

## **I. OVERVIEW OF THE FUNDING OPPORTUNITY**

**Broad Agency Announcement for Extramural Research (Program Specific) for the  
Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Defense Medical Research and Development Program (DMRDP)**

**Joint Program Committee 2 (JPC-2) Military Infectious Diseases Research  
Program (MIDRP) and JPC-6/Combat Casualty Care Research Program (CCCRP)/  
Battlefield Wound Management and Infection Research (BWMIR) Award**

**Announcement Type: Initial**

**Funding Opportunity Number: W81XWH-22-S-DMRDP-BWMIR**

**Assistance Listing Number: 12.420 Military Medical  
Research and Development**

### **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Proposal/Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), October 20, 2022
- **Proposal/Application Submission Deadline:** 11:59 p.m. ET, November 16, 2022
- **End of Proposal/Application Verification Period:** 5:00 p.m. ET, November 21, 2022
- **Peer Review:** January 2023
- **Programmatic Review:** March 2023

*This broad agency announcement must be read in conjunction with the General Submission Instructions, which are available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”*

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## II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

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

This funding opportunity announcement is a broad agency announcement (BAA) through the fiscal year 2022 (FY22) Defense Medical Research and Development Program (DMRDP) for the Battlefield Wound Management and Infection Research (BWMIR) Award. For the remainder of the announcement, this BAA will be referenced as the DMRDP BWMIR. Specific submission information and additional administrative requirements can be found in the document titled “General Submission Instructions,” available in Grants.gov along with this BAA.

**This BAA for DMRDP is intended to solicit extramural research and development ideas** using the authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). This BAA is issued under the provisions of the Competition in Contracting Act (CICA) of 1984 (Public Law 98-369), as implemented in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016 and in Department of Defense Grant and Agreement Regulations (DoDGARs) 22.315. In accordance with FAR 35.016, projects funded under this BAA must be for *applied research* not related to the development of a specific system or hardware procurement. Research and development funded through this BAA is intended and expected to benefit and inform both military and civilian medical practice and knowledge.

***This BAA is intended for extramural applicants only. For definitions and additional information, see [Section II.C.1, Eligible Applicants](#).*** Intramural applicants applying through intramural organizations should use the separate funding opportunity announcement that is available through the electronic Biomedical Research Application Portal (eBRAP) at <https://eBRAP.org/> under funding opportunity number W81XWH-22-DMRDP-BWMIR.

### II.A. Program Description

Proposals/applications to the FY22 Joint Program Committee 2/Military Infectious Diseases Research Program (JPC-2/MIDRP) and JPC-6/Combat Casualty Care Research Program (CCCRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by 10 USC 4001. As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Development Command (USAMRDC) Congressionally Directed Medical Research Programs (CDMRP) provides DMRDP execution management support for DHP core research program areas, including the JPC-2/MIDRP and JPC-6/CCCRP. This funding opportunity announcement and subsequent awards will be managed and executed by CDMRP on behalf of the JPC-2/MIDRP and JPC-6/CCCRP.

The JPC-2/MIDRP and JPC-6/CCCRP are two of three major research program areas within the DHP. The JPC-2/MIDRP and JPC-6/CCCRP are committees of Department of Defense (DOD) and non-DOD medical and military technical experts in combat casualty care- and infectious disease-related program areas.

The MIDRP strives to defeat infection by developing solutions to prevent, treat, and diagnose naturally occurring infectious disease threats to eliminate their impacts on operational readiness of DOD personnel. 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 casualty rates. Improved diagnosis and treatment of infectious disease casualties is necessary to protect the U.S. Armed Forces. Due to the ever-increasing resistance to presently available treatments, continued countermeasure developments need to be pursued. The vision of the MIDRP wound infections capability area is to conduct basic and applied research leading to the development of rapid identification, prevention, and effective treatment solutions to mitigate complications from multidrug-resistant wound infections in multi-domain operations (MDOs) and during prolonged care. However, without understanding how current standard of care interventions work best to prevent, delay, or treat infection, MIDRP cannot lead and develop new medical countermeasures.

The CCCRP strives to optimize survival and recovery from combat-related injury in current and future operational scenarios. This is accomplished through the development of knowledge and materiel solutions for the acute and early management of combat-related trauma; including point-of-injury, en route, and forward surgical care. Service Members face many threats in hostile fire arenas, whether conducting large-scale mechanized warfare, low-intensity conflicts, or operations other than war. Military casualties may wait for hours before definitive health care can be provided. Furthermore, initial treatment and subsequent evacuation may occur in austere environments characterized by limited supplies and limited diagnostic and life-support equipment, and provision of acute and critical care is labor-intensive and must frequently be provided by non-physician medical personnel. The primary challenge for combat casualty care research is to overcome these limitations by providing biologics, pharmaceuticals, and devices that enhance the capability of first responders to effectively treat casualties as close to the geographic location and time of injury as possible, with a reduced logistical footprint.

The overarching gap in battlefield wound management and infection research is in understanding the complex physiology of combat traumatic wounds to guide researchers and physicians in their efforts to better manage these wounds and limit infection. The DOD seeks to address this gap through refined preclinical and clinical studies to inform clinical practice guidelines aimed at delivering better care for these devastating wounds.

### **II.A.1. FY22 DMRDP BW MIR Focus Areas**

The DMRDP BW MIR Award will support the research and development of materiel and knowledge products to address critical gaps in combat traumatic wound management and control of infection, in operational environments. Specifically, research that supports the understanding of physiological processes of combat-associated traumatic wounds and infections in preclinical and clinical models represents a key priority for the JPC-2/MIDRP and JPC-6/CCCRP. The Focus Areas below broadly describe areas of particular interest for funding under the FY22

DMRDP BW MIR. **To meet the intent of the award mechanism, proposals/applications submitted to the FY22 DMRDP BW MIR *must address at least one of the FY22 DMRDP BW MIR Focus Areas listed below.*** Research not aligned to at least one Focus Area will not be considered for funding. Selection of the appropriate FY22 DMRDP BW MIR Focus Area(s) is the responsibility of the applicant.

- Understanding appropriate wound prophylaxis/empiric treatment strategies throughout continuum of care, regardless of injury status, through preclinical and clinical studies to inform clinical practice guidelines for:
  - Managing hemorrhagic shock/super-massive transfusion, traumatic limb ischemia (secondary to vascular disruption or tourniquet use), complex soft tissue injury/blast injury, open fracture, and/or frost bite, including evaluation of antimicrobial dosing and tissue penetration studies.
  - Expanding the understanding of antibiotic use in tissue injury (e.g., systemic versus topical), especially in the context of hemorrhage/resuscitation, blast, and/or delayed evacuation times
- Understanding combat traumatic wound physiology and wound progression through preclinical and clinical studies to inform clinical practice guidelines and standard of care efficacy and gaps.
- Optimizing [prolonged care](#) management of penetrating torso injury by developing solutions for prevention/management of deep space infections (e.g., bacterial or fungal) and delays in care of penetrating abdominal injury.
- Development of analysis and decision support tools to guide traumatic combat wound care and casualty management to triage, prevent and/or treat infections. Examples include:
  - Technologies to determine the types of wound infections at risk of progression to complications and sepsis;
  - Tools to evaluate tissue status before devitalization; and
  - Guided triage/intervention techniques to be used by front-line providers at early stages of care.

## **II.A.2. Award Background**

Force strength and lethality are primary missions of the Armed Forces; therefore, operational readiness must include the ability of healthcare providers to render medical treatment to allow maximal return to duty among military Service Members. In the wars in Iraq and Afghanistan, the U.S. military achieved the highest rate of survival from battlefield injuries in history. The wounded-to-killed ratio more than doubled, from 4:1 during last century's world wars, to 10:1

today.<sup>1</sup> Substantial credit for this achievement is due to a 2009 congressional mandate that stated wounded Warfighters should be provided with life-saving care within 60 minutes of injury, a timespan that was previously referred to as the “golden hour.” This timeframe was defined by technical and tactical advantages supporting movement of the Warfighter. Current trauma care has shifted away from a specific “golden hour” time frame, especially in evolving battlespace environments. Historically, numerous multi-Service medevac assets, forward surgical teams (Role 2), and combat support hospitals (Role 3) were made available across the battlespace environment enabling rapid transportation of casualties away from the point of injury. Future combat scenarios may require Warfighter operations and movement against peer or near-peer adversaries in large-scale combat operations (i.e., MDO) where evacuation capabilities are delayed or unavailable. The expanded battlespace of competitive and armed conflict as well as medical and casualty care may require support for dispersed and sometimes isolated Forces under difficult conditions such as dense urban, subterranean, maritime, high-altitude, dust storm, extreme environments, and other austere conditions. *Limited access to clinic-based providers and potential restriction on Warfighter movement necessitates the ability to bring effective and efficient life-saving capabilities closer to the point of injury and with the ability to provide prolonged care (greater than 72 hours) where necessary.*

Prolonged care is a critical challenge to combat casualty care and consists of initial damage control efforts in the out-of-hospital or austere environments using limited resources. Effective prolonged care is intended to sustain a critically injured patient until the patient arrives at the next appropriate level of care, while decreasing patient mortality and morbidity. Focusing on wound infection and wound management solutions and strategies addresses multidisciplinary aspects of multimodal therapies and surgical treatment. Advancements will lead to faster recovery, fewer lost duty days, reduced healthcare and training time costs, and reduced mortality caused by pathogens in combat traumatic wounds.

Combat traumatic wound infections in a prolonged care environment are a major risk to Warfighter survivability and their ability to return to battle, posing a significant burden to a Military Health System that has little to no capacity for significant periods of time during MDOs. Research has shown that greater than 30% of all combat wounds become infected.<sup>2</sup> That percentage is expected to rise in a prolonged care environment; hence, integrated interventions provided by Tactical Combat Casualty Care (TCCC) providers at the point of injury are critically important to diminish the occurrence of infection in battlefield wounds.

Trauma care in complex and austere environments is not limited to military contexts. Civilian emergency medical care provided in rural settings or during natural disasters, public health crises, and mass casualty events draw on lessons learned in battlefield medicine. Solutions addressing medical challenges during combat operations can be integrated into civilian-based practice to minimize the morbidity and mortality of traumatic injuries in any environment to achieve a goal of zero preventable deaths, regardless of environment. The JPC-2/MIDRP and

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<sup>1</sup>Kotwal RS, Howard JT, Orman JA, et al. 2016. The effect of a golden hour policy on the morbidity and mortality of combat casualties. *JAMA Surgery* 151(1):15-24.

<sup>2</sup> Tribble DR, Murray CK, Lloyd BA, et al. 2019. After the battlefield: Infectious complications among wounded warriors in the Trauma Infectious Disease Outcomes Study. *Mil Med* 184(Suppl 2):18-25.

JPC-6/CCCRP expect approaches and technologies developed under the DMRDP BWMIR to improve survivability of injuries sustained in both combat and civilian settings.

## **II.B. Award Information**

The DMRDP BWMIR Award seeks to enhance combat traumatic wound care capabilities throughout the medical continuum of care, which may be complicated by combat operations, limited resources, austere conditions, and/or mass casualty events. The intent of the FY22 DMRDP BWMIR Award is to support research that will increase the understanding of complex wound physiology and infection control in order to support future application and maturation of products, technologies, and clinical practice. Research that advances and/or repurposes existing solutions and has the potential to be broadly applicable is advantageous, but not required. Additionally, submissions may present advances benefiting military health and medicine as well as the general public.

Applicants may leverage existing resources in translational research to address high-impact research ideas or unmet needs to enable the delivery of life-saving care to the Warfighter during prolonged and en route care in austere and combat environments. ***For this award mechanism, the definition of “leveraging” is as follows: carrying out a research project based on existing resources in order to amplify potential gains in knowledge or accelerate technical maturity.*** Research of interest may include knowledge products, i.e., “knowledge resulting from research with the potential to improve individual or public health,”<sup>3</sup> and solutions that can accelerate the introduction of military-relevant health products or technologies into clinical and/or operational use. Projects should take into consideration the varied expertise levels of targeted medical providers, available resources, and the possible diverse environmental conditions in combat situations. Proposal/application submissions are encouraged to include characteristics relevant to military use in the pre-hospital, combat operational setting. Submissions that propose solutions to advance civilian trauma care are not precluded, since civilian trauma and trauma care in the military are mutually influential and may be co-occurring in certain situations.

**Applications in response to this BAA may *not* be used to support fundamental basic research.** For this BAA, basic research is defined as research directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward process or products in mind. Applied and preclinical research, including animal studies, that is already supported by substantial preliminary or published data, and is designed to validate clinical translation, is appropriate for this award mechanism.

**This BAA may be used to support preclinical research, clinical research, and small-scale clinical trials (e.g., first in human, phase 1/1b).** *Phase 2 and phase 3 clinical trials for U.S. Food and Drug Administration (FDA) licensure of drugs and definitive/pivotal testing for device clearance by the FDA will NOT be permitted under this BAA.* **This BAA may *not* be used to support studies requiring an exception from informed consent (EFIC).**

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<sup>3</sup>Engel CC, Silbergliitt R, Chow BG, et al. 2019. Development of a knowledge readiness level framework for medical research. Santa Monica, CA: RAND Corporation, RR-2127-OSD.  
[https://www.rand.org/pubs/research\\_reports/RR2127.html](https://www.rand.org/pubs/research_reports/RR2127.html).

***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. **Note:** Studies that meet the requirements for Institutional Review Board (IRB) Exemption 4 are not considered CDMRP-defined clinical research. IRB Exemption 4 refers to research involving the collection or study of existing de-identified specimens or data, if these sources are publicly available.

***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 IRB-approved informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in Code of Federal Regulations, Title 32, Part 219 (32 CFR 219).

***The proposed research must be relevant to active-duty Service Members and the American public.***

**The FY22 DMRDP BW MIR Award has two different funding level options based on the scope of the research proposed. It is the responsibility of the applicant to select the funding level that is most appropriate for the proposed research project.** The government reserves the right to fund a proposal/application at a lower funding level.

**Funding Level 1:** Preclinical research studies supported by substantial preliminary or published data. Clinical research and clinical trials are not allowed. Anticipated total costs of Funding Level 1 will not exceed \$1.2 million (M).

**Funding Level 2:** Studies including clinical research or clinical trials supported by substantial preliminary or published data. Research proposed under Funding Level 2 may include some preclinical activities, but must include some aspect of clinical research or a clinical trial. Anticipated total costs of Funding Level 2 will not exceed \$2.2M.

For projects proposing a clinical trial or clinical studies:

- ***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 Investigational New Drug (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 FY22 DMRDP BW MIR Award 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, the FDA has provided guidance at <https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application>.

- If the investigational product is a device, then an Investigational Device Exemption (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 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 FY22 DMRDP BWMIR Award 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.
- If the proposed clinical trial of an investigational product will be conducted at international sites, evidence that an application to the relevant national regulatory agency of the host country(ies) has been submitted or approved must be included in the FY22 DMRDP BWMIR Award proposal/application.
- ***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 9, Regulatory Strategy](#), for further details.
- If a clinical trial is proposed in the DMRDP BWMIR Award proposal/application, the trial must be initiated no later than **month 9** of the initial period of performance.

Refer to [Section II.D.6, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2023. For additional information refer to [Section II.F.1, Federal Award Notices](#).

***The JPC-2/MIDRP and JPC-6/CCCRP expect to allot approximately \$9.39M of FY22 and \$7.29M of FY23 DHP RDT&E funds to support approximately 7 to 10 DMRDP BWMIR Award proposals/applications. Funding of proposals/applications received is contingent upon the availability of federal funds for this program as well as the number of proposals/applications received, the quality and merit of the proposals/applications as evaluated by scientific and programmatic review, and the requirements of the government. It is anticipated that awards made from this FY22 funding opportunity will be funded with FY22 funds, which will expire for use on September 30, 2028; and FY23 funds, which will expire for use on September 30, 2029. As of the release date of this funding opportunity announcement, the FY23 Defense Appropriations Bill has not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this funding opportunity announcement is approximate and subject to realignment. Funding of applications received in response to this funding opportunity announcement is contingent upon the availability of federal funds for this program. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds.***

Proposals/applications received in response to both the extramural FY22 DMRDP BWMIR BAA and the intramural program announcement (W81XWH-22-DMRDP-BWMIR) will be evaluated and considered for funding together. The government reserves the right to fund any combination of extramural and/or intramural proposals/applications.

The USAMRDC executes its extramural research program primarily through the awarding of contracts, assistance agreements (grants and cooperative agreements), and Other Transaction Agreements (OTAs). 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.

**An assistance agreement (grant or cooperative agreement)** is appropriate when the federal government transfers a “thing of value” to a “state, local government,” or “other recipient” to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a **grant** award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a **cooperative agreement** will be made (31 USC 6305) and the award will identify the specific substantial involvement. Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award.

**A contract** is required when the principal purpose of the instrument is to acquire property or services for the direct benefit or use of the U.S. government.

**An Other Transaction (OT)** will also be considered as a vehicle for award under this BAA, in accordance with 10 USC 4021 and 10 USC 4022. The OT authorities were created to give the DOD the flexibility necessary to adopt and incorporate business practices that reflect commercial industry standards and best practices into its award instruments. When leveraged appropriately, OTs provide the government with access to state-of-the-art technology solutions from traditional and non-traditional defense contractors (NDCs), through a multitude of potential teaming arrangements tailored to the particular project and the needs of the participants. OTs can help to foster new relationships and practices involving traditional and NDCs, especially those that may not be interested in entering into FAR-based contracts with the government; broaden the industrial base available to government; support dual-use projects; encourage flexible, quicker, and cheaper project design and execution; leverage commercial industry investment in technology development and partner with industry to ensure DOD requirements are incorporated into future technologies and products; and collaborate in innovative arrangements. OTs are not FAR-based procurement contracts, grants, cooperative agreements, or cooperative research and development agreements.

The award type, along with the start date, will be determined during the negotiation process.

Please see Appendix 2, Section E, of the General Submission Instructions for more information.

**Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers:** All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), OHARO's 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 OHARO 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 Human Research Protections Office Resources and Overview document available on the eBRAP "Funding Opportunities & Forms" web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

If the proposed research involves more than one institution, a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. 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.

**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 Landis, S.C., et al., A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 ([www.nature.com/nature/journal/v490/n7419/full/nature11556.html](http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html)). While these standards were written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in research and should be applied consistently across translational studies. Projects that include research on animal models are required to submit [Attachment 8, Animal Research Plan](#), as part of the proposal/application package to describe how these standards will be addressed. 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 <https://arriveguidelines.org/arrive-guidelines>.

**Use of DOD or Department of Veterans Affairs (VA) Resources:** If the proposed research involves access to active-duty military or Veteran patient populations and/or DOD 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. Refer to [Section II.D.2.b.ii, Full Proposal/Application Submission Components](#), for detailed information. Refer to the General Submission Instructions, Appendix 1, for additional information.

**Research Involving Animals:** All research funded by the FY22 DMRDP BMWIR involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHARO 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 3 to 4 months for ACURO regulatory review and*

*approval processes for animal studies.* Refer to the General Submission Instructions, Appendix 1, for additional information.

The CDMRP intends that information, data, and research resources generated under awards funded by this BAA be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Submission Instructions, Appendix 2, Section L.

## **II.C. Eligibility Information**

### **II.C.1. Eligible Applicants**

#### **II.C.1.a. Organization: All organizations, including international organizations, are eligible to apply.**

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

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

**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.** Applicants from an intramural organization should apply through eBRAP under the funding opportunity number W81XWH-22-DMRDP-BWMIR. These terms are defined below.

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

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

Submissions from intramural DOD organizations to this BAA will be withdrawn.

***Proposals/applications from intramural Principal Investigators (PIs) 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.

**The USAMRAA makes awards to eligible organizations, not to individuals.**

### **II.C.1.b. Principal Investigator**

Independent investigators at all academic levels (or equivalent) are eligible to be named by the organization as the PI in the proposal/application.

There are no limitations on the number of proposals/applications for which an investigator may be named as a PI.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by, or affiliated with, an eligible organization.

The CDMRP strongly encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at <https://orcid.org/>.

### **II.C.2. Cost Sharing**

Cost sharing/matching may be an eligibility requirement for OT awards.

### **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 (FAPIS):*** To protect the public interest, the federal government ensures the integrity of federal programs by conducting business with qualified recipients only. The USAMRDC 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 <https://www.sam.gov/SAM/>. The USAMRDC also reviews and considers information about the applicant in the Office of Management and Budget-designated integrity and performance system, currently FAPIS, prior to making an award. Refer to the General Submission Instructions, Appendix 3, for additional information.

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

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 and Defense Federal Acquisition Regulation Supplement, Subpart 219.704 (DFARS 219.704). A mutually agreeable plan will be developed during the award negotiation process and incorporated as part of the resultant contract.

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

Refer to [Section II.H.1, 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 and Submission Information**

### **II.D.1. eBRAP and Grants.gov**

**eBRAP** (<https://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 (<https://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.

***Intramural DOD Submissions:*** Pre-application content and forms and full application packages (which must be submitted under funding opportunity number W81XWH-22-DMRDP-BWMIR rather than this BAA) must be accessed and submitted at eBRAP.org.

***Note: Proposals/applications from an intramural DOD organization or from an extramural federal organization may be submitted to Grants.gov through a research foundation.***

### **II.D.2. Content and Form of the 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. The submission process should be started early to avoid missing deadlines. There are no grace periods. Refer to [Table 1, Full Proposal/Application Guidelines](#) for full proposal/application submission guidelines.

**Pre-Proposal/Pre-Application Submission:** All pre-proposal/pre-applications must be submitted through eBRAP (<https://eBRAP.org/>).

**Full Proposal/Application Submission:** Full proposals/applications must be submitted through Grants.gov (<https://www.grants.gov>).

***Submitting Extramural Organizations:*** Full proposals/applications from extramural organizations must be submitted through Grants.gov Workspace. Proposals/applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DOD or other federal organizations or investigators will be considered extramural submissions. Proposals/applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. See definitions in [Section II.C.1, Eligible Applicants](#).

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

***The proposal/application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-proposal/pre-application and full 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](mailto:help@eBRAP.org) or 301-682-5507 prior to the proposal/application submission deadline.

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

*During the pre-proposal/pre-application process, eBRAP assigns