include the study intervention that he/she will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will experience. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures. Discuss how compliance with GLP, GMP, and other regulatory considerations will be established, monitored, and maintained, as applicable.
- **Clinical Monitoring Plan:** Describe how the study will be conducted by and monitored for ICH E6 (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) GCP compliance, by an independent clinical trial monitor (or clinical research associate). The monitoring plan should describe the types of monitoring visits to be conducted, the intervals (based on level of risk), how corrective actions will be reported to the Sponsor and PI, and how they will be corrected and prevented by the clinical trial site/PI.

- **Attachment 8: Data Management (no page limit):** Upload as “Data_Manage.pdf.” The Data Management attachment should include the components listed below.

- **Data Management:** Describe all methods used for data collection to include the following:
 - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
 - **Confidentiality:**
 - ❖ Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and

confidentiality of study records, particularly those containing identifying information, should be addressed.

- ❖ Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of the DoD are eligible to review study records.
- ❖ Address requirements for reporting sensitive information to state or local authorities.

- **Data capture, verification, and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, the process for locking the database at study completion, and the length of time data will be stored. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. For FDA-regulated studies, compliance with 21 CFR 11 is required.
- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.

– **Laboratory Evaluations:**

- **Specimens to be collected, schedule, and amount:** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.
- **Evaluations to be made:** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
- **Storage:** Describe specimen storage, to include location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the plan to store specimens for future use to include considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.
- **Labs performing evaluations and special precautions:** Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.

- **Attachment 9: Study Personnel and Organization (no page limit):** Start each document on a new page. Combine into one document and upload as “Personnel.pdf.” The Study Personnel and Organization attachment should include the components listed below.
 - **Organizational Chart:** Provide an organizational chart that identifies key members of the study team and provides an outline of the governing structure for multi-institutional studies. Identify collaborating organizations, centers, and/or departments and name each person’s position on the project. Identify the data and clinical coordinating center(s) and note any involvement from Contract Research Organizations, as appropriate. If applicable, identify the FDA regulatory sponsor and any external consultants or other experts who will assist with FDA applications. While there is no specified format for this information, a table(s) or diagram is recommended.
 - **Study Personnel Description:** Briefly describe the roles of the individuals listed in the organizational chart on the project. Describe relevant experience and qualifications that demonstrate appropriate expertise for the given role. An external research monitor (if applicable) and study coordinator(s) should be included.
 - **Study Management Plan:** Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial is multi-institutional, clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. Provide a regulatory submission plan for the master protocol and master consent form by the lead organization; include a single IRB/EC pathway whenever possible. If applicable, describe how communication and data transfer between the collaborating institutions will occur, as well as how data, specimens, and/or imaging products obtained during the study will be handled and shared.
- **Attachment 10: Surveys, Questionnaires, and Other Data Collection Instruments, if applicable (no page limit):** Upload as “Surveys.pdf.” The Surveys, Questionnaires, and Other Data Collection Instruments attachment should include a copy of the most recent version of surveys, questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study. Describe how and when the instrument(s) will be administered. Describe how the instrument(s) will be adapted to the subject population, if applicable.
- **Attachment 11: Impact Statement (two-page limit):** Upload as “Impact.pdf.”
 - Identify the volunteer population(s) that will participate in the proposed intervention, describe how they represent the target population that would benefit from the intervention, and describe the potential impact of the proposed clinical trial on the outcomes of individuals with the targeted disease or condition.

- Describe the short-term impact: Detail the anticipated outcomes that will be directly attributed to the results of the proposed clinical trial.
 - Describe the long-term impact: Explain the long-range vision for implementation of the intervention in the clinic or field, and describe the anticipated long-term benefits for the targeted population.
 - Describe any relevant controversies or treatment issues that will be addressed by the proposed clinical trial.
 - Describe any potential issues that might limit the impact of the proposed clinical trial.
 - Describe how the intervention represents an improvement over currently available interventions and/or standards of care.
- **Attachment 12: Transition Plan and Regulatory Strategy (three-page limit):**
Upload as “Transition.pdf.” Describe/discuss the methods and strategies proposed to move the intervention to the next phase of development (clinical trials, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Applicants are encouraged to work with their organization’s Technology Transfer Office (or equivalent) to develop the transition plan. PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development. The post-award transition plan should include the components listed below.
- The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication. Describe in detail the FDA regulatory strategy, to include considerations for compliance with GMP, GLP, and GCP (if appropriate).
 - Details of the funding strategy to transition to the next level of development and/or commercialization (e.g., partners, internal/external funding opportunities to be applied for). Include a description of collaborations and other resources that will be used to provide continuity of development.
 - For Knowledge Products, a description of collaborations and other resources that will be used to provide continuity of development including proposed development or modification of CPG and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. A “Knowledge Product” is a non-materiel product that addresses an identified need, topic area, or capability gap, is based on current evidence and research, aims to transition into medical practice, training, tools, or to support materiel solutions (systems to develop, acquire, provide, and sustain medical solutions and capabilities), and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.

- A brief schedule and milestones for transitioning the intervention to the next phase of development (next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by the FDA).
- Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the Government’s ability to access such products or technologies in the future.
- A risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 13: IND/IDE Documentation:** If submitting multiple documents, start each document on a new page. Combine and upload as a single file named “IND-IDE.pdf.”
 - Complete the IND/IDE Documentation Form, which is available for download on the Full Announcement page for this BAA on Grants.gov.
 - State whether the trial requires regulation by the FDA. If FDA regulation is required, describe the planned indication for the proposed product and whether an IND/IDE is necessary. Identify the IND/IDE sponsor. If an IND or IDE is required, it must be submitted to the FDA *prior to submission of the full proposal/application*.
 - If an IND or IDE has already been obtained for the investigational drug or device pertaining to the indication to be studied, provide evidence in the form of formal communication (e.g., letterhead correspondence) from the FDA.
 - If an IND or IDE application has been submitted, provide an explanation of the status of the IND or IDE application (e.g., past the critical 30-day period, pending response to questions raised by the Agency, on clinical hold). Provide a summary of previous meetings with the FDA on development of this product, if appropriate. A copy of the Agency meeting minutes should be included if available. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application.
 - If an IND or IDE is not required for the proposed study, or if it qualifies for an abbreviated IDE, provide evidence in the form of formal communication (e.g., letterhead correspondence) from the FDA or the IRB of record to that effect. Devices qualifying for an abbreviated IDE must comply with the abbreviated IDE requirements but do not require the submission of an IDE application to the FDA.
- **Attachment 14: Military Relevance Statement (one-page limit):** Upload as “MilRel.pdf.”
 - Describe how the proposed study is responsive to the healthcare needs of military Service members, Veterans, and/or beneficiaries. Provide information about the incidence and/or prevalence of the disease or condition in the general population as well as in military Service members, Veterans, and/or beneficiaries.

- If active duty military, military families, and/or Veteran population(s) will be used in the proposed research project, describe the population(s) and the appropriateness of the population(s) for the proposed study. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., military Service members, Veterans, and/or beneficiaries).
- If applicable, show how the proposed research project aligns with DoD and/or VA areas of research interests. Provide a description of how the knowledge or technology gained from the research could be implemented in a dual-use capacity to benefit the civilian population and address a military need, as appropriate.
- **Attachment 15: DoD Military Budget Form(s), if applicable:** Upload as “MFBudget.pdf.” If a Military Facility (MHS facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the DoD Military Budget Form, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Submission Instructions, Section III.A.8., for detailed information.

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

- PI Biographical Sketch (five-page limit): Upload as “Biosketch_LastName.pdf.”
- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch_LastName.pdf.”
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”

Research & Related Budget: Refer to the General Submission Instructions, Section III.A.5, for detailed information.

Budget Justification (no page limit): Upload as “BudgetJustification.pdf.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

Project/Performance Site Location(s) Form: Refer to the General Submission Instructions, Section III.A.6, for detailed information.

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

NOTE: Proposals/Applications from **Federal agencies** must include in their budget justifications a **Federal Financial Plan**. Proposals/Applications from organizations that include **collaborations with DoD Military Facilities** must comply with special requirements. Refer to the General Submission Instructions, Section III.A.5, Research & Related Budget, for detailed information.

APPENDIX III: DOD AND VA WEBSITES

PIs are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with DoD or VA investigators is also encouraged. Below is a list of websites that may be useful in identifying additional information about DoD and VA areas of research interest, ongoing research, or potential opportunities for collaboration.

Air Force Office of Scientific Research
<http://www.wpafb.af.mil/afri/afosr/>

Air Force Research Laboratory
<http://www.wpafb.af.mil/afri/>

Armed Forces Radiobiology Research
Institute
<http://www.usuhs.edu/afri/>

Clinical and Rehabilitative Medicine
Research Program
<https://crmp.amedd.army.mil>

Combat Casualty Care Research Program
<https://ccc.amedd.army.mil>

Congressionally Directed Medical Research
Programs
<http://cdmrp.army.mil>

Defense Advanced Research Projects
Agency
<http://www.darpa.mil/>

Defense Health Agency
<https://health.mil/dha>

Defense Technical Information Center
<http://www.dtic.mil>

Defense Threat Reduction Agency
<http://www.dtra.mil/>

Military Health System Research
Symposium
<https://www.mhsrs.net/>
Military Infectious Diseases Research
Program
<https://midrp.amedd.army.mil>

Military Operational Medicine Research
Program
<https://momrp.amedd.army.mil>

Naval Health Research Center
<http://www.med.navy.mil/sites/nhrc>

Navy Bureau of Medicine and Surgery
<http://www.med.navy.mil/>

Naval Medical Research Center
www.med.navy.mil/sites/nmrc

Navy and Marine Corps Public Health
Center
<http://www.nmcphc.med.navy.mil/>

Office of Naval Research
<http://www.onr.navy.mil/>

Office of the Under Secretary of Defense for
Acquisition, Technology and Logistics
<http://www.acq.osd.mil/>

Telemedicine and Advanced Technology
Research Center
<http://www.tatrc.org/>

Uniformed Services University of the Health
Sciences
<http://www.usuhs.edu/research>

U.S. Army Aeromedical Research
Laboratory
www.usaarl.army.mil

U.S. Army Center for Environmental Health
Research
<http://usacehr.amedd.army.mil>

U.S. Army Institute of Surgical Research
<http://www.usaisr.amedd.army.mil/>

U.S. Army Research Institute of
Environmental Medicine
<http://www.usariem.army.mil/>

U.S. Army Medical Research Institute of
Infectious Diseases
<http://www.usamriid.army.mil/>

U.S. Army Medical Research and Materiel
Command
<http://mrmc.amedd.army.mil>

U.S. Army Research Institute for Behavioral
and Social Sciences
<https://ari.altess.army.mil/>

U.S. Army Research Laboratory
<http://www.arl.army.mil>

U.S. Army Research, Development and
Engineering Command
www.army.mil/rdecom

U.S. Army Resiliency Directorate
<http://www.army.mil/readyandresilient/>

U.S. Department of Defense Blast Injury
Research Program
<https://blastinjuryresearch.amedd.army.mil/>

U.S. Department of Veterans Affairs, Office
of Research and Development
<http://www.research.va.gov>

U.S. Naval Research Laboratory
<http://www.nrl.navy.mil>

Walter Reed Army Institute of Research
<http://www.wrair.army.mil/>

APPENDIX IV: PROCEDURES FOR ACQUISITION, PROCESSING, STORAGE, AND SHIPMENT OF BIO-FLUIDS

The following pre-analytical variables should be recorded when collecting bio-fluids:

- Time of sample collection
- Time of sample freezing and the interval between collection and freezing
- Temperature of freeze
- Needle size and type (21 G preferred)
- Tube collection order
- Tube labels
- Centrifugation parameters
- Handling, shipping, and storage temperature
- Tube handling
- Small aliquot size
- Sample storage quality control

The following subject characteristics should be recorded when collecting bio-fluids:

- Fasting and diet
- Therapy
- Time of day
- Physical activity
- Acute state (rested?)
- Body position

APPENDIX V: NATIONAL INSTITUTE OF MENTAL HEALTH DATA ARCHIVE — INFORMED CONSENT

Psychological Health, Human Subjects Studies Informed Consent and Data Repository

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send deidentified information about your health and behavior and in some cases, your genetic information, to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. NIMH will also report to Congress and on its website about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at <https://data-archive.nimh.nih.gov>.

APPENDIX VI: ACRONYMS AND ABBREVIATIONS

ACOS/R&D	Associate Chief of Staff for Research and Development
AFARS	Army Federal Acquisition Regulation Supplement
ARRIVE	Animal Research: Reporting <i>In Vivo</i> Experiments
ARS	Acute Radiation Syndrome
BAA	Broad Agency Announcement
BoNT	Botulinum Neurotoxin
BPE	Biomedical Performance Enhancement
BSV	Biosurveillance
BSVE	Biosurveillance Ecosystem
CASEVAC	Casualty Evacuation
CCCRP	Combat Casualty Care Research Program
CCSI	Combat Casualty Simulation Initiative
CDE	Common Data Element
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CIH	Complementary and Integrative Health
CPG	Clinical Practice Guidelines
CNACI	Child Care National Agency Check and Inquiries
COI	Conflict of Interest
CRM RP	Clinical and Rehabilitative Medicine Research Program
DFARS	Defense Federal Acquisition Regulation Supplement
DoD	Department of Defense
DoDAF	DoD Architecture Framework
DoDEA	Department of Defense Education Activity
DoDGARs	DoD Grant and Agreement Regulations
DoDI	Department of Defense Instruction
DTRA	Defense Threat Reduction Agency
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
EO	Executive Order
FAP IIS	Federal Awardee Performance and Integrity Information System
FAR	Federal Acquisition Regulation
FAQs	Frequently Asked Questions
FDA	U.S. Food and Drug Administration
FedBizOpps	Federal Business Opportunities

FFRDC	Federally Funded Research and Development Center
FHIR	Fast Healthcare Interoperability Resources
FITBIR	Federal Interagency Traumatic Brain Injury Research
FSD	Federal Service Desk
FY	Fiscal Year
GA	Tabun
GB	Sarin
GD	Soman
GCP	Good Clinical Practices
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GSA	General Services Administration
HIT	Health Informatics or Information Technology
HITI	Health Information Technology and Informatics
HL7	Health Level 7
HRPO	Human Research Protection Office
ICH E6	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IRB	Institutional Review Board
IT	Information Technology
JBCF	Joint Biosurveillance Common Framework
JCM	Joint Casualty Management
JETS	Joint Evacuation and Transport Simulation
JMLIS	Joint Medical Logistics and Infrastructure Support
JSTO-CBD	Joint Science and Technology Office for Chemical and Biological Defense
LAR	Legally Authorized Representative
LET	Linear Energy Transfer
MBDRP	Medical Biological Defense Research Program
MCDRP	Medical Chemical Defense Research Program
MCM	Medical Countermeasure
MDO	Multi-Domain Operations
MedSim	Medical Simulation
MHS	Military Health System
MIDRP	Military Infectious Diseases Research Program
MOMRP	Military Operational Medicine Research Program
MSISRP	Medical Simulation and Information Sciences Research Program
MUM-T	Manned-Unmanned Teaming
NATO	North Atlantic Treaty Organization

NDA	National Institute of Mental Health Data Archive
NIMH	National Institute of Mental Health
NMS	Neuromusculoskeletal
NPC	Non-Profit Corporation
NRAP	National Research Action Plan
NSOCM	NATO Special Operations Combat Medic
ORP	Office of Research Protections
PFC	Prolonged Field Care
PI	Principal Investigator
POINTS	Point of Injury Training Simulation
PTSD	Post-Traumatic Stress Disorder
RHERP	Radiation Health Effects Research Program
RTD	Return to Duty
SAM	System for Award Management
SBIR	Small Business Innovation Research
SOW	Statement of Work
STEM	Science, Technology, Engineering, or Mathematics
TBI	Traumatic Brain Injury
TFF	Total Force Fitness
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
VA	Department of Veterans Affairs