I. OVERVIEW OF THE FUNDING OPPORTUNITY

Defense Health Agency Science & Technology

BROAD AGENCY ANNOUNCEMENT
for Extramural Medical Research

Funding Opportunity Number: HT942523SBAA1

Announcement Type: Initial

Assistance Listing Number: 12.420
Military Medical Research and Development

KEY DATES

Release/Posted Date: October 1, 2022

Closing Date: September 30, 2027, 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, 2022, through September 30, 2027, 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.

Table of Contents

I. OVERVIEW OF THE FUNDING OPPORTUNITY 1

I.A. New for Fiscal Year 2023 – Fiscal Year 2027 5

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY 6

II.A. Strategic Research Plan Descriptions 7

II.A.1. Military Infectious Diseases 7

II.A.2. Combat Casualty Care 9

II.A.3. Traumatic Brain Injury 11

II.A.4. Psychological Health 12

II.A.5. Sensory Systems 13

II.A.6. Musculoskeletal Injury 14

II.A.7. Environmental Exposures 15

II.A.8. Directed Energy/Radiation Health 15

II.B. Award Information 16

II.B.1. Clinical Trial Support 18

II.B.2. Use of Military and Department of Veterans Affairs Populations or Resources 18

II.B.3. Technology Requirements and Standards 19

II.B.4. Data Sharing 20

II.B.5. Funds Available and Anticipated Number of Awards 21

II.B.6. Award Amounts and Periods of Performance 21

II.B.7. Mechanisms of Support 22

II.C. Eligibility Information 24

II.C.1. Eligible Applicants 24

II.C.2. Cost-Sharing 25

II.C.3. Other 25

II.D. Proposal/Application Submission Information 26

II.D.1. Where to Obtain the Proposal/Application Submission Package 26

II.D.2. Content and Form of Proposal/Application Submission 27

II.D.3. Unique Entity Identifier and System for Award Management 49

II.D.4. Submission Dates and Times 49

II.D.5. Intergovernmental Review 50

II.D.6. Funding Restrictions 50

II.D.7. Other Submission Requirements 50

II.E. Proposal/Application Review and Selection Information 51

II.E.1. Criteria for Research Proposals/Applications Without a Clinical Trial 51

II.E.2. Proposal/Application Selection Process 54

II.E.3. Risk, Integrity and Performance Information 55

II.E.4. Notification of Proposal/Application Review Results 56
II.F. Federal Award Administration Information 56
II.F.1. Federal Award Notices 56
II.F.2. Administrative and National Policy Requirements 57
II.F.3. Reporting Requirements 57
II.G. Federal Awarding Agency Contacts 58
II.G.1. eBRAP Help Desk 58
II.G.2. Grants.gov Contact Center 58
II.H. Other Information 59
II.H.1. Contractor/Recipient Qualification 59
II.H.2. Proprietary Information 59
II.H.3. Administrative Actions 59
II.I. Checklist for Research Proposal/Application Submission Without a Clinical Trial 62

APPENDIX I. RESEARCH AREAS OF INTEREST 64
I. Military Infectious Diseases 64
II. Combat Casualty Care 67
III. Traumatic Brain Injury 69
IV. Psychological Health 70
V. Sensory Systems 71
VI. Musculoskeletal Injury 72
VII. Environmental Exposures 72
VIII. Directed Energy/Radiation Health 72

APPENDIX II. CLINICAL TRIALS 74
I. Important Aspects of Clinical Trials 74
II. Full Proposal/Application Submission Components for Studies With a Clinical Trial 76
III. Review Criteria for Research Proposals/Applications With a Clinical Trial 94
IV. Checklist for Research Proposal/Application Submission With a Clinical Trial 99

APPENDIX III. DOW AND VA WEBSITES 101

APPENDIX IV. PROCEDURES FOR ACQUISITION, PROCESSING, STORAGE, AND SHIPMENT OF BIOFLUIDS 103

APPENDIX V. NATIONAL INSTITUTE OF MENTAL HEALTH DATA ARCHIVE – INFORMED CONSENT 104

APPENDIX VI. TECHNOLOGY READINESS LEVELS AND KNOWLEDGE READINESS LEVELS 105

APPENDIX VII: FY23–FY27 DHA S&T BAA ADDENDUM –FY26 NEW PROGRAM

INCREASES.....106

APPENDIX VIII. ACRONYMS AND ABBREVIATIONS.....109

I.A. New for Fiscal Year 2023 – Fiscal Year 2027

The fiscal year 2023–2027 (FY23–FY27) Defense Health Agency (DHA) BAA for Extramural Medical Research contains several changes from previous versions. Read each section carefully. Note the following:

- The open period of the BAA is 5 years and will be amended annually with any updates.
- The "Research Areas of Interest" can be found in Appendix I.
- 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, United States Code, Title 31, Sections 6301-6308 (31 USC 6301-6308), which provides the legal criteria to select a procurement contract or an assistance agreement. The award type, along with the start date, will be determined during the negotiation process.
- For assistance agreements:
    - The total period of performance may be proposed for up to a maximum of 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 War's (DOW) implementation of Office of Management and Budget guidance in Code of Federal Regulations, Title 2, Part 200 (2 CFR 200), "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards." DOW implementation is located in Chapter XI of 2 CFR.
- For contract awards:
    - The total period of performance may be proposed for up to 5 years in length; additional periods may be considered.
    - Any contract awarded under this BAA will be governed by the various provisions of the Federal Acquisition Regulation (FAR) and the Defense Federal Acquisition Regulation Supplement (DFARS).
- For other transactions:
    - Regarding Other Transaction Agreements (OTAs) that utilize the authority within 10 USC 4021 or 4022, the period of performance will be dependent upon each specific award made.

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

The DHA strives 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 (S&T), 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 DHA. General information on the DHA can be obtained from health.mil/STPMD. The publicly releasable DHA Strategic Research Plans (SRPs) described in this document (except Directed Energy/Radiation Health) can be obtained from health.mil/STPMD.

This BAA is intended to solicit extramural research and development ideas using the authority provided by 10 USC 4001. The BAA is issued under the provisions of the Competition in Contracting Act of 1984 (Public Law 98-369), as implemented in FAR 6.102(d)(2) and 35.016 and in Department of Defense 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. This BAA utilizes competitive procedures in accordance with 10 USC 3012 for the selection for award of S&T proposals/applications. For the purposes of this BAA, S&T includes activities involving basic research, applied research, advanced technology development, and, under certain conditions, may include activities involving advanced component development and prototypes.

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 DHA's Science and Technology (S&T) SRPs, 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," which is available on Grants.gov along with this BAA.

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 management agent for this BAA is the Defense Health Agency Science & Technology. (DHA S&T) The DHA S&T coordinates the management of the Electronic Biomedical Research Application Portal (eBRAP) system, pre-proposal/pre-application and full proposal/application

receipt and review, and other key process oversight. Refer to Section II.G, Federal Awarding Agency Contacts, for additional information.

The DHA S&T's supporting acquisition office, the Defense Health Agency Contracting Activity (DHACA), will be the awarding and administering office for proposals/applications selected for funding, unless approval is obtained from the DHACA Senior Contracting Official to allow another federal acquisition office to execute and administer an award.

II.A. Strategic Research Plan Descriptions

The scope of research priorities included in this funding opportunity are limited to research that is approved for funding and not the full scope of the respective SRPs. Priorities listed are not in order of importance. Priorities support basic (6.1), applied (6.2), and advanced technology development (6.3) research efforts.

The following DHA S&T criteria apply to scope for inclusion in an SRP and associated SRP-based S&T program planning:

- Medical research providing knowledge or materiel products relating to preventing, stabilizing, preserving, repairing, and/or resolving diseases or injuries affecting Service Members across military operational environments
- Medical research addressing Joint Military Health System (MHS) capability requirements or gaps
- Research that is operationally relevant, transition-oriented, traceable to clinical practice, informs military doctrine, and/or informs health or product development

Research areas that do not meet these criteria, and are excluded from SRPs and this funding opportunity, include:

- Human performance enhancement (beyond baseline)
- Medical surveillance
- Non-research infrastructure maintenance
- Healthcare policy assessments
- Personal protective equipment/weapon systems evaluation
- Non-medical Military Occupational Series (MOS) training
- Clinical practice implementation science

II.A.1. Military Infectious Diseases

The Joint Force operates in areas of the world where endemic and emerging infectious diseases present substantial and immediate health risks to U.S. personnel. Future operational scenarios, to

include large-scale combat operations (LSCOs), pose an increased risk of infectious diseases due to degraded natural environmental disease barriers and public health infrastructure, as well as the potential for delayed evacuation times. Current national, military, and biodefense strategies and subsequent requirements documents specify a worldwide force protection capability to prevent, diagnose, and treat endemic and emerging infectious disease threats to protect the Joint Force.

Likewise, wound infection resulting from complex traumatic injuries in a prolonged care environment poses a substantial threat to the operational effectiveness of deployed forces. During prolonged care scenarios to include LSCO environments, infection and complications secondary to injury will develop in the prehospital setting through Role 3. While recent conflicts typically managed infection at higher roles of care, future conflicts in contested environments with near-peer adversaries will require management in-theater due to delayed casualty evacuation and/or treatment. While most infected wounds during insurgency operations over the last 20 years were not initially colonized with multidrug-resistant organisms (MDROs), the prevalence of MDRO infections significantly increased as casualties moved through higher roles of care. The inability to prevent, delay, or treat wound infections in a prolonged care environment will increase the prevalence and severity of infected wounds. Similarly, a concomitant increase in MDRO wound infections will occur across the continuum of care. Therefore, closing the gap on the impact of wound infections on the Joint Force requires countermeasures to prevent, diagnose, and treat both initial wound infections and MDRO infections across the continuum of care.

The scope of funded research in the DHA Military Infectious Diseases (MID) SRP relates to the prevention, diagnosis, and treatment of military-relevant infectious diseases, including combat-associated wound infections to serve the overall goal of maintaining unit and individual readiness, preserving operational effectiveness, and accelerating return to duty following infection.

Priorities are identified based on an assessment of current and future medical and operational needs, existing research gaps validated by the military medical community, or both. The MID SRP places an emphasis on the following:

- **Prevent:** Develop solutions to prevent endemic and emerging infectious diseases, including combat-associated wound infections, to maintain readiness and preserve operational effectiveness. Prevention is the most desirable infectious disease countermeasure because it prevents disease from occurring (versus treatment post-infection), is the most cost-effective approach, and reduces unit loss rate.

- **Diagnose:** Develop solutions to diagnose endemic and emerging infectious diseases, with a specific focus on diagnosing combat-associated wound infections and predicting wound-infection-associated sepsis, in order to maintain readiness, preserve operational effectiveness, and accelerate return to duty.

- **Treat:** Develop solutions to treat endemic and emerging infectious diseases, including combat-associated wound infections, to maintain readiness, preserve operational effectiveness, and accelerate return to duty.

Research Areas of Interest for the MID SRP 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

Combat Casualty Care (CCC) encompasses the assessment, diagnosis, treatment, stabilization, and disposition (return to duty or evacuation) of Service Members. Care provided at the point of need (PON) includes: far-forward at point of injury, en route, and within extended pre-hospital environments. The scope of funded research in the CCC SRP includes solutions for the acute and early management of combat-related trauma, including point of injury, prolonged and en route care.

The CCC SRP prioritizes identifying, developing (when necessary), evaluating, and transitioning methods, therapeutics, and technologies aimed at improving acute and early combat-related trauma management solutions. The continuum of care is defined as an integrated system that guides care at PON and tracks wounded, ill, or injured (WII) Service Members through the various roles of care (ROC; 1, 2, and 3) by facilitating seamless operational medicine.

Priorities are identified based on an assessment of current and future medical and operational needs and/or existing research gaps validated by the military medical community. The CCC SRP places an emphasis on the following:

- **Tactical Combat Casualty Care (TCCC):** TCCC encompasses advanced medical solutions to assess, treat, and stabilize combat-related injuries at PON through ROC 1, and the having the ability to hold patients longer when evacuation is challenged. Future large-scale, multi-domain combat operations will significantly contest the military's "Golden Hour" or "Golden Day" paradigm. Responding to this challenge and taking measures to maintain high rates of survival and recovery among wounded Service Members will require innovative solutions that sustain/build medical capabilities as far forward as possible. This priority focuses on solutions to support PON to immediately stabilize injured Service Members and continuation of care for return to duty or evacuation.

- **Resuscitative Strategies and Care:** Advanced resuscitative care is paramount for battlefield survivability at PON and anywhere along the continuum of care. Delays in evacuation and high casualty rates in the future battlespace will place further demands on advanced trauma care if casualties deteriorate and need to be resuscitated again anywhere in the evacuation chain. Effective hemorrhage control and replacement of lost blood volume are the lifesaving, battle-proven treatments most likely to mitigate hemorrhagic shock and blood loss. The ability to provide enough resuscitative products, including whole blood, at the point of need in the future battlespace for large numbers of casualties remains a critical medical challenge. This priority focuses on forward resuscitative and augmenting solutions (blood, blood products, and substitutes) to wounded Service Members experiencing complications from trauma, shock, or other life-threatening conditions in austere and resource-limited environments.

- **Care of Complex Injuries and Organ Support:** Providers in the future battlespace will be challenged with managing large casualty volumes, high acuity care, and limited resources. Across the continuum of care, far forward providers need adaptable medical solutions to manage complex injuries and address respiratory, cardiovascular, metabolic, and immunologic consequences of trauma, shock, organ failure, and burn. Prolonged and

resource-limited settings further drive the need to develop tools that support the wounded across various operational platforms in diverse and isolated environments. This priority focuses on activities that seek to resolve critically identified Joint deficiencies associated with casualty care for WII Service Members in a complex and resource-limited operational environment.

- **Forward Surgical Care:** Contested and resource-limiting environments will limit evacuation and PON support from larger medical elements. It will be incumbent upon medical, evacuation, and logistics elements to position surgical assets farther forward and in greater isolation than in recent theaters. Forward surgical care, also known as damage control surgery (DCS), is a principal component of military medicine, enabling medical personnel to provide lifesaving surgical interventions to injured Service Members. Activities within this priority include identifying and developing new or leveraging existing knowledge and materiel solutions needed to surgically stabilize life-threatening injuries closest to PON. Performance of these critical surgical interventions promotes survivability of injured Service Members and helps to further prevent or mitigate a casualty's irreversible physiological deterioration. As we prepare for the future fight without the benefits of the "Golden Hour," the battlefield medical system must be modernized to maximize the further-forward surgery paradigm and bring with it medical solutions that will ensure expeditious surgical care to wounded Service Members in theatre.

- **Functional Recovery from Traumatic Wound and Burn Injuries:** Significant increases in the frequency and severity of traumatic wound and burn injuries are predicted to challenge capability and capacity in a future battlespace. Urban dense terrain and multi-domain operations (MDOs) of the future are expected to generate complex wounds and burn injuries that will require advanced prolonged care and stabilization when tactical evacuations to robust rear element medical care infrastructures are delayed. Under current doctrine, these wound and burn casualties will quickly overwhelm providers and available resources in an already strained and complex operational environment. Moreover, the specialized care needed for burn patients comes with significant challenges as even a small number of burn casualties can deplete a large number of resources quickly. As a result, the need for aggressive battlefield wound and burn care technologies are paramount to providing advanced care to wounded Service Members. Activities within this priority focus on yielding knowledge and advanced materiel solutions needed to assess, treat, and manage complex wounds and burn injuries in any pre-hospital, resource-limited battlespace environment.

- **Effects of Transport on Complex Injuries:** As the military engages in future MDOs, contested air, land, and sea superiority will result in significantly extended evacuation times for WII Service Members. Distinct from previous research and development efforts, the future battlespace will require military en route care research to focus on the intersection of the patient, their injury or illness, the stresses of transport, and the environment of care in addition to the multimodal transport platform that may be used. Casualty care providers will need to better understand the effects of prolonged transport time, mode(s) of transport, and environmental factors that can negatively impact Service Members with complex/ polytraumatic injuries under these extended and diverse conditions. Activities within the Effects of Transport on Complex Injuries capability requirement focus on understanding and advancing knowledge to better enable effective casualty support and treatment during

transportation from PON to more advanced ROCs, in between ROCs via various evacuation platforms, and scalability. Understanding the physiological response to transport is not only needed to inform future practice guidelines and policy decisions for anticipated conflicts, but provides necessary operational and medical data, highlights important deficiencies in the current system, and offers information that can be used to create robust solutions for medical evacuation support in the future battlespace.

- **En Route Care:** Patient movement throughout the continuum of care is termed "en route care," which provides medical capability during patient transport to preserve clinical conditions. En route care is transport by regulated or unregulated vehicles or platforms from the point of injury through definitive care by (1) ground transport; (2) rotary or fixed-wing transport; (3) maritime transport from surface and underwater; and (4) nontraditional space medical mobility systems. Effective en route care is critical to ensure optimal medical outcomes and maintain operational advantage. Activities within this priority include modalities to increase care provider capability and capacity during cognitive overload, and mass evacuation scenarios with Service-specific platforms.

The Research Areas of Interest for the CCC SRP are found in Appendix I.II. ***Applicants are urged to read and consider these before preparing their proposals/applications.***

II.A.3. Traumatic Brain Injury

Traumatic Brain Injury (TBI) is a collective term used for multiple different physiological states that are consequences of physical damage to the brain. This type of damage typically arises from an external force and can be penetrating, contact non-penetrating closed-head, effects from blast and blast overpressure, as well as other energies and forces; TBI is also seen with polytrauma. The human brain is among the most heterogeneous organs in the body, and trauma can cause the most varying source of disease, making brain injury a very complex medical issue to solve, especially rapidly. The earlier brain injury can be addressed, the better outcome is expected of the patient. The two main overarching gaps existing with TBI in combat and early management are objective diagnosis/prognosis and treatment. Both of these can vary depending on the injury types; however, it may be possible that the diverse types of injuries share common objectives, rapid biomarkers, and treatment interventions. Some injuries are quite different from others; for instance, mild TBI (mTBI) in theater may yield no physical impairments yet lead to cognitive and psychological issues which can greatly reduce unit readiness and combat effectiveness.

The scope of funded research in the TBI SRP relates to the diagnosis and treatment of military-relevant brain injuries, including combat-associated TBI, polytrauma, blast, and blast overpressure, while recognizing the vast diversity of the injury types. Early diagnosis, prognosis, and treatment can serve to prevent further damage seen in repetitive mTBI, blast overpressure, and more severe injuries.

Priorities are identified based on an assessment of current and future medical and operational needs, existing research gaps validated by the military medical community, or both. The TBI SRP places an emphasis on the following:

Diagnose/prognose and monitor: Develop solutions to objectively diagnose the injury,

prognosticate outcomes, and monitor recovery to inform treatment options, maintain readiness, preserve operational effectiveness, and accelerate return to duty.

Treat: Develop solutions to initiate early treatment for the spectrum of TBI categories, including interventions for milder injuries, to maintain readiness, preserve operational effectiveness, and accelerate return to duty. This includes developing interventions for moderate and severe injuries at ROC 1 and 2 to improve outcomes in prolonged care scenarios.

Prevent: Develop capabilities to prevent further brain damage by providing early warnings and management of potential injuries arising from blast overpressure in both training and combat environments.

Focus areas include:

- **TBI assessment and diagnosis:**
    - Development of noninvasive far forward TBI assessment tools
    - Fluid-based biomarker tools to identify and assess TBI far forward
    - Advanced analytic tools for TBI management and diagnosis
- **TBI pre-hospital and deployed treatment:**
    - Minimally invasive intracranial access for Role 2 and mobile medical care
    - Therapeutic interventions to treat/stabilize penetrating and severe TBI
    - Therapeutic interventions to treat mild/moderate TBI
- **TBI countermeasures to prevent adverse brain health effects and performance degradation resulting from hazardous/injurious exposures:**
    - Modulating concussion health performance criteria, particularly for blast injuries
    - Modulating concussion health performance criteria, particularly for impact injuries

Out-of-scope areas include: training for forward responders, the management of chronic effects of TBI, neurodegenerative disease, epilepsy, and spinal cord injuries.

The Research Areas of Interest for the TBI SRP are found in Appendix I.III. ***Applicants are urged to read and consider these before preparing their proposal and applications.***

II.A.4. Psychological Health

The scope of funded research in the Psychological Health SRP includes developing solutions to maintain Service Member readiness, improve behavioral health diagnoses, and provide behavioral health interventions that enable rapid return to duty. Priorities focus on advancing

psychological health research for the military community and encompass multiple domains, including clinical conditions and psychological readiness.

Priorities are identified based on an assessment of current and future medical and operational needs, existing research gaps validated by the military medical community, or both. The Psychological Health SRP places an emphasis on the following:

- **Development of Assessment Tools:** Identify objective, non-self-report factors to inform the development of tools that assess, monitor, and document Service Members' current psychological states, enabling comparison across relevant time points and supporting decision-making interventions.

- **Models of Care for Efficient Interventions:** Develop recognition, vectoring, and referral protocols, as well as effective psychological health models and/or models incorporating non-specialty medical personnel, for early intervention of psychological health conditions among Service Members.

- **Medically Appropriate Return-to-Duty Guidelines:** Develop and validate core elements of Joint Services return-to-duty criteria.

- **Solutions to Optimize Psychological Readiness:** Develop Service Member, unit, and leadership tools to improve and maximize psychological readiness and performance.

The Research Areas of Interest for the Psychological Health SRP are found in Appendix I.IV. ***Applicants are urged to read and consider these before preparing their proposals/applications.***

II.A.5. Sensory Systems

The Sensory Systems SRP is structured into modalities to cover a range of distinct research areas within medical S&T research, and priorities focus to characterize basic mechanisms and advance assessment, diagnosing, monitoring, and treatment of sensory injuries, dysfunctions, or illnesses. The scope of funded research in the Sensory Systems SRP focuses on developing improved pain and anesthesia techniques for use in the battlefield and medical treatment facilities resulting in solutions for improving pain treatment and promising early-stage products with enhanced efficacy/safety profiles.

Priorities are identified based on an assessment of current and future medical and operational needs, existing research gaps validated by the military medical community, or both. The Sensory Systems SRP places an emphasis on the following:

- **Stabilization Tool Development:** Optimize stabilization solutions and point-of-injury care of sensory injury to preserve function and readiness.

- **Treatment Tool Development:** Develop knowledge and materiel solutions for the repair or mitigation of sensory injury or illness.

Focus areas include:

- Improved pain control
    - Development of stabilization and treatment tools to improve pain control (e.g., reducing care demand, repurposing existing compounds)
    - Development of therapeutics with minimal impairment of Service Member operational capabilities
    - Identification of acute risk factors associated with the development of chronic pain (the chronicity of pain)
- Battlefield anesthesia and advanced sedation
    - Development of novel hemo-stable anesthetic agents with minimal impact on blood pressure and cardiovascular function
    - Development of long-lasting, reversible sedatives for prolonged care and transport
    - Development of vaporizor-free, operationally relevant delivery techniques

Out-of-scope areas include: polymorbidities and injuries associated with TBI; training medical providers to examine, assess, and treat injuries or illnesses; regenerative, restorative, and transplant capabilities; sensory system capability enhancements; longitudinal care for sensory injuries and illnesses; peripheral nerve and spinal cord damage; and chronic pain.

The Research Areas of Interest for the Sensory Systems SRP are found in Appendix I.V. ***Applicants are urged to read and consider these before preparing their proposals/applications.***

II.A.6. Musculoskeletal Injury

The scope of funded research in the Musculoskeletal Injury (MSKI) SRP focuses on developing treatment strategies, technologies, and techniques to address musculoskeletal injuries close to the point of injury in pre-hospital environments. Additionally, it supports solutions that provide initial in-theater protection and preservation while facilitating later aspects of care, including reconstruction, long-term rehabilitation, and recovery.

Priorities are identified based on an assessment of current and future medical and operational needs, existing research gaps validated by the military medical community, or both. The MSKI SRP places an emphasis on the following:

- **Initial Care for Musculoskeletal Injuries:** Develop treatment strategies, technologies, and techniques to mitigate sequelae and optimize outcomes for Service Members in garrison and forward-deployed settings.

Focus areas include:

- MSKI rehabilitation interventions, technologies, and techniques to treat MSKIs in pre-hospital interventions

- Therapeutic interventions to accelerate recovery from MSKIs
- Solutions for the preservation of musculoskeletal health

Out-of-scope areas include: treatment of spinal cord injury.

The Research Areas of Interest for the MSKI SRP are found in Appendix I.VI. ***Applicants are urged to read and consider these before preparing their proposal and applications.***

II.A.7. Environmental Exposures

The Environmental Exposures SRP includes priorities to counter health threats, disease, and non-battle injury through the prevention, assessment, and treatment of military-relevant environmental exposures. Priorities are identified based on an assessment of current and future medical and operational needs, existing research gaps validated by the military medical community, or both. The Environmental Exposures SRP places an emphasis on the following:

- **Environmental Exposure and Health Risk Prevention:** Develop mechanisms and/or countermeasures to prevent health threats associated with environmental exposures.
- **Environmental Exposures Treatment:** Develop means to treat the harmful effects of extreme environmental exposures

The scope of funded research in the Environmental Exposures SRP focuses on developing objective physiological and functional measures to reliably determine when Service Members can safely return-to-duty following a frostbite injury, providing next-generation guidelines and treatments for exertional heat illness, and providing Maximum Exposure Guidelines (MEGs) for combustion products by developing assessment methodologies and vulnerability factors of key hazards.

Focus areas include:

- Extreme heat
- Cold
- Toxic exposures

Out-of-scope areas include: weaponized chemical, biological, radiological and nuclear (CBRN), blast, infectious disease, and noise.

The Research Areas of Interest for the Environmental Exposures SRP are found in Appendix I.VII. ***Applicants are urged to read and consider these before preparing their proposals/ applications.***

II.A.8. Directed Energy/Radiation Health

The Directed Energy and Radiation Health SRP address injuries and adverse health effects from exposure to non-ionizing radiation and ionizing radiation. Priorities are identified based on an

assessment of current and future medical and operational needs and/or existing research gaps validated by the military medical community. The Directed Energy and Radiation Health SRP places an emphasis on the following:

Directed Energy: The term directed energy is defined for military applications as the ability to project non-ionizing electromagnetic energy, either broadly for communication and surveillance or in a focused manner to produce defensive or offensive effect(s), at militarily relevant distances. Given the non-kinetic nature of directed energy threats, the elicitation of a bioeffect may compromise well-being, resulting in an adverse health effect that prompts healthcare assessment and treatment. This area of research should add clarity to discriminators in which bioeffects become adverse health effects following radiofrequency, optical, or acoustic exposures in an operational environment. The overarching focus is to improve capabilities and knowledge available to distinguish between a "bioeffect" and an injurious "adverse health effect" resulting from directed energy exposures via established mechanisms. Research deliverables should have direct applications to relevant directed energy safety standards and/or clinical practice guidelines (CPGs).

Radiation Health: Radiation health promotes warfighter health and readiness through activities that support the discovery and development of medical capabilities to counter threats from acute ionizing radiation exposure. Research efforts to be considered include discovery and development of: radiation pre-exposure prophylaxis candidates; biomarkers to support diagnosis or to inform effective treatment modalities; characterization of the mechanism(s) of radiation injury and/or the mechanism(s) of action of medical countermeasures; and characterization of combined injuries resulting from radiation exposures in the presence of trauma injuries (e.g., hemorrhage, severe burn). Capabilities are intended for use in operational military environments, including ROC 1 through 3.

The Research Areas of Interest for the Directed Energy/Radiation Health SRP are found in Appendix I.VIII. ***Applicants are urged to read and consider these before preparing their proposals/applications.***

II.B. Award Information

This BAA may be used to support applied research, preclinical research, clinical research, and clinical trials/testing (or equivalent). BAA proposals/applications that include a clinical trial have additional proposal/application and review requirements (see Appendix II). ***The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.***

Clinical research is defined as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research.

A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. Funded trials are required to post a copy of the Institutional Review Board (IRB)-approved informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. ***Note:*** A Food and Drug Administration (FDA)-regulated clinical investigation is always a clinical trial, but not all clinical trials are FDA-regulated clinical investigations.

Research Involving Human Anatomical Substances, Human Data, Human Subjects, or Human Cadavers: All DOW-funded research involving new and ongoing research with human anatomical substances, human data human subjects, or human cadavers must be reviewed and approved by the DHA Office of Research and Regulatory Compliance (ORRC), Office of Human Research Oversight (OHRO), prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is ***not*** required. Allow up to 3 months to complete the OHRO regulatory review and approval processes following submission of ***all required and complete*** documents to the OHRO. Refer to the General Submission Instructions, Appendix 1, and the Office for Human Research Protections Office Resources and Overview document available on the eBRAP "Funding Opportunities & Forms" web page (ebrap.org) for additional information.

If the proposed research involves more than one institution, plans for the multi-institutional structure governing the research protocol(s) should be outlined. In addition, a written plan for single IRB review arrangements must be provided for research conducted in the United States involving more than one institution. The lead institution 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. Communication and data transfer between or 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 application. A separate intellectual and material property plan agreed on by all participating institutions is also required for multi-institutional clinical research/trials.

Research Involving Animals: All research funded by the BAA involving new and ongoing research with animals must be reviewed and approved by the DHA ORRC Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is ***not*** required. ***Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

Rigor of Experimental Design: All projects should adhere to accepted standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. Core standards are described in S.C. Landis et al., "A call for transparent reporting to optimize the predictive value of preclinical research," *Nature* 2012, 490:187-191 (nature.com/articles/nature11556). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Applicants should consult the Animal

Research: Reporting *In Vivo* Experiments (ARRIVE) guidelines 2.0 to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at arriveguidelines.org/arrive-guidelines.

II.B.1. 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. Full proposal/application submission is described in Appendix II; refer to Appendix II, Section IV, Checklist for Research Proposal/Application Submission With a Clinical Trial, in preparing the full proposal/ application.

For projects proposing a clinical trial:

- ***If an Investigational New Drug (IND) or Investigational Device Exemption (IDE) is required for the study, the IND/IDE application must be submitted to the FDA by the proposal/application submission. It is the responsibility of the applicant to provide evidence from the IRB of record or the FDA if an IND/IDE is not required.*** Refer to Attachment 12, Regulatory Strategy (Appendix II), for further details.

- If the clinical trial of an investigational product will be conducted at international sites, evidence that an application has been submitted to the relevant national regulatory agency of the host country(ies) is required by the above deadlines.

- Clinical trials must be initiated no later than 12 months after the award date.
  Note: The government reserves the right to withhold or withdraw funding if an IND or IDE is necessary to conduct the study but has not been obtained within 6 months of the award date.

II.B.2. Use of Military and Department of Veterans Affairs Populations or Resources

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

Use of DOW or VA Resources: If the proposed research involves access to active-duty military and/or Veteran patient populations and/or DOW or VA resources or databases, the proposal/ application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Use Attachment 2: Supporting Documentation, to provide relevant documentation to demonstrate access to DOW and/or VA populations or resources. Refer to the General Submission Instructions, Appendix 1, for additional information.

45 CFR Section 46.114 (Cooperative Research) of the Common Rule requires any institution located in the United States that is engaged in cooperative research to rely upon approval by a

single IRB for that portion of the research that is conducted in the United States. For multi-site studies with collaborating VA institutions engaged in non-exempt human subjects research, and for which the use of a single IRB is determined to be not appropriate for the particular research context, a memorandum from the VA Office of Research and Development approving exception of the single IRB requirement must be sought and provided to the OHARO OHRO during the human research protection official review of the project.

Access to certain DOW or VA patient populations, resources, or databases may only be obtained by collaboration with a DOW or VA investigator who has a substantial role in the research and may not be available to a non-DOW or non-VA investigator if the resource is restricted to DOW or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DOW or non-VA investigator collaborating with the DOW and/or VA. ***If the proposal/application is recommended for funding, 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).***

Conducting DOW-Funded Human Research with Military Populations: There are unique requirements and limitations for compensating DOW-affiliated personnel for study participation and for conducting research with military Service Members or their Families/children and research with populations from U.S. Special Operations Command may require additional reviews and approvals. Additional information regarding conducting DOW-funded human research with military populations can be found in the Conducting Research with Military Populations Guide.

II.B.3. 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 DOW Information Management/IT standards for interoperability, cybersecurity, as well as the DOW Architecture Framework (DOWAF) and viewpoints, as follows:

a. DOWAF and viewpoints

b. DOD Instruction (DoDI) 8500.01 March, 14, 2014, “Cybersecurity”

c. DoDI 8510.01 July 19, 2022, “Risk Management Framework (RMF) for DoD Systems”

d. Any products expected to provide data to MHS Genesis, the DOW 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 and Fast Healthcare Interoperability Resources standards in order to ultimately provide integration with MHS Genesis.

e. All software-based research products, including computer code, software code, data, and metadata, should be provided as deliverables, and electronic versions need to be able to be uploaded to standards-based electronic repositories. Metadata (i.e., the data dictionary and data model) as well as data (i.e., cases) generated in the research should be provided in an

industry-standard format for access by the government in an open-source data repository of electronic deliverables.

f. Any information systems that are owned or operated by the contractor, and that process, store, or transmit Federal contract information not intended for public release, are subject to the basic safeguarding requirements detailed under the FAR and DFARS.

g. OTAs may establish nonstandard requirements.

II.B.4. Data Sharing

The DHA 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, the use of CDEs continues to be required. The DHA 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 (phenxtoolkit.org) in all studies involving human subjects, as applicable.

- 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 Spinal Cord Injury | National Institute of Neurological Disorders and Stroke (NINDS) Common Data Elements (nih.gov).

- Military Suicide Research Consortium CDEs were developed across two consortium phases are available through the VA HSRD SPRINT Portal.

TBI research data elements must be reported using the NINDS TBI. For the most current version of the NINDS TBI CDEs, go to the NINDS Common Data Elements website Use of the TBI CDEs is required wherever possible in an effort to create standardized definitions and guidelines about the kinds of data to collect and the data collection methods that should be used in clinical studies of TBI. ***Use of UDEs is strongly discouraged and subject to program approval.***

If the project includes the collection of biofluids, 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 biofluids can be found in Appendix IV.

For projects involving TBI, PIs may be required to report data to government identified databases and establish unique data sharing requirements.

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) nda.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).

OTAs may establish unique data sharing requirements.

II.B.5. 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 DHA and is appropriate for a research area described within this BAA may be utilized to fund proposals/applications.

II.B.6. 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 and development contract awards, the total period of performance may be proposed for up to 5 years in length; additional periods may be considered. For OTAs that utilize the authority within 10 USC 4021 or 4022, the period of performance will be dependent upon each specific award made. 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.

Organizations seeking additional or continuation funding must work with their respective PIs to 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 & Related Budget.

II.B.7. Mechanisms of Support

The DHA 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 USC 6301-6308), which provides the legal criteria to select a procurement contract or an assistance agreement. Refer to the General Submission Instructions, Appendix 2, Section D, for additional information.

Proposers awarded a Grant, Cooperative Agreement, Procurement Contract or Other Transaction for Research or Prototypes, based on their response to this BAA, shall follow the applicable rules and regulations governing these various award instruments but, in all cases, should appropriately identify any potential restrictions on the government's use of any Intellectual Property contemplated under the award instrument in question; refer to Attachment 8: Data and Research Resource Sharing Plan. This includes both noncommercial Items and commercial Items.

II.B.7.a. Procurement Contract: A legal instrument that, consistent with 31 USC 6303, reflects a relationship between the federal government and a state government, local government, or other entity/contractor when the principal purpose of the instrument is to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the federal government.

Contracts are primarily governed by the following regulations:

a. FAR

b. DFARS

II.B.7.b. Grant: A legal instrument that, consistent with 31 USC 6304, is used to enter into a relationship:

a. The principal purpose is to transfer a thing of value to the recipient to carry out a public purpose of support or stimulation authorized by a law or the United States, rather than to acquire property or services for the federal government's direct benefit or use;

b. In which substantial involvement is not expected between the federal government and the recipient when carrying out the activity contemplated by the grant; and

c. No fee or profit is allowed.

II.B.7.c. Cooperative Agreement: A legal instrument that, consistent with 31 USC 6305, is used to enter into the same kind of relationship as a grant (see definition "grant"), except that substantial involvement (collaboration, participation, or intervention in the research) is expected between the federal government and the recipient when carrying out the activity contemplated by the cooperative agreement. The term does not include "cooperative research and development agreements" as defined in 15 USC 3710a. No fee or profit is allowed.

II.B.7.d. Other Transactions for Research: The DHA will also consider the use of Other Transactions for Research as a vehicle for award under this BAA. In accordance with 10 USC 4021, "Research projects: transactions other than contracts and grants," such other transactions shall not be entered into unless the following conditions are satisfied:

a. To the maximum extent practicable, no other transaction entered into shall provide for research that duplicates research being conducted under existing programs carried out by DOW.

b. The funds provided by the government under another transaction authorization shall not exceed, to the extent that the Secretary of Defense determines practicable, the total amount provided by other parties to the other transaction.

II.B.7.e. Other Transactions for Prototypes: The DHA will also consider the use of Other Transactions for Prototypes as a vehicle for award under this BAA. In accordance with 10 USC 4022, "Authority of the Department of Defense to carry out certain prototype projects": No official of an agency shall enter into a transaction (other than a contract, grant, or cooperative agreement) for a prototype project under the authority of 10 USC 4022 unless one of the following conditions is met:

a. There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project.

b. All significant participants in the transaction other than the Federal Government are small businesses (including small businesses participating in a program described in section 9 of the Small Business Act [15 USC 638]) or nontraditional defense contractors.

c. At least one-third of the total cost of the prototype project is to be paid out of funds provided by sources other than the federal government.

d. The senior procurement executive for the agency determines in writing that exceptional circumstances justify the use of a transaction that provides for innovative business arrangements or structures that would not be feasible or appropriate under a contract, or would provide an opportunity to expand the defense supply base in a manner that would not be practical or feasible under a contract.

In accordance with 10 USC 4022(f), any other transaction for prototypes awarded under this BAA may provide for the award of a follow-on production contract or transaction to the participants in the transaction without the use of competitive procedures.

Additional information can be found in the most current version of the Other Transactions Guide for Prototype Projects at TAB A1 – DoD OT Guide JUL 2023_final.pdf (osd.mil).

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organizations

Awards are made to eligible organizations, not to individuals. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations. Refer to the General Submission Instructions, Appendix 3, Section B, for general eligibility information.

Note: In accordance with FAR 35.017-1(c)(4), 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 DHA 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 will 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.

Proposals/applications for this BAA may only be submitted by extramural organizations. Submissions from intramural DOW organizations to this BAA will be withdrawn. These terms are defined below.

Extramural Organization: An eligible non-DOW organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOW, and research institutes.

Intramural DOW Organization: A DOW laboratory, DOW military treatment facility, and/or DOW activity embedded within a civilian medical center. ***Intramural Submission: A proposal/application submitted by a DOW organization for an intramural investigator working within a DOW laboratory or military treatment facility or in a DOW activity embedded within a civilian medical center.***

Proposals/applications from intramural investigators may be submitted extramurally through a research foundation. ***It is permissible, however, for an intramural investigator to be named as a collaborator on a proposal/application submitted through an extramural organization. In this case, 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. For more information, refer to the General Submission Instructions, Section III.

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

Generally, there is no requirement for cost-sharing, matching, or cost participation to be eligible for award under this BAA. Cost-sharing and matching is not an evaluation factor used under this BAA. Exceptions may exist if the applicant is proposing the use of a Research OTA or Prototype OTA as an award instrument. Cost-sharing requirements may be found at 32 CFR 37 for Technology Investment Agreements (TIAs). Cost-sharing requirements for OTAs are stated in 10 USC 4021 for Research OTAs and 10 USC 4022 for Prototype OTAs.

In addition, if cost-sharing is proposed on a grant or cooperative agreement proposal/ application submitted by a nonprofit or institution of higher education, the award will be subject to the restrictions at 2 CFR 200.306. If cost-sharing is proposed on a contract proposal/application, the award will be subject to the restrictions at FAR 35.003(b).

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 conducting business with qualified recipients only. The DHA utilizes the Exclusions within the Performance Information functional area of SAM to identify individuals and organizations unqualified to receive federal awards. More information about Exclusions reported in SAM is available at sam.gov/SAM. The DHA also reviews and considers information about the applicant in the Office of Management and Budget-designated integrity and performance system, currently FAPIIS, prior to making an award. Refer to the General Submission Instructions, Appendix 3, for additional information.

Conflict of Interest (COI): All awards must be free of COIs that could bias the research results. Prior to award of a contract, grant, or agreement, applicants will be required to disclose all potential or actual COIs along with a plan to manage them. An award may not be made if it is determined by the Contracting, Grants, or Agreements 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.

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

Subcontracting Plan: If the resultant award is a contract that exceeds $750,000 and the offeror is other than a small business, the contractor will be required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.704. The subcontracting plan will have to comply with the requirements in FAR 19.704 and DFARS 219.704. A mutually agreeable plan will be developed during award negotiation process and incorporated as part of the resultant contract. This requirement is not applicable to assistance agreements or OTAs.

Refer to Section II.H.3, Administrative Actions, for a list of administrative actions that may be taken if a pre-proposal/pre-application or proposal/application does not meet the administrative, eligibility, or ethical requirements defined in this BAA.

II.D. Proposal/Application Submission Information

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

To obtain the complete Grants.gov proposal/application package (hereinafter, submission package), including all required forms, perform a Grants.gov (grants.gov) basic search using the Funding Opportunity Number **HT942523SBAA1**.

eBRAP (ebrap.org) is a secure web-based system that allows PIs to submit their pre-proposals/ pre-applications, view and verify extramural full proposals/applications submitted to Grants.gov (grants.gov), receive communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance.

Grants.gov is a federal system required to be utilized by agencies to receive and process extramural grant proposals/applications. Full proposals/applications may only be submitted to Grants.gov after submission of a pre-proposal/pre-application through eBRAP.

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

Extramural Submission:

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

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

Submission is a two-step process requiring both ***pre-proposal/pre-application*** (eBRAP.org) and ***full proposal/application*** (Grants.gov) as indicated below. Refer to Table 1, Full Application Guidelines for full proposal/application submission guidelines. ***Note:*** Investigator(s) proposing a clinical trial should refer to Appendix II for a detailed description of the requirements for such a proposal/application.

Pre-Proposal/Pre-Application Submission: Submission of a pre-proposal/pre-application is required and must be submitted through eBRAP. If the DHA is interested in receiving a full proposal/application, the PI will be sent an invitation via eBRAP to submit.

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 eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the proposal/application deadline.

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 Step 1: Pre-Proposal/Pre-Application Submission Content

During the pre-proposal/pre-application process, eBRAP assigns each submission is assigned a unique log number. This unique eBRAP log number is required during the full proposal/ application submission process.

To begin the pre-proposal/pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

Note: Proposals/applications for this BAA may only be submitted by extramural organizations. Submissions from intramural DOW organizations to this BAA will be withdrawn.

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

All pre-proposal/pre-application components must be submitted by the PI through eBRAP (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.

The applicant organization and associated PI 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 eBRAP Help Desk at help@eBRAP.org or 301-682-5507. A change in PI or organization after submission of the pre-proposal/pre-application may be allowed after review of a submitted written appeal (contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507) and at the discretion of the DHACA Contracting, Agreements, or Grants Officer.

The pre-proposal/pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Submission Instructions, Section II.B, for additional information on pre-proposal/pre-application submission):

- **Tab 1 – Application Information**

  Submission of proposal/application information includes assignment of primary and secondary research classification codes, which may be found at ebrap.org. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contact**

  Enter contact information for the PI. Enter the organization's Business Official responsible for the sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 Research & Related 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]), 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 COI in the review of the pre-proposal/pre-application (including those with whom the PI has a personal or professional relationship).

- **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, Human Data, 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 Pre-application 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.

- **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

DHA scientists and/or contracted, non-governmental subject matter 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 calendar days of submission, PIs should receive email notification via eBRAP regarding disposition of their pre-proposals/pre-applications.

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

Proposals/applications will not be accepted unless notification of invitation has been received.

The DHA 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 (grants.gov). See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Proposal/Application Submission Guidelines

Extramural organizations must submit full proposals/applications through Grants.gov. 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 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 Grants.gov How to Apply For Grants page for further information about the Grants.gov Workspace submission process.

Submissions of extramural applications through eBRAP may be withdrawn.

Do not password protect any files of the proposal/application package, including the Project Narrative.

Table 1. Full Proposal/Application Submission Guidelines

Proposal/Application Package Location
Download proposal/application package components for HT942523SBAA1 from Grants.gov (grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the proposal/application components and routing of the proposal/application package through the applicant organization for review prior to submission.

Full Proposal/Application Package Components

SF424 Research & Related Application for Federal Assistance Form: Refer to the General Submission Instructions, Section III.A.1, for detailed information.

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

- Attachments (for submissions without clinical trial)
- Research & Related Personal Data (for submissions without clinical trial)
- Research & Related Senior/Key Person Profile (Expanded) (for submissions without clinical trial)
- Research & Related Budget (for submissions without clinical trial)
- Project/Performance Site Location(s) Form (for submissions without clinical trial)
- Research & Related Subaward Budget Attachment(s) Form (for submissions without clinical trial)
- Attachments (for submissions with clinical trial)
- Research & Related Personal Data (for submissions with clinical trial)
- Research & Related Senior/Key Person Profile (Expanded) (for submissions with clinical trial)
- Research & Related Budget (for submissions with clinical trial)
- Project/Performance Site Location(s) Form (for submissions with clinical trial)
- Research & Related Subaward Budget Attachment(s) Form (for submissions with clinical trial)

Proposal/Application Package Submission

Create a Grants.gov Workspace.
Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.

Submit a Grants.gov Workspace Package.
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 needs to be modified, an updated Grants.gov proposal/application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking Identification ***prior to*** the proposal/application submission deadline. ***Do not password protect any files of the application package, including the Project Narrative.***

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.

Proposal/Application Verification Period

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 proposal/application package may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***.

Further Information

Tracking a Grants.gov Workspace Package.
After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission.

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

The full proposal/application package must be submitted using the unique eBRAP log number to avoid delays in proposal/application processing.

II.D.2.b.ii. Full Proposal/Application Submission Components Without a Clinical Trial

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).

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

Attachments for Proposals/Applications Without a Clinical Trial

Note: Components and attachments for a proposal/application with a clinical trial are provided in Appendix II.

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

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names, i.e., 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.

- **Attachment 1: Project Narrative (15-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 (uniform resource locators; web addresses) 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 proposal/application.

  A detailed innovative/state-of-the-art description of the research (relating to the Research Areas of Interest identified in Section II.A and Appendix I) 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 historical 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 U.S. 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.

- Describe how the proposed research is designed to achieve reproducible and rigorous results, including controls, sample size estimation, randomization, statistical analysis, and data handling.

- 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 clinical research studies involving human subjects, describe the recruitment plan to include relevant support and justification for sample size, study inclusion criteria, and data collection instruments, as well as 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. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. Describe the statistical model and data analysis plan with respect to the study objectives as appropriate to the type of study. 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. Investigators must develop protocols for research with human subjects and/or human anatomical substances that are specific to the DOW-supported effort outlined in the submitted proposal/application. The research protocol submitted for OHRO review MUST only include those activities funded by the DOW, as referenced in the Statement of Work (SOW). The OHRO will NOT review protocols submitted for DOW-funded activities if such studies have been added to an ongoing/existing protocol.

- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets. For clinical research studies, further details of clinical research components (including the required strategy for the inclusion of women and minorities appropriate to the objectives of the study, see Senate Report 115-290 (S. 3159), 2019) will be required in see Attachment 10: Human Subject Recruitment and Safety Procedures, as applicable.

- 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 DHA OHRO; this does not include the additional time required for local IRB review and approval, as stated above.

- For animal studies, allow at least 2 to 3 months for regulatory review and approval by the DHA ACURO; this does not include the additional time required for local IACUC review and approval, as stated above.

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

- **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.

  There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the proposal/application.

  - **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 existing 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 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 are now accountable. There is no form for this information.

  - **Publications and/or Patent Abstracts:** Include a list of relevant publication URLs and/or patent abstracts. If articles 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. A letter from each organization involved in the project should be provided. Letters of support not requested in this BAA, such as those from members of Congress, do not impact proposal/application review or funding decisions.

- **Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual or organization that demonstrates that the investigator has the support of resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on a proposal/application submitted through an extramural organization, 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, two-page limit per letter is recommended):** 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 DOW Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOW 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 Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA Non-Profit Corporation (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.

- **Collaboration with Military Facility (if applicable):** *If the project involves collaboration with a Military Facility, special requirements apply.* A DOW researcher, to include collaborating DOW 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 (if applicable):** Describe present or prospective joint sponsorship of any portion of the program outlined in the proposal/application. In the absence of agreements between/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/all 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."

  - **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. Refer to the General Submission Instructions, Appendix 2, Sections C and D, for more information about disclosure of proprietary information.

    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 (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations. Address any impact of intellectual property issues on product development and subsequent government access to products supported by this BAA. Demonstrate 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.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  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 (two-page limit): Upload as "SOW.pdf".** The SOW outlines and establishes the performance expectations and milestones for which the DHA 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. The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (ebrap.org). Recommended strategies for assembling the SOW can be found at ebrap.org. Refer to either the "***Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work***" or "***Example: Assembling a Generic Statement of Work***", whichever format is most appropriate for the proposed effort, and use the blank SOW format titled "Suggested SOW Format". The SOW must be in PDF format prior to attaching.

  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 DHA ORRC 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. Describe how the anticipated outcomes could be implanted in a dual-use capacity to address the healthcare needs of military Service Members, Veterans, and/or their beneficiaries, as well as the civilian population, as appropriate.

- **Attachment 7: 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).

  - As applicable, show how the proposed research project aligns with DOW and 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 8: 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.

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

- **Attachment 9: Post-Award Transition Plan (two-page limit): Upload as "Transition.pdf".** Describe the methods and strategies proposed to move the anticipated research outcomes to the next phase of development or clinical application (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. Applicants 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 project's anticipated research outcomes including knowledge products, clinical products for development, etc.
- Using Appendix VI as a guide, describe the maturity of the product and provide the current and projected research technology or knowledge readiness level (as appropriate) at the end of the proposed project or knowledge outcome.
- A description of the scientific or technical requirements needed to advance the research findings. Include steps necessary for FDA regulatory approval for the planning indication, and compliance with Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), and Good Clinical Practice (GCP) guidelines as appropriate.
- A timeline with defined milestones and deliverables describing the expected post-award progress of the results toward the next phase of development and eventual clinical impact.
- An assessment of the opportunities available and potential barriers that would impact the progress of commercializing and/or translating the study results into clinical practice.
- A plan for management of intellectual property.
- Details of the funding strategy to transition to the next level of investigation, development, and/or commercialization (e.g., partners, internal/external funding opportunities to be applied for).
- A description of collaborations and other resources that will be used to provide continuity of development.
- A plan to distribute the findings or intervention to the civilian and/or military communities.

- **Attachment 10: Human Subject Recruitment and Safety Procedures for Clinical Research (no page limit), if applicable; required for all studies recruiting human subjects: Upload as "HumSubProc.pdf".** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below, where applicable.

  Applicants 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 until applicable regulatory documents are reviewed and approved by the DHA ORRC***to ensure that applicable regulations have been met.***

- **Study Population:** Describe the availability of 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). Provide a table of anticipated enrollment counts at each study site. Demonstrate that the research team has access to the proposed study population at each site, and describe the efforts that will be made to achieve accrual goals. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical studies (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention.

  Identify ongoing clinical studies that may compete for the same patient population and how they may impact enrollment progress. Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex. ***For clinical research proposing to include military personnel, refer to the General Submission Instructions, Appendix 1, for more information.***

- **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical study. 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.

- **Women and Minorities in the Study:** Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and congressional legislation in Senate Report 115-290 (S. 3159), 2019, special attention is given to inclusion of women and/or minorities in studies funded or supported by the DHA. Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex, race, and ethnicity, and an accompanying rationale for the selection of subjects. Provide a planned enrollment table(s) with the proposed enrollment distributed on the basis of sex, race, and ethnicity. The Public Health Service (PHS) Inclusion Enrollment Report may be downloaded from eBRAP at ebrap.org.

- **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, healthcare provider identification of potential subjects, recruitment databases, advertising).

  - 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 study, 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 study.

  - 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 reassessing capacity over the course of a long-term study and describe any relevant procedures to ensure 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 performance site's IRB office should be consulted for guidance regarding who can serve as LAR for research at the study site. ***Note:*** In compliance with 10 USC 980, if the research will include an intervention or interaction with subjects for the primary purpose of obtaining data regarding the effect of the intervention or interaction, the application must describe a clear intent to benefit all for human subjects who cannot give their own consent to participate in the proposed study. 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 study, 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 IRB office 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. ***Note:*** 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 exposed to as a result of participation in the study. 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:**

    - Appropriate to the study's level of risk, describe how safety monitoring 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, including 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, and 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.

  - **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.

- **Attachment 11: Data Management (no page limit), if applicable; required for all studies recruiting human subjects: Upload as "Data_Manage.pdf".** The Data Management attachment should include the components listed below.

- **Data Management:** Describe all methods used for data collection, including 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 DOW 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 the 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. Describe the database lock process. For FDA-regulated studies, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) is required.
  - **Data reporting:** Describe how data will be reported and how it will be ensured that the documentation will support a regulatory filing with the FDA, if applicable.
  - **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, including 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, including 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 including considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.

- **Laboratories performing evaluations and special precautions:** Identify the laboratory performing each evaluation, the applicable quality standard, and 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 12: Regulatory Strategy (no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".** ***(Attachment 12 is required for human subjects studies using an investigational drug or device.)*** Provide the information requested below and provide supporting documentation as applicable.

  Will data collected under this proposal be submitted to the FDA (or submitted later to, or held for inspection by, the FDA), as part of an application for a research or marketing permit?

  – If yes, describe how the planned data will contribute to a research or marketing application with the FDA.

  Clinical trials must be initiated no later than 12 months after the award date. ***Note: The government reserves the right to withhold or withdraw funding if an IND or IDE is necessary to conduct the clinical trial but has not been obtained within 6 months of the award date.***

  – State the product/intervention name.

  For products/interventions that do not require regulation by the FDA or an international regulatory agency:

  – Explain why the product/intervention is exempt from FDA oversight. Provide evidence that the proposed study does not require regulation by the FDA. If the proposed study will be conducted at international sites, provide equivalent information relevant to the host country(ies) regulatory requirements.

For products/interventions that require regulation by the FDA and/or an international regulatory agency:

- State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the United States.

- If the product is marketed in the United States, state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).

- If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification. Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.

- **If an IND or IDE is required for the work proposed, the IND/IDE application must be submitted to the FDA prior to submission of the full proposal/ application.** The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed clinical study. Provide the date of submission, the application number, and existing copy of the FDA letter acknowledging the submission. If there are any existing cross-references in place, provide the application number(s) and associated sponsor(s). Provide an explanation of the status of the application (e.g., past the critical 30-day period, pending response to questions raised by the FDA, on clinical hold, on partial clinical hold). If the IND or IDE application has been placed on clinical hold or partial hold, explain the conditions that must be met for release of the hold. Provide a summary of any previous meetings with the FDA on development of this product. 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 available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.

- If an active IND or IDE for the investigational product is in effect, but the amendment is needed to include the proposed study, describe the type and nature of the amendments(s) and timeline for submission. Indicate whether the amendment increases the risk of the intervention.

- If the study will be conducted at international sites, provide equivalent information and supporting documentation relevant to the product indication/label and regulatory approval and/or filings in the host country(ies).

- Provide the current status for manufacturing development (e.g., manufacturer's name, GMP-compliant lots available, status of stability testing.), non-clinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support phase 1 testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).

- Describe the overall regulatory strategy and product development plan that will support the planned product indication/label. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy. Include considerations for compliance with current GMP, GLP, and GCP guidelines.

- **Attachment 13: Representations: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (ebrap.org). For more information, see the General Submission Instructions, Appendix 5, Section B, Representations.

- **Attachment 14: Suggested Intragovernmental/Intramural Budget, *if applicable*: Upload as "IGBudget.pdf".** If a Military Facility (MHS facility, research laboratory, medical treatment facility, dental treatment facility, or a DOW activity embedded within a civilian medical center) will be a collaborator in performance of the project, complete a separate budget using, "Suggested Intragovernmental/Intramural Budget," available for download on the eBRAP "Funding Opportunities & Forms" web page (ebrap.org), including a budget justification for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Submission Instructions, Section III.A.8, for detailed information.

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681(a) et seq.), the DOW is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in proposals/ applications in science, technology, engineering, and/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. Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and senior/key person's current/pending support information must be attached to the individual's profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.

- **Biographical Sketch:** Upload as "Biosketch_LastName.pdf".
  - The DHA staff and reviewers use biosketches to evaluate whether research teams are equipped with the expertise necessary to carry out the proposed research.
  - Biosketches must conform to the federal-wide Biographical Sketch Common Form. To prepare their biosketch attachments, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for the NIH or the U.S. National Science Foundation (NSF).
- **Current/Pending Support:** Upload as "Support_LastName.pdf".
  - Current and pending (other) support information are used to assess the capacity or any conflicts of commitment that may impact the ability of the individual to carry out the research effort as proposed. The information also helps to assess any potential scientific and budgetary overlap/duplication with the project being proposed.
  - Current and pending support documentation must conform to the federal wide format. To prepare their Current and Pending Support form, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for NIH or NSF.

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.

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

Extramural Subaward: Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Submission Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the proposal/application verification period. If these components are missing, upload them to eBRAP before the end of the proposal/ application verification period.

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

Intramural DOW Collaborator(s): Complete the Suggested Intragovernmental/ Intramural Budget and upload to Grants.gov attachment form as Attachment 14. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOW Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

II.D.3. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in SAM (sam.gov) and receive confirmation of an "Active" status before submitting a proposal/application through Grants.gov. As published in the *Federal Register* on July 10, 2019, the unique entity identifier (UEI) for awards management generated through SAM will be used instead of the Data Universal Numbering System (DUNS) number as of April 2022. ***All federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI.*** DHA will transition to use of the UEI beginning with FY22 announcements and utilize the latest SF424, which includes the UEI. The DUNS will no longer be accepted.

Applicant organizations will not go to a third-party website to obtain an identifier. During the transition, your SAM registration will automatically be assigned a new UEI displayed in SAM. (For more information, visit the General Services Administration: Unique Entity Identifier update | GSA). Current SAM.gov registrants are assigned their UEI and can view it within SAM.gov. ***Authorized Organizational Representatives with existing eBRAP accounts should update their organizational profile to include the UEI prior to submission of the full application to Grant.gov (see Section II.D.4, Submission Dates and Times below).*** Refer to the General Submission Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.4. Submission Dates and Times

This is a continuously open announcement through September 30, 2027; 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, 2027, 11:59 p.m. Eastern Time. If an invited proposal/application is not submitted by September 30, 2027, 11:59 p.m. Eastern Time, the applicant must wait for the next available opportunity for submission, i.e., the release of the FY28 BAA (to be posted to Grants.gov October 1, 2027). No proposal/application received under this BAA will be considered for funding after 24 months from the date of submission.

Applicant Verification of Full Proposal/Application Submission in eBRAP

eBRAP allows an organization's representatives and PIs to view and modify the full proposal/ application submissions associated with them. Following retrieval and processing of the full proposal/application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full proposal/application submission. 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. eBRAP does not confirm the accuracy of file content. Proposal/application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant's responsibility to review all proposal/application components and ensure proper ordering as specified in the BAA. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full proposal/application package must be submitted.*** Other proposal/application components may be changed until the end of the proposal/application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the proposal/application verification period. If these components are missing, upload them to eBRAP before the end of the proposal/application verification period. After the end of the proposal/application verification period, the full proposal/application cannot be modified.

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 proposal/application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified.

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. Additionally for assistance awards, the applicant institution must certify that all proposed key personnel have completed research security training within one year of application. See Sec III.A.2 of the General Submission Instructions for further information.

II.E. Proposal/Application Review and Selection Information

II.E.1. Criteria for Research Proposals/Applications Without 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 feasible; 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 development 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; and 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.
     - How well the proposed research is designed to achieve reproducible and rigorous results, including controls, sample size estimation, randomization, statistical analysis, and data handling.
     - How well plans to collect specimens and conduct laboratory evaluations are addressed, if applicable. To what degree the data collection instruments, if applicable, are appropriate to the proposed study.
   - **Impact/Outcomes**
     - How well the potential impact of the research in the field, the significance of this impact, and when the impact can be anticipated are demonstrated.

- The degree to which the results of this research are expected to impact the intended beneficiaries.
- To what degree the anticipated outcomes could be implemented in a dual-use capacity to address the healthcare needs of military Service Members, Veterans, and/or their beneficiaries and to benefit the civilian population, if applicable.
- How well the intervention addresses the clinical needs and how it compares with currently available interventions and/or standards of care.

- **Recruitment, Accrual, and Feasibility (for studies recruiting human subjects)**
  - How well the availability of human subjects for the clinical research and the prospect of their participation is addressed.
  - Whether access to the proposed human subjects population is demonstrated.
  - To what degree 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.
  - For clinical research studies, how well the proposal/application describes a plan to recruit subjects, including description of the inclusion and randomization criteria and whether the exclusion criteria are justified.
- **Ethical Considerations (for studies recruiting human subjects)**
  - How well the evidence shows that procedures are consistent with sound research design and, when appropriate, that these procedures are already in use for diagnostic or treatment purposes.
  - Whether the level of risk to human subjects is minimized and clearly communicated through informed consent.
  - How well safeguards are described and suitable for vulnerable populations.
  - The degree to which confidentiality and/or privacy issues are appropriately considered.
- **Transition Plan**
  - How well the proposal/application demonstrates feasible methods and strategies to move the project's findings to the next phase of development or clinical application.
  - Whether the proposal/application appropriately addresses available opportunities and potential barriers that could impact the progress of commercializing and/or translating the study results to the next level of development (next-phase clinical trials, transition

to industry, delivery to the market, incorporation into clinical practice, and/or approval by the FDA) are achievable.

- Whether the timeline for expected post-award progress is reasonable and contains appropriate milestones and deliverables for advancing the study results toward clinical impact.
- Whether the funding strategy described to bring the anticipated research outcomes to the next level of development is reasonable and realistic.
- To what degree the proposed collaborations and other resources for providing continuity of development are established and/or achievable.
- How well the plan is described for distribution of the findings or intervention to the civilian and/or military communities.
- 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.
- 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.
- 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.

- **PI and Key Personnel Qualifications:** How well the qualifications, capabilities, and experience of the proposed PI and other key personnel 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:** How well the proposed facilities and equipment, population resources, or unique combinations of these, 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 composition 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. Proposal/Application Selection Process

All invited proposals/applications are evaluated by DHA scientists, and/or contracted, non-governmental subject matter experts, other federal agency representatives, clinicians, consumers, or combinations thereof, using a two-tier review process. The first tier is peer review of proposals/applications against established criteria to determine technical merit, where each proposal/application is assessed for its own merit, independent of other proposals/applications. The second tier is programmatic review, a comparison-based process in which proposals/ applications with high scientific and technical merit are further evaluated for relevance to the mission of the DHA and its programs.

All DHA review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that proposal/application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review 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.3. Risk, Integrity and Performance Information

Prior to making an award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

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

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 a recipient's qualification prior to award, according to the qualification standards of the DoDGARs, Section 22.415.

The information solicited through Curricula Vitae (CVs), biographical sketches, and current and pending support disclosures is collected to evaluate the technical, scientific, and managerial merit of proposed project personnel may be used to conduct authorized research-security risk assessments, including identifying and mitigating potential foreign influence, foreign-talent recruitment program participation, undisclosed foreign funding, conflicts of interest or commitment that could pose a risk to national security or the integrity of the federally funded research enterprise. Information will be used only for authorized Government purposes and handled in accordance with applicable law and policy. The authority for collection of this information is 10 U.S.C. § 4001, Research and development projects; Section 1286 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019, Pub. L. No. 115-232, § 1286, as amended (10 U.S.C. § 4001 note), Initiative To Support Protection of National Security Academic Researchers From Undue Influence and Other Security Threats; and, as applicable to the specific research and development award, 42 U.S.C. § 6605, Disclosure of funding sources in applications for Federal research and development awards, and 42 U.S.C. §§ 19231–19232, relating to foreign talent recruitment programs. Collection is also consistent with National Security Presidential Memorandum-33 and applicable Department of War policy. The principal purposes for which the information will be used are those stated above. Risk review information will be shared with the Department-wide Fundamental Research Risk Review Repository in accordance with Department policy. In accordance with National Security Presidential Memorandum 33 and all associated laws, all fundamental research funded by the DOW must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly

those pertaining to influence from foreign entities specified in law or policy. Implementation of mitigation discussions and utilization of the OUSD R&E Decision Matrix must decrease risk malign of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

II.E.4. 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 calendar days of submission. Each PI will receive a peer review summary statement on the strengths and weaknesses of the proposal/application.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

The PI should receive disposition regarding the full proposal/application via an email from eBRAP within 180 days of submission. **A recommended-for-funding notification is NOT an authorization to begin performance nor a guarantee of an award.** If selected for funding, a representative from the DHACA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

The awarding agency will be the DHACA. The DHACA Contracting, Agreements, 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 DHACA Contracting, Agreements, 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 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 DHACA General Research Terms and Conditions for Institutions of Higher Education, Hospitals, and Non-Profit Organizations and the DHACA General Research Terms and Conditions for For-Profit Organizations available at the USAMRAA Resources page 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 found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this BAA.

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

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

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

Refer to full text of the latest DOD R&D General Terms and Conditions, DHA General Research Terms and Conditions: Addendum to the DoD R&D General Terms and Conditions and for further information.

Certification Regarding Disclosure of Funding Sources. The proposing entity must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI, Partnering PIs (if applicable), and all key personnel:

- Certify that the current and pending support provided on the application is current, accurate, and complete;
- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and
- Have been made aware of the requirements under Section 223(a)(1) of this Act.

False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (18 USC 1001).

II.F.3. Reporting Requirements

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

Technical/scientific reporting requirements may include:

- 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 ebrap.org and completed for submission and application.

- PHS Inclusion Enrollment Reporting Requirement (only required for clinical research studies): Enrollment reporting on the basis of sex, race, and ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the "Funding Opportunities & Forms" web page (ebrap.org) in eBRAP.

The Award Terms and Conditions will specify if more frequent reporting is required.

Key personnel must provide updated applicable disclosure forms—pending/current support and/or biographical sketch—when changes occur during the period of performance of the award.

Awards resulting from this BAA may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10.0 million (M) are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Submission Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

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

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

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the

Synopsis page for the BAA or by responding to the prompt provided by Grants.gov when first downloading the submission package. If the submission package is updated or changed, the original version of the 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 and/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 receipt of proposals/applications, 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 recruiting human subjects without clinical trials:

- Attachment 10, Human Subject Recruitment and Safety Procedures, is missing.
- Attachment 11, Data Management, is missing.

For proposals/applications with clinical trials:

- Attachment 6, Human Subject Recruitment and Safety Procedures, is missing.
- Attachment 7, Intervention, is missing.
- Attachment 8, Data Management, is missing
- Attachment 13, Regulatory Strategy, 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 in 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 Identification.

II.H.3.c. Withdrawal

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

- The proposal/application fails to conform to this BAA description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- 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 DHA 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, Section 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 has been funded, or selected for funding, through another mechanism may result in withdrawal.

- The proposal/application requiring an IND/IDE (or international equivalent) does not include documentation of submission in the Regulatory Strategy (Attachment 12 for proposals/ applications without clinical trials; Attachment 13, Regulatory Strategy for proposals/ applications with clinical trials).

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, Agreements, or Grants Officer for a determination of the final disposition of the proposal/ application.

II.I. Checklist for Research Proposal/Application Submission Without a Clinical Trial

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	Military Relevance Statement: Upload as Attachment 7 with file name "MilRel.pdf"	
	8	Data and Research Resource Sharing Plan: Upload as Attachment 8 with file name "Sharing.pdf"	
	9	Post-Award Transition Plan: Upload as Attachment 9 with file name "Transition.pdf"	
	10	Human Subject Recruitment and Safety Procedures: Upload as Attachment 10 with file name "HumSubProc.pdf" if applicable	
	11	Data Management: Upload as Attachment 11 with file name "Data_Manage.pdf" if applicable	
	12	Regulatory Strategy: Upload as Attachment 12 with file name "Regulatory.pdf" if applicable	
	13	Representations: Upload as Attachment 13 with the file name "RequiredReps.pdf"	
	14	Suggested Intragovernmental/Intramural Budget: Upload as Attachment 14 with file name "IGBudget.pdf" if applicable	
Research & Related Personal Data		Complete form as instructed.	

Grants.gov Application Components	Upload Order	Action	Completed
Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
		Attach PI 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 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.	
Research & Related Subaward Budget Attachment(s) Form		Complete form as instructed.	

APPENDIX I. RESEARCH AREAS OF INTEREST

I. Military Infectious Diseases

Research and development of solutions for the prevention, treatment, and diagnosis of military-relevant infectious diseases. Solutions can include materiel products as well as knowledge product research to advance clinical practice guidelines to address the diseases listed below. Solutions should minimize the infectious disease threat to the Joint Force, maintain readiness, and preserve operational effectiveness.

Specifically, the MID area of interest intends to fund studies to develop preclinical safety and efficacy data to file an IND with the FDA to support first-in-human studies. For solutions at a higher level of maturity, MID intends to fund activities to execute phase 1 and/or 2a clinical studies, including cGMP manufacturing if required, to advance the product.

- **Prevent:** MID supports the development of solutions to prevent endemic and emerging infectious diseases and solutions to prevent infections (including antimicrobial-resistant infections) resulting from traumatic wounds, to eliminate their impacts on operational effectiveness. Prevention is the most desirable infectious disease countermeasure because it prevents disease from occurring (versus treatment post-infection), is the most cost-effective approach, and reduces unit loss rate. Prevention solutions can include the repurposing of existing countermeasures and/or the evaluation of existing standard of care approaches for military-specific use cases. The MID area of interest supports development of animal models; efficacy testing *in vitro*; efficacy and safety testing in validated preclinical animal models; cGMP manufacture; and safety and efficacy testing in clinical trials of prophylactics for the following:
    - Prevent military-relevant endemic and emerging infectious diseases, including in austere or contested environments
        - **Prevent bacterial diarrhea:** The focus is on development of solutions to prevent bacterial diarrhea resulting from high-priority pathogens (*Campylobacter jejuni*, enterotoxigenic *Escherichia coli*, *Shigella,* and enteroaggregative *E. coli*) in operational settings. A self-administered oral intervention (not a vaccine) targeting multiple high-priority pathogens is desired.
        - **Prevent dengue fever:** Develop products, including prophylactic drugs and vaccines, to prevent all four serotypes of dengue fever.
        - **Prevent emerging infectious diseases (EIDs):** Develop products, including vaccines and immunoprophylactics, to prevent EIDs specific to Africa and/or Asia (AFRICOM and INDOPACOM). Proposed products must address priority pathogens (hantavirus, Crimean-Congo hemorrhagic fever, and/or Lassa fever) and may include additional military-relevant pathogens within AFRICOM and/or INDOPACOM to demonstrate agility of the proposed product.

- **Develop pathogen-agnostic and/or broad-spectrum prophylactics:** Target the diseases listed above, including host-directed prophylactics.

- **Develop agile platforms for rapid development of prophylactics:** Create platforms targeting the diseases listed above that can rapidly pivot to address future unknown EIDs.

- **Prevent battlefield transfusion infections with HIV:** Develop products with an emphasis on antibody candidates as immunoprophylactic solutions.

  - Prevent battlefield and complex traumatic wound infections, including MDR

    - Develop solutions to prevent or delay wound infections (bacterial, fungal, and/or antimicrobial-resistant) following battlefield and complex traumatic wounds (excluding burn wounds), including in austere or contested environments, for use at the point of injury and in prolonged care environments (Roles 1 and 2), without negatively impacting wound healing. High-priority pathogens include *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Staphylococcus aureus*, and invasive fungal infections.

  - Emerging requirements to prevent endemic and EIDs, antimicrobial-resistant wound infections, or infections resulting from traumatic wounds to eliminate their impacts on operational effectiveness

- **Treat:** The MID area of interest supports the development of solutions to treat endemic and emerging infectious diseases and solutions to treat wound infections, including antimicrobial-resistant infections, resulting from traumatic wounds to eliminate their impacts on operational effectiveness. Improved treatment solutions for infectious disease casualties are necessary to return Service Members to duty. The MID area of interest supports development of animal models; efficacy testing *in vitro*; efficacy and safety testing in validated preclinical animal models; cGMP manufacture; and safety and efficacy testing in clinical trials of novel treatments for the following:

  - Treatments for military relevant endemic and emerging infectious diseases, including in austere or contested environments

    - **Treat dengue fever:** Develop antibody (IgG and IgA) immunotherapeutics to treat dengue fever (against all four serotypes).

    - **Treat emerging infectious diseases:** Develop products, including antiviral drugs and immunotherapeutics targeting both the virus and host, to treat EIDs specific to Africa and/or Asia (AFRICOM and INDOPACOM). Proposed products must address priority pathogens (hantavirus, Crimean-Congo hemorrhagic fever, and/or Lassa fever) and may include additional military-relevant pathogens within AFRICOM and/or INDOPACOM to demonstrate agility of the proposed product.

    - **Develop pathogen-agnostic and/or broad-spectrum treatments:** Target the diseases listed above, including host-directed treatments.

        - **Develop agile platforms for rapid development of treatments:** Create platforms targeting diseases listed above, which can rapidly pivot to future unknown EIDs.

    - **Treat sepsis:** Develop products (including immune modulators, novel drugs, and immunotherapeutics) to treat sepsis following complex traumatic wounds (excluding burn wounds), including use in austere or contested environments.

    - **Treat battlefield and complex traumatic wound infections (bacterial, fungal, and/or antimicrobial-resistant):** Develop solutions to treat wound infections following battlefield and complex traumatic wounds (excluding burn wounds), including those in austere or contested environments, for use at the point of injury and in prolonged care environments (Roles 1 and 2), without negatively impacting wound healing. High-priority pathogens include *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Staphylococcus aureus*, and invasive fungal infections.

    - Emerging requirements to treat endemic and emerging infectious diseases, antimicrobial-resistant wound infections, or infections resulting from traumatic wounds to eliminate their impacts on operational effectiveness.

- **Diagnose:** The MID area of interest supports the development of solutions to diagnose wound infections to mitigate their impacts on operational effectiveness. Improved diagnostic solutions for wound infection casualties are necessary to accurately inform treatment decisions and ultimately return Service Members to duty. The MID supports the identification of targets for diagnostic assay design; optimization of assays on selected platforms; and validation and testing of diagnostic assays and platforms for the following:

    - Diagnose battlefield wound infections (including antimicrobial resistance infections)

        - **Detect wound infections and sepsis:** Develop diagnostics for the detection of infections and/or sepsis following battlefield and complex traumatic wounds (excluding burn wounds), including in austere or contested environments.

        - **Enable early detection of wound infections:** Develop diagnostics for detection of wound infections (bacterial and fungal, including MDROs) following battlefield and complex traumatic wounds (excluding burn wounds), including before Service Members become ill.

        - **Detect sepsis prior to onset:** Develop diagnostics for detection of sepsis, ideally prior to the onset of sepsis, following complex traumatic wounds (excluding burn wounds).

    - Emerging requirements to diagnose endemic and emerging infectious diseases, antimicrobial-resistant wound infections, or infections resulting from traumatic wounds to eliminate their impacts on operational effectiveness.

II. Combat Casualty Care

The Combat Casualty Care area of interest supports the research and development of solutions for the acute and early management of combat-related trauma, including point of injury, prolonged care, and en-route care, to include:

- **Research and development of products 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 and emerging settings including point of injury and scenarios in which a casualty cannot be transported through traditional levels of care (i.e., prolonged care) is of high interest. Included in this area of interest are blood shelf-life extenders, blood analogues, and knowledge products to establish guidance for the use of whole blood versus component therapy in pre-hospital settings; advanced blood products to optimize resuscitation for hemorrhage and shock including hemoglobin-based oxygen carriers for providing resuscitative care during the gap between trauma and administration of blood-based fluids; anti-shock products to include those mitigating endotheliopathy and coagulopathy; platelet-like products to promote clotting; and knowledge products for blood-based therapies including studies to efficiently and effectively determine best practices, products and methods for pre-hospital emergent trauma care. Potential capability products include blood shelf-life extenders, lyophilized blood products, blood analogues, platelet solutions, modified universal blood, advanced blood products to optimize resuscitation for hemorrhage and shock, anti-shock drugs, platelet-like products, knowledge products for delivery of blood, blood products, and resuscitative support.

- **Development and translation into clinical practice of effective management of forward resuscitative measures to include burn at PON through the continuum of care:** This effort is focused on the development of resuscitative interventions and strategies for casualties in far forward environments through clinical study platforms, anti-shock and burn therapies, and automated triage/patient documentation. This integrated approach will provide a spectrum of solutions needed to address effective management of forward resuscitation. Potential capability products include early lifesaving burn fluid resuscitation with limited fluid volumes and noninvasive routes of fluid administration (e.g., limited fluid volume burn resuscitation, devices to predict burn sepsis to inform targeted, early treatment initiation to prevent burn shock; advanced provider assist technologies for burn fluid resuscitation in prolonged care and mass casualty); tools to optimize burn fluid resuscitation including fluid status monitoring; deliver early prediction, diagnosis, and treatment for burn sepsis and shock; improved solutions for patient documentation, scalable triage, and semi-autonomous, autonomous, or unmanned systems across all operational environments and connectivity conditions for the effective management of forward resuscitative management.

- **Identify and develop new and/or improve existing solutions for severe hemorrhage at PON:** The objective of this effort is to develop capabilities to control severe, non-compressible hemorrhage in austere environments using topical, endovascular, and intracavitary solutions. Potential capability products include endovascular hemostatic devices; injectable hemostatic solutions; topical hemostatic guidance; hemostatic dressings for internal use; non-compressible torso hemorrhage localization via endovascular sensing/ contrast enhanced ultrasound; endotheliopathy/coagulopathy of trauma biomarkers and

treatments; and data driven, advanced semi-autonomous critical care solution for rapid and reliable central and peripheral venous by minimally trained access in austere environments.

- **Develop solutions to provide prolonged care and stabilization of complex wounds or burns:** Prolonged care is field medical care applied beyond doctrinal planning timelines in order to decrease patient mortality and morbidity. Prolonged field care uses limited resources and is sustained until the patient arrives at the next appropriate level of care (DOW Instruction 1322.24: Medical Readiness Training). This effort is focused on clinically relevant, safe and effective, operationally suitable, affordable and supportable solutions across all **levels** of care. These solutions target validated gaps and aim to deliver capabilities that save lives on the battlefield. This includes developing products and procedures for nonsurgical wound debridement and wound healing, as well as preventing and treating bacterial and fungal infections in both wounds and burns. Additionally, it prioritizes promoting burn wound closure, functional dermal recovery, and preventing or reducing burn progression. Finally, this effort seeks to develop advanced treatment capabilities for burn injuries caused by emerging operational threats, including prehospital treatments to replace damaged skin, reduce the need for skin grafts, and improve functional skin healing.

- **Identify, develop, and evaluate solutions to treat combined and complex injuries (e.g., ballistic, blast, blunt, and burn):** Solutions that can enable ongoing resuscitation and critical care to ensure availability at point of need to preserve life during LSCOs are needed. Efforts are focused on understanding the mechanisms and molecular pathways at play to better identify therapeutic targets for mitigating organ injury developing from complex injuries and enable better care for our Warfighters. Potential capability products include therapeutics to mitigate and/or treat kidney and lung injury and ischemia reperfusion injury; efforts to understand and treat combined injuries; solutions and guidelines for managing complex and combined injuries to provide medical providers with the necessary tools to preserve the lives of our injured Warfighters; solutions to understand the mechanisms of injury for repurposed therapeutics; de novo therapeutics for the treatment of combined injuries; and clinical decision support tools.

- **Develop solutions to optimize clinical capabilities during transport:** The objective of this effort is to develop recommendations and technological tools for maintaining and improving the capability and capacity of medical providers (basic and advanced skilled providers) to be able to provide critical care and lifesaving interventions in resource-limited and/or prolonged care transport environments. As examples, developing and leveraging ML and AI, multi-sensory cueing, mixed/augmented/virtual reality systems technologies, and contactless patient monitoring solutions can decrease cognitive burden of medical providers. In addition, tools driven by ML/AI can provide real-time casualty and provider assignment as well as decision support to decrease manpower requirements and cognitive burden for medical providers. Potential capability products include development of predictive models to identify low systolic blood pressure events and algorithms to help care providers rapidly align medical requirements with medical resources to maximize clinical capacity at the point of care.

III. Traumatic Brain Injury

Research and development of solutions for the diagnosis, treatment, and prevention of further brain injuries can include materiel products as well as knowledge product research to advance clinical practice to address the concerns listed below. Solutions should minimize the brain injury threat to the Total Force, maintain readiness, and preserve operational effectiveness.

- **Diagnose:** The TBI area of interest supports the development of solutions to objectively diagnose and monitor TBIs to rely less on objective human interpretation and questionnaires that may be time-consuming and not conducive for use with mass casualties. Rapid diagnosis and assessment of TBIs serve to return Warfighters to duty sooner and inform higher echelons for treatment options. Additionally, the standard for detecting intracranial hemorrhage (ICH) is a head computed tomography scan (CT), which is not available at Roles 1 and 2. Consequently, capabilities to detect and monitor ICH farther forward in combat environments are greatly needed to conserve limited evacuations and inform treatment options. The TBI area of interest supports preclinical and clinical research for discovery, safety, and efficacy testing. Preclinical research should be performed in validated animal models given the heterogeneous nature of human brains and trauma, and at times follow GLP practices; clinical studies are expected to use cGMP-manufactured technology, and follow appropriate GCP practices. Materiel technologies need to consider no to low cold-chain requirements, minimal power requirement and use in adverse environments. Collectively, rapid diagnosis and monitoring serve better in mass casualties and when rapid movement is needed due to the combat environment. Specific research areas of interest include:

    - Objective diagnosis and monitoring of mild TBI to prevent inappropriate evacuations and better inform unit combat readiness. Diagnosis and monitoring are also needed for blast overpressure in training and combat, as well as for more severe injuries to better inform prolonged care, treatment, and evacuation needs. This area also includes the establishment of clinical thresholds for blast, blast overpressure, and impact.

    - Detection of ICH throughout the entire cranial, with ability to measure the hemorrhage size, depth, location, and whether the ICH is expanding or decreasing over time.

    - Objective biomarkers such as intracranial pressure (ICP), cerebral oxygenation, and fluid-based markers across all brain injury severities; some markers may work across the spectrum of injury types and others may not which can necessitate further clinical evaluation.

    - Leverage artificial intelligence and machine learning (AI/ML) to better inform far-forward diagnosis and monitoring of brain injury over time; this type of technology needs to be clinically adopted before acceptable use.

- **Treat:** The TBI area of interest supports the development of early, acute solutions to treat the full spectrum of brain injuries including mTBI that can prevent reductions in combat effectiveness, blast overpressure which may serve to prevent long-term damage, and more severe injuries where early treatment can greatly improve quality of life and return-to-duty

sooner. The TBI area of interest supports preclinical and clinical research for discovery, safety and efficacy testing. Preclinical research should be performed in validated animal models given the heterogeneous nature of human brains and trauma, and at times follow GLP practices; clinical studies are expected to use cGMP manufactured technology and follow appropriate GCP practices. Specific research areas of interest include:

  - Treatment of closed-head injuries with ICH via pharmaceutical interventions or minimally invasive devices that are capable of assessing and evacuating the ICH.

  - Therapy interventions that can be acutely administered to stabilize the injury, prevent further damage, and possibly improve clinical outcomes.

  - Acute treatment of closed-head TBI without ICH (such as mild TBI and blast overpressure) to prevent further damage and symptoms such as cognitive, psychological and memory impairments and pain.

- **Prevent:** The TBI area of interest supports preventing further damage following any type of TBI which can be through improved diagnosis, monitoring and earlier treatment interventions. Monitoring and managing blast overpressure and repetitive head impacts is supportive which may prevent permanent damage and loss of combat effectiveness. The TBI area of interest supports prevention of further TBI injury in the training and combat environments. Specific research areas of interest include:

  - Objective diagnosis and monitoring of brain health and injury in training environments that can prevent or stop potential damaging effects to the brain and improve combat effectiveness, unit cohesion and confidence.

  - Objective diagnosis and monitoring of brain health and injury in combat environments that can prevent or stop potential damaging effects to the brain and improve combat effectiveness, unit cohesion and confidence.

IV. Psychological Health

The Psychological Health area of interest supports the research and development of solutions that maintain Service Member readiness, improve behavioral health diagnoses, and provide behavioral health interventions that enable rapid return to duty, to include:

- Research on psychological interventions across all environments to enable rapid return to duty. Specific research areas of interest include:

  - Identify, refine, and/or evaluate repurposed drugs and new drug compounds for interventions to mitigate symptoms of acute stress reactions among Service Members.

  - Develop and evaluate early non-pharmacological solutions, including scalable approaches, that are intended to intervene early to prevent psychological symptoms from progressing to chronic disorders (e.g., posttraumatic stress disorder) among Service Members.

- Characterize, test, and/or refine precision treatment approaches (e.g., treatment biomarkers, AI/ML-driven algorithms) designed to identify Service Members who are or are not likely to respond well to a particular psychological treatment.

- Develop, refine, and/or evaluate new psychological treatment devices and/or alternative psychotherapy formats or approaches that require fewer clinical provider hours, utilize minimal medical provider support, and/or increase Service Member accessibility to care.

- Research to develop an integrated ecosystem of solutions for use by medical assets across all environments to rapidly identify individuals at risk of experiencing psychological distress symptoms that put the mission at risk. AI, ML, and deep learning will be used to enable more data-driven decisions in mental health. Specific research areas of interest include:

  - Develop AI/ML-based algorithms and objective markers to rapidly identify and screen Service Members experiencing psychological symptoms and provide early decision support.

  - Refine, improve, and/or determine the practicality of aids (tools) that can be used by medical practitioners for the rapid recognition and accurate diagnosis of psychological health conditions among Service Members.

  - Develop and test solutions for vectoring Service Members to the most appropriate mental health resources in various environments.

- Research to develop solutions that optimize Service Member readiness and performance, enhance physical and psychological well-being, and ensure the overall effectiveness of the fighting force. Specific research areas of interest include:

  - Predictive mental health capabilities and intervention response optimization in operational/combat environments. Develop decision-enabling solutions that will identify or predict Service Member susceptibility to developing mental health disorders when exposed to operational and combat stressors, and deliver targeted approaches to keep Service Members in the fight and reduce medical evacuations.

V. Sensory Systems

The Sensory Systems area of interest is structured into modalities to cover a range of distinct research areas within medical S&T research with the following key areas:

- **Pain Treatment:** Develop and evaluate advanced pain-control solutions tailored for military settings. These innovations aim to enhance pain management for injured Service Members, both on the battlefield and in medical facilities.

- **Battlefield Anesthesia and Advanced Sedation:** Develop portable, titratable anesthesia solutions that provide hemodynamically stable, respiratory-preserving, and rapidly reversible sedation for austere and prolonged field care environments.

VI. Musculoskeletal Injury

The MSKI area of interest focuses on developing treatment strategies, technologies, and techniques to address musculoskeletal injury close to the point of injury in the pre-hospital environment, as well as solutions to provide initial in-theater protection and preservation to facilitate later aspects of care including reconstruction, long-term rehabilitation, and recovery. Specific research areas of interest include:

- **MSKI Pre-Hospital Interventions:** Develop or evaluate rehabilitation interventions, technologies, and techniques to treat MSKI in pre-hospital environments:
    - Interventions, technologies, and techniques to treat MSKIs in pre-hospital environments
    - Therapeutic interventions to accelerate recovery from MSKIs
    - Preservation of musculoskeletal health

VII. Environmental Exposures

The Environmental Exposures area of interest seeks to counter health threats, disease, and non-battle injury through prevention, assessment, and treatment across a wide range of military-relevant environmental exposures, currently supporting the following limited range of topics and efforts:

- Identification of blood biomarkers associated with frostbite recovery state
- Development of physical test batteries to determine individualized frostbite recovery and recurrence across multiple body areas
- Identification of biomarkers to predict risk of heat injury
- Predictive models to support heat illness prevention in Service Members
- Field measurements of submicron and other particulates in partial complete combustion emissions to which Service Members are exposed

VIII. Directed Energy/Radiation Health

Directed Energy: This research area of interest should add clarity to discriminators in which bioeffects become health effects following radiofrequency, optical, or acoustic exposures in operational environments. The overarching focus is to improve capabilities and knowledge available to distinguish between a "bioeffect" and an injurious "adverse health effect" resulting from directed energy exposures via established mechanisms. Research deliverables should have direct applications to relevant directed energy safety standards and/or clinical practice guidelines.

Radiation Health: This research area of interest is focused on the development of medical countermeasures (MCMs) to counter 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. (Therapeutics research should provide novel concepts that show improved capabilities compared to existing FDA approved radiation therapeutics.) Various routes of administration (IM, oral, IV, etc.) will be considered. Research in biomarkers and biodosimetry in support of MCM development may also be considered.

Combined Injury: Countermeasures that may have an indication for one or more other injuries will be considered. Combined injury research includes a CBRN injury in combination with trauma and/or burn injuries. Research objectives include: characterizing mechanisms of injury, development and the validation of *in silico*, *ex vivo*, or *in vivo* models; characterizing interactions among therapeutics from trauma management and chemical and/or radiation therapeutics; demonstrating the utility of repurposing existing trauma treatments and countermeasures (e.g., blood products) to manage combined injuries; and demonstrating solutions that address medical specific alterations in medical care including diagnosis, triage, prognostication, and treatment for Warfighters.

APPENDIX II. CLINICAL TRIALS

I. Important Aspects of Clinical Trials

A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. ***NOTE:*** FDA-regulated clinical investigation is always a clinical trial, but not all clinical trials are FDA clinical investigations.

If the proposed clinical trial involves the use of a drug that has not been approved by the FDA for the proposed investigational use, then an IND application to the FDA that meets all requirements under 21 CFR 312 may be required. It is the responsibility of the applicant to provide evidence from the IRB of record or the FDA if an IND application is not required. ***If an IND application is required, evidence that an IND application has been submitted or IND authorization without clinical hold status has been secured must be included in the proposal/ application.*** The IND application should be specific for the product (i.e., the product should not represent a derivative or alternate version of the investigational agent described in the IND application) and indication to be tested in the proposed clinical trial. For more information on IND applications, refer to the FDA Investigational New Drug Application (IND) Guidance.

If the investigational product is a device and will be assessed under a Significant Risk (SR) Device Study, then an IDE application to the FDA that meets all requirements under 21 CFR 812 may be required. It is the responsibility of the applicant to provide evidence if an IDE application is not required or if the device qualifies for an abbreviated IDE application. ***If an IDE application is required, evidence that an IDE application submission or IDE authorization without clinical hold status has been secured must be included in the proposal/application.*** The IDE application should be specific for the device (i.e., should not represent a derivative or modified version of the device described in the IDE application) and indication to be tested in the proposed clinical trial. For more information on IDE applications, refer to the FDA Investigational Device Exemption (IDE) Guidance.

If an IND or IDE is required for the work proposed, the IND/IDE application must be submitted to the FDA prior to submission of the full proposal/application. The government reserves the right to withhold or withdraw funding if an IND or SR IDE is necessary to conduct the proposed study but has not been obtained within 6 months of the award date.

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

- **Clinical Trial Start Date:** The proposed clinical trial is expected to begin no later than 12 months after the award date.

- **Preliminary data are required:** 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 and/or laboratory/preclinical evidence.

- **Study Population:** The application should demonstrate the availability of and access to a suitable patient population that will support a meaningful outcome for the study. The application should include a discussion of how accrual goals will be achieved, as well as the strategy for inclusion of women and minorities in the clinical trial appropriate to the objectives of the study; refer to Senate Report 115-290 (S. 3159), 2019. The application should demonstrate how 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?).

- **Intervention Availability:** The application should demonstrate the documented availability of and access to the drug/compound, device, and/or other materials needed, as appropriate, for the proposed duration of the study.

- **Personnel and Environment:** The application should demonstrate the study team's expertise and experience in all aspects of conducting clinical trials, including appropriate statistical analysis, knowledge of FDA processes (if applicable), and data management. The 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 application should show strong institutional support and, if applicable, a commitment to serve as the FDA regulatory sponsor, ensuring all sponsor responsibilities described in the 21 CFR 312, Subpart D, are fulfilled.

- **Statistical Analysis and Data Management Plans:** The application should include a clearly articulated statistical analysis plan, a power analysis reflecting sample size projections that will answer the objectives of the study and a data management plan and use of an appropriate database to safeguard and maintain the integrity of the data. If FDA-regulated, the trial must use a 21 CFR 11-compliant database and appropriate data standards.

For funded research that meets the definition of a clinical trial per section 102(b) of the Common Rule, the awardee conducting the trial is required to post a copy of the IRB-approved informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in section 116(h) of the Common Rule. Refer to the General Submission Instructions, Appendix 1, Section B.4, for further details.

For all funded applicable clinical trials (ACTs), the awardee conducting the ACT must register it at clinicaltrial.gov in accordance with FDA requirements. Refer to the General Submission Instructions, Appendix 1, Section B.4., 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. In accordance with 32 CFR 219.114, a single IRB pathway is required for any U.S.-based research sites. The IRB-approved master protocol and consent form must be reviewed by the OHRO prior to distribution to the

additional sites for IRB review. Communication and data and specimen management among the collaborating institutions 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 DOW or other government-funded clinical trial networks if appropriate.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOW-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the DHA (ORRC, OHRO, prior to research implementation. This administrative review requirement is in addition to the local IRB or EC review. Local IRB/EC approval at the time of submission is ***not*** required. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of ***all required and complete*** documents to the OHRO. Refer to the General Application Instructions, Appendix 1, and the Office for Human Research Protections Resources and Overview document available on the eBRAP "Funding Opportunities & Forms" web page (ebrap.org) for additional information.

II. Full Proposal/Application Submission Components for Studies With a Clinical Trial

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 Research & Related Application for Federal Assistance Form:** Refer to the General Submission Instructions, Section III.A.1, for detailed information.

Attachments for Proposals/Applications with a Clinical Trial

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. If recommended for funding, the clinical trial protocol will be requested.

- **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., treatment, prevention, diagnostic), the study phase or class (if applicable), and the study model (e.g., single group, parallel, crossover). Outline the proposed methodology in sufficient detail to show a clear course of action. Describe the type of study to be performed (e.g., treatment, prevention, diagnostic), the study phase or class (if applicable), and the study model (e.g., single group, parallel, crossover). Outline the proposed methodology in sufficient detail to show a clear course of action.

    - Identify the intervention to be tested and describe the projected outcomes.

    - Define the primary and any secondary or interim endpoints/outcome measures, outline why they were chosen, and describe how and when they will be measured. Include a description of appropriate controls. Outline the timing and procedures planned during the follow-up period.

- Describe and justify the study population and the inclusion and exclusion criteria that will be used to meet the needs of the proposed clinical trial.

- 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).

- Define each arm/study group of the proposed trial, if applicable. Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures). Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).

- Outline whether subjects, clinicians, data analysts, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias.

- If using psychometric measures, describe their reliability and validity.

- Describe potential problem areas and discuss alternative methods/approaches that may be employed to overcome them. Estimate the potential for subject loss to follow-up, and how such loss will be handled/mitigated.

- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives, including the strategy for how sex will be considered as a biological variable. This should include a brief discussion of what is currently known regarding sex differences in the applicable research area and the statistical analysis plan that will be utilized in the proposed study to consider sex as a biological variable and, at a minimum, will collect data disaggregated by sex. If needed, provide a strong rationale for the proposal of a single-sex study, addressing why a study in both sexes is not warranted.

  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 and all proposed correlative studies. 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.

  For phase 3 clinical trials, describe plans for the valid and sufficiently powered analysis of group differences on the basis of sex, race, and/or ethnicity as appropriate for the scientific goals of the study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

- **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.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the proposal/application.

- **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 existing 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 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 are now accountable. There is no form for this information.

- **Publications and/or Patent Abstracts:** Include a list of relevant publication URLs and/or patent abstracts. If articles 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. A letter from each organization involved in the project should be provided. Letters of support not requested in this BAA, such as those from members of Congress, do not impact proposal/application review or funding decisions.

- **Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual or organization that demonstrates that the investigator has the support of resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on a proposal/application submitted through an extramural organization, 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, two-page limit per letter is recommended):** 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 DOW Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOW 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.

- **Collaboration with Military Facility (if applicable):** *If the project involves collaboration with a Military Facility, special requirements apply.* A DOW researcher, to include collaborating DOW 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 (if applicable):** Describe present or prospective joint sponsorship of any portion of the program outlined in the proposal/application. In the absence of agreements between/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/all 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."

    - **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. Refer to the General Submission Instructions, Appendix 2, Sections C and D, for more information about disclosure of proprietary information.

      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 (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations. Address any impact of intellectual property issues on product development and subsequent government access to products supported by this BAA. Demonstrate 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.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  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 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 (three-page limit): Upload as "SOW.pdf".** The SOW outlines and establishes the performance expectations and milestones for which the DHA 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. The **s**uggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (ebrap.org). Recommended strategies for assembling the SOW can be found at ebrap.org. Refer to the ***"Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work,"*** and use the blank SOW format titled "Suggested SOW Format." The SOW must be in PDF format prior to attaching.

  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 DHA ORRCregulatory 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 subject's 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.

  Applicants 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 until applicable regulatory documents are reviewed and approved by the DHA ORRC***to ensure that DOW regulations have been met.***

- **Study Population:** Describe the availability of 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). Provide a table of anticipated enrollment counts at each study site. Demonstrate that the research team has access to the proposed study population at each site, and describe the efforts that will be made to achieve accrual goals. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical studies (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention. Identify ongoing clinical studies that may compete for the same patient population and how they may impact enrollment progress. Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex. ***For clinical research proposing to include military personnel, refer to the General Submission Instructions, Appendix 1, for more information.***

- **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical study. 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.

- **Women and Minorities in the Study:** Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and congressional legislation in Senate Report 115-290 (S. 3159), 2019, special attention is given to inclusion of women and/or minorities in studies funded or supported by the DHA. Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex, race, and ethnicity, and an accompanying rationale for the selection of subjects. Provide a planned enrollment table(s) with the proposed enrollment distributed on the basis of sex, race, and ethnicity. The PHS Inclusion Enrollment Report may be downloaded from eBRAP at ebrap.org.

- **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, healthcare provider identification of potential subjects, recruitment databases, advertising).

  - 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 study, 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 study.

  - 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 reassessing capacity over the course of a long-term study and describe any relevant procedures to ensure continued consent.

  - Describe the plan for the consent of the individual's LAR to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The performance site's IRB office should be consulted for guidance regarding who can serve as LAR for research at the study site. ***Note:*** In compliance with 10 USC 980, if the research will include an intervention or interaction with subjects for the primary purpose of obtaining data regarding the effect of the intervention or interaction, the application must describe a clear intent to benefit for all human subjects who cannot give their own consent to participate in the proposed study. 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 study, 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 IRB office 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. ***Note:*** 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 exposed to as a result of participation in the study. 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:**

    - Appropriate to the study's level of rise, describe how safety monitoring 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, including 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, and 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.

  - **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.

- **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. Describe how the intervention addresses the clinical needs and how it compares with currently available interventions and/or standards of care. 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. The description of the 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 and stability (as appropriate) of the intervention. Describe measures to ensure consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).

- **Study Procedures:** Describe the interaction with the human subject to including study intervention that they 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. Clearly delineate research procedures from routine clinical procedures. Discuss how compliance with current GLP, GMP, GCP, 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 current 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".** Describe the data management plan in accordance with DOW Instructions 3200.12, Enclosure 3, Section 3.c. Also, refer to General Submission Instructions, Section III, A.2, "Attachments Form, Attachment 2, Supporting Documentation," for more detailed information. The Data Management attachment should include the components listed below.

  - **Data Management:** Describe all methods used for data collection, including 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 DOW 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 the 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. Describe the database lock process. For FDA-regulated studies, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) is required.

- **Data reporting:** Describe how data will be reported and how it will be ensured that the documentation will support a regulatory filing with the FDA, if applicable.

- **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, including 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, including 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 including considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.

- **Laboratories performing evaluations and special precautions:** Identify the laboratory performing each evaluation, the applicable quality standard, and 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. Include any separate laboratory or testing centers. Identify the data and clinical coordinating center(s) and note any involvement from Contract Research Organizations, as appropriate. Identify and provide justification for the inclusion of international sites, 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. ***Note:*** This item may be made available for programmatic review.

  - **Study Personnel Description:** Briefly describe the composition of the study team, including roles of the individuals listed in the organizational chart on the project. Study coordinator(s) should be included. Describe how the levels of effort for each individual are appropriate to successfully support the proposed research. Describe relevant background and qualifications that demonstrate appropriate expertise to accomplish the proposed work, including previous interactions with the FDA, if applicable.

  - **Study Management Plan:** Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial involves more than one institution, 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 institution. If the research involves more than one institution, a single IRB/EC review for all U.S.-based research sites institutions located in the United States. If applicable, describe how communication and data transfer between/among 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: Research Data Collection Instruments, if applicable (no page limit): Upload as "Data_Collection.pdf".** The Research Data Collection Instruments attachment should include a copy of the most recent version of 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. If the adaptation results in a deviation from validated instruments, please justify.

- **Attachment 11: Impact and Relevance to Military Health Statement (three-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 including how they may impact patient care and/or quality of life.

  - 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 and strategies that may be employed to overcome those issues.

  - Describe how the intervention represents an improvement over currently available interventions and/or standards of care.

  - 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 DOW and 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 12: Post-Award Transition Plan (two-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).

- Using Appendix VI as a guide, describe the maturity of the product and provide the current and projected research technology or knowledge readiness level (as appropriate) at the end of the proposed project or knowledge outcome.

- A description of the scientific or technical requirements needed to advance the research findings. Include steps necessary for FDA regulatory approval for the planning indication, and compliance with GMP, GLP, and GCP guidelines as 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 timeline with defined milestones and deliverables describing the expected post-award progress of the results toward the next phase of development and eventual clinical impact.

- 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: Regulatory Strategy (no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file**

named "Regulatory.pdf". Provide the information requested below and provide supporting documentation as applicable.

Clinical trials must be initiated no later than 12 months after the award date. ***Note: The government reserves the right to withhold or withdraw funding if an IND or IDE is necessary to conduct the clinical trial but has not been obtained within 6 months of the award date.***

- State the product/intervention name.

For products/interventions that do not require regulation by the FDA or an international regulatory agency:

- Explain why the product/intervention is exempt from FDA oversight. Provide evidence that the proposed study does not require regulation by the FDA. If the proposed study will be conducted at international sites, provide equivalent information relevant to the host country(ies) regulatory requirements.

For products/interventions that require regulation by the FDA and/or an international regulatory agency:

- State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the United States.

- If the product is marketed in the United States, state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).

- If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification. Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.

- **If an IND or IDE is required for the work proposed, the IND/IDE application must be submitted to the FDA prior to submission of the full proposal/ application.** The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed pilot clinical trial. Provide the date of submission, the application number, and existing copy of the FDA letter acknowledging the submission. If there are any existing cross-references in place, provide the application number(s) and associated sponsor(s). Provide an explanation of the status of the application (e.g., past the critical 30-day period, pending response to questions raised by the FDA, on clinical hold, on partial clinical hold). If the IND or IDE application has been placed on

clinical hold or partial hold, explain the conditions that must be met for release of the hold. Provide a summary of any 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 available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.

- If an active IND or IDE for the investigational product is in effect, but the amendment is needed to include the proposed study, describe the type and nature of the amendments(s) ***and provide evidence of the submission within the proposal/ application***. Indicate whether the amendment increases the risk of the intervention.

- If the study will be conducted at international sites, provide equivalent information and supporting documentation relevant to the product indication/label and regulatory approval and/or filings in the host country(ies).

- Provide the current status for manufacturing development (e.g., manufacturer's name, GMP-compliant lots available, status of stability testing, etc.), non-clinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support phase 1 testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).

- Describe the overall regulatory strategy and product development plan that will support the planned product indication or product label change (if applicable). Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy. Include considerations for compliance with current GMP, GLP, and GCP guidelines. Identify and address the impact of intellectual property issues on product development and subsequent government access to products supported by this BAA.

- **Attachment 14: Representations: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (ebrap.org). For more information, see the General Submission Instructions, Appendix 5, Section B, Representations.

- **Attachment 15: Suggested Intragovernmental/Intramural Budget, if applicable: Upload as "IGBudget.pdf".** If a Military Facility (MHS facility, research laboratory, medical treatment facility, dental treatment facility, or a DOW activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget using "Suggested Intragovernmental/Intramural Budget," available for download on the eBRAP "Funding Opportunities & Forms" web page (ebrap.org), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under

subaward costs. Refer to the General Submission Instructions, Section III.A.8., for detailed information.

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681(a) et seq.), the DOW is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in proposals/ applications in 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." The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (ebrap.org) in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in an uneditable PDF format.

- PI 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 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.

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

Extramural Subaward: Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Submission Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the proposal/application verification period. If these components are missing, upload them to eBRAP before the end of the proposal/ application verification period.

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

Intramural DOW Collaborator(s): Complete the Suggested Intragovernmental/ Intramural Budget and upload to Grants.gov attachment form as Attachment 15. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOW Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

III. Review Criteria for Research Proposals/Applications With a Clinical Trial

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.
    - How the anticipated outcomes of the proposed clinical trial will address sex as a biological variable or whether the justification for a single-sex study is sufficiently strong.
- **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, 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.
  - For all phases of trials except phase 3, whether the proposed analysis plan incorporates sex as a biological variable in a manner that is appropriate for the proposed research and, at a minimum, will collect data disaggregated by sex. Alternatively, whether the justification for a single sex study is sufficiently strong.
  - If a phase 3 trial is proposed, whether the plans for the valid analysis of group differences on the basis of sex, race, and/or ethnicity are appropriate for the proposed research.

- **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 GMP, GLP, and 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.
  - 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 confidentiality and 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 application appropriately addresses available opportunities and potential barriers that could impact the progress of commercializing and/or translating the study results into clinical practice to the next level of development (next-phase clinical trials, transition to industry, delivery to the market, incorporation into clinical practice, and/or approval by the FDA) are achievable.

  - 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 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 timeline for expected post-award progress is reasonable and contains appropriate milestones and deliverables for advancing the study results toward clinical impact.

  - 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.

  - If applicable, to what degree the intellectual and material property plan is appropriate.

  - 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.

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 composition 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.

IV. Checklist for Research Proposal/Application Submission With a Clinical Trial

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"	
	Research Data Collection Instruments: Upload as Attachment 10 with file name "Data_Collection.pdf," if applicable	
	Impact and Relevance to Military Health Statement: Upload as Attachment 11 with file name "Impact.pdf"	
	Post-Award Transition Plan: Upload as Attachment 12 with file name "Transition.pdf"	
	Regulatory Strategy: Upload as Attachment 13 with file name "Regulatory.pdf"	
	Representations: Upload as Attachment 14 with file name "RequiredReps.pdf"	
	Suggested Intragovernmental/Intramural Budget: Upload as Attachment 15 with file name "IGBudget.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 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 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.	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed.	

APPENDIX III. DOW AND VA WEBSITES

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

Air Force Office of Scientific Research
https://www.afrl.af.mil/AFOSR/

Air Force Research Laboratory
https://www.afrl.af.mil

Armed Forces Radiobiology Research Institute
https://afrri.usuhs.edu/home

Congressionally Directed Medical Research Programs
https://cdmrp.health.mil

Defense Advanced Research Projects Agency
https://www.darpa.mil/

Defense Health Agency
https://www.dha.mil/

Science & Technology Portfolio Management
https://health.mil/STPMD

Defense Technical Information Center
https://www.dtic.mil

Military Health System Research Symposium
https://mhsrs.health.mil/MHSRS

Naval Health Research Center
Naval Health Research Center (navy.mil)

Navy Bureau of Medicine and Surgery
https://www.med.navy.mil/

Naval Medical Research Command
Navy Medicine > Naval Medical Research Command

Navy and Marine Corps Public Health Center
https://www.med.navy.mil/Navy-Marine-Corps-Public-Health-Center/Pages/Home/

Office of Naval Research
https://www.onr.navy.mil/

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

Uniformed Services University of the Health Sciences
USUHS, Research, Overview

U.S. Air Force 59th Medical Wing
https://wilfordhall.tricare.mil/About-Us

U.S. Army Aeromedical Research Laboratory
https://usaarl.health.mil/

U.S. Army Combat Capabilities Development Command
https://devcom.army.mil/

U.S. Army Institute of Surgical Research
https://usaisr.health.mil/

U.S. Army Medical Research and Development Command
https://mrdc.health.mil/

U.S. Army Medical Research Institute of Chemical Defense
https://usamricd.health.mil/

U.S. Army Medical Research Institute of Infectious Diseases
https://usamriid.health.mil/

U.S. Army Research Institute of Environmental Medicine
https://usariem.health.mil/

U.S. Army Research Institute for Behavioral and Social Scienceshttps://research.ari.army.mil/

U.S. Army Research Laboratory
https://arl.devcom.army.mil

U.S. Army Sharp, Ready & Resilient Directorate
https://www.armyresilience.army.mil/sharp/index.html

U.S. Department of Defense Blast Injury Research Program
https://blastinjuryresearch.health.mil/

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

U.S. Naval Research Laboratory
https://www.nrl.navy.mil

Walter Reed Army Institute of Research
https://wrair.health.mil/

APPENDIX IV. PROCEDURES FOR ACQUISITION, PROCESSING, STORAGE, AND SHIPMENT OF BIOFLUIDS

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

- 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 biofluids:

- 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 NDA. The NDA is a data repository run by the 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.

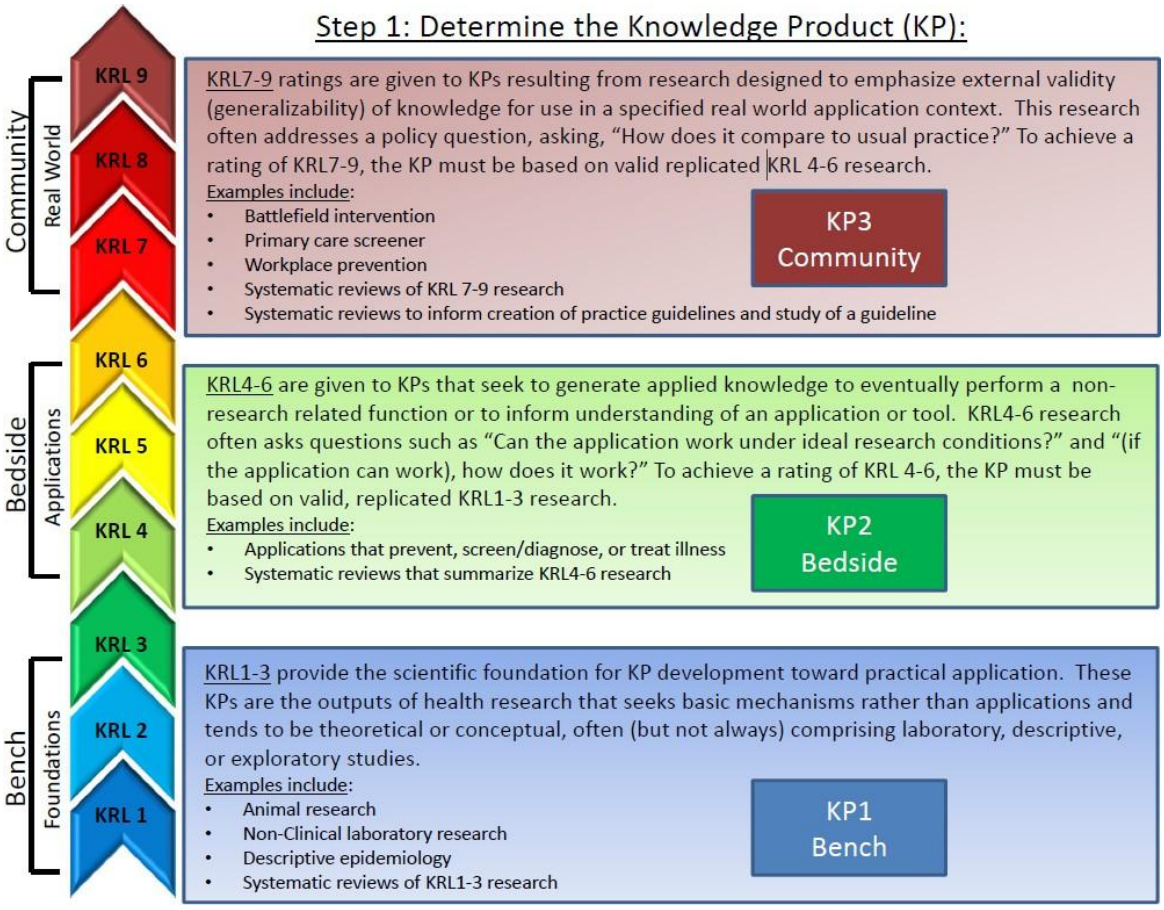
You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind.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

APPENDIX VI. TECHNOLOGY READINESS LEVELS AND KNOWLEDGE READINESS LEVELS

Technology Readiness Levels (TRLs): TRLs are used to categorize the product maturity of materiel solutions. The DOW Technology Readiness Assessment (TRA) Deskbook, is a reference for systematic assessment of technical maturity of relevant materiel solutions. For biomedical applications, Biomedical TRL definitions and descriptions have been developed which account for regulatory context for technology maturity and *intended context of use*.

Information on Biomedical TRLs can be found in Appendix E of the DOW TRA Deskbook (July 2009, Technology Readiness Assessment (TRA) Deskbook (dtic.mil).

Knowledge Readiness Levels (KRLs): The scientific maturity of knowledge products resulting from biomedical research are not assessed in the same manner as materiel solutions. At the request of the U.S. Army Medical Research and Development Command, the Rand Corporation developed and released a framework to assess the relative scientific maturity of knowledge products. This process is described in a 2019 Rand Corporation Report. The figures below represent a quick reference guide for assessing KRLs for knowledge products.



APPENDIX VII: FY23–FY27 DHA S&T BAA ADDENDUM – FY26 NEW PROGRAM INCREASES

The FY26 Consolidated Appropriations Act included funding for new targeted program increases that were directed to the Defense Health Agency (DHA) and aligned with specific DHA Science & Technology (DHA S&T) research program areas for management. The Defense Health Agency Contracting Activity (DHACA) is soliciting proposals/applications for these research capability focus areas of interest on behalf of the DHA and the managing program offices.

All proposals/applications for this FY26 DHA S&T Addendum should specifically address at least one of the following capability areas and must be of clear scientific merit and direct relevance to military health. If the proposed research does not specifically address at least one of the focus areas, it does not meet the intent and will not be selected for funding.

FY26 new program increases submission and review dates and times:

- **Pre-Proposal/Pre-Application Submission Deadline:** 11:59 p.m. Eastern Time, 4 December 2026
- **Invitation to Submit a Proposal/Application:** 11 December 2026
- **Full Proposal/Application Submission Deadline:** 11:59 p.m. Eastern Time, 15 January 2027
- **Peer Review:** January 2027
- **Programmatic Review:** March 2027
- **Final Award:** NLT 30 September 2027

The FY26 capability areas for the DHA S&T CSI Program Increases are listed below:

Specialized Musculoskeletal Assessment and Remote Treatment

DHA S&T is interested in the development of capabilities and technologies (i.e. software, biological models and sensor-based solutions) that support Warfighter musculoskeletal assessment and remote treatments that will directly benefit the warfighter and improve readiness.

Capabilities of interest include:

- Solutions that enable the ability to provide remote care and rehabilitation solutions to service members as well as veterans in remote or austere environments, by providing technologies, including, but not limited to:
  - ✓ Telehealth and remote monitoring software platforms, and
  - ✓ Portable rehabilitation solutions.

- Development and refinement of solutions for diagnostics and personalized care, consisting of but not limited to:

    - ✓ Organ-on-a-chip devices (muscle, bone, cartilage and mechanostimulation),
    - ✓ Biomarkers,
    - ✓ Physiological/biomechanical performance assessment,
    - ✓ Tissue Engineering, and
    - ✓ Nutritional modeling.

- Solutions to improve readiness for duty, including but not limited to:
    - ✓ Physiological/biomechanical performance assessment,
    - ✓ Biomarkers, and
    - ✓ Sensor and feedback solutions to improve rehabilitation.

DHA S&T expects to allot approximately $7.15(M) to fund one Award proposal/application. The anticipated total costs budgeted for the entire period of performance for an FY26 Specialized Musculoskeletal Assessment and Remote Treatment Award must not exceed **$7.15M**.

Non-Invasive Detection of Threat Exposure: Warfighters encounter significant challenges in operational environments due to various hazards, threats, and stressors. Servicemembers are routinely exposed to hazardous elements, including burn pits, heavy metals, pesticides, and other airborne, soil, and water contaminants throughout their careers. To safeguard force health and readiness, the Department of War (DoW) and the Military Health System (MHS) must thoroughly understand these exposures to apply effective medical interventions. DHA S&T is soliciting the following research capability/product:

- Development of a mobile breath-based diagnostic technology that will provide clinical evidence of disease in service members exposed to environmental, occupational and/or infectious hazards.

- ***DHA S&T expects to allot approximately $4.77(M) to fund one Award proposal/application.*** The anticipated total costs budgeted for the entire period of performance for a FY26 Non-Invasive Detection of Threat Exposure Award must not exceed **$4.77M**.

Traumatic Brain Injury (TBI) Research Infrastructure Expansion

- Development of capabilities and technologies to assess and diagnose TBI with high sensitivity, treat and rehabilitate post-injury, and develop mechanisms of neuroprotection and cognitive enhancement in military-relevant settings.

Capabilities and technologies should include but is not limited to:

- ✓ the development and delivery of biological models,
- ✓ biomedical imaging,
- ✓ identification of therapeutic targets using *in vitro*, large animals (i.e., swine),
- ✓ computational TBI software, and
- ✓ data analysis solutions to evaluate injury progression mechanisms

- o Maintain large animal vivarium, surgical suites and classroom facilities to advance TBI research

Strategies should focus on a patient-centered approach, using datasets that can be directly applied to human TBI.

DHA S&T expects to allot approximately $11.5(M) to fund one Award proposal/application. The anticipated total costs budgeted for the entire period of performance for a FY26 Traumatic Brain Injury (TBI) Research Infrastructure Expansion Award must not exceed **$11.5M**.

APPENDIX VIII. ACRONYMS AND ABBREVIATIONS

ACOS/R&D	Associate Chief of Staff for Research and Development
ACT	Applicable Clinical Trial
ACURO	Animal Care and Use Review Office
AI	Artificial Intelligence
ARRIVE	Animal Research: Reporting *In Vivo* Experiments
ARS	Acute Radiation Syndrome
BAA	Broad Agency Announcement
CBRN	Chemical, Biological, Radiological or Nuclear
CCC	Combat Casualty Care
CDE	Common Data Element
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
cGMP	Current Good Manufacturing Practice
COI	Conflict of Interest
CPG	Clinical Practice Guidelines
DFARS	Defense Federal Acquisition Regulation Supplement
DHA	Defense Health Agency
DHA S&T	Defense Health Agency Science and Technology
DHACA	Defense Health Agency Contracting Activity
DOW	U.S. Department of War
DoDAF	Department of Defense Architecture Framework
DoDGARs	Department of Defense Grant and Agreement Regulations
DoDI	Department of Defense Instruction
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
EID	Emerging Infectious Disease
EO	Executive Order
FAPIIS	Federal Awardee Performance and Integrity Information System
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
FFRDC	Federally Funded Research and Development Center

FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
ICH	Intracranial Hemorrhage
ICH E6	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
IT	Information Technology
KRL	Knowledge Readiness Level
LAR	Legally Authorized Representative
LSCO	Large-Scale Combat Operation
LET	Linear Energy Transfer
MCM	Medical Countermeasure
MDO	Multi-Domain Operation
MDRO	Multidrug-Resistant Organism
MHS	Military Health System
MID	Military Infectious Diseases
ML	Machine Learning
MOS	Military Occupational Series
MSKI	Musculoskeletal Injury
mTBI	Mild TBI
NDA	National Institute of Mental Health Data Archive
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NINDS	National Institute of Neurological Disorders and Stroke
NPC	Non-Profit Corporation
NRAP	National Research Action Plan
NSF	U.S. National Science Foundation
OHRO	Office of Human Research Oversight (previously, Human Research Protection Office [HRPO])

OHARO	Office of Human and Animal Research Oversight (previously, Office of Research Protections [ORP])
OTA	Other Transaction Agreement
OUSD	Office of the Under Secretary of Defense
PHS	Public Health Service
PI	Principal Investigator
PON	Point of Need
R&E	Research and Engineering
ROC	Roles of Care
ROC 1	Role of Care 1
ROC 2	Role of Care 2
SAM	System for Award Management
SOW	Statement of Work
SR	Significant Risk
SRP	Strategic Research Plan
S&T	Science and Technology
STEM	Science, Technology, Engineering, or Mathematics
TBI	Traumatic Brain Injury
TCCC	Tactical Combat Casualty Care
TIA	Technology Investment Agreement
TRA	Technology Readiness Assessment
TRL	Technology Readiness Level
UDE	Unique Data Element
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USC	United States Code
VA	U.S. Department of Veterans Affairs
WII	Wounded, Ill, or Injured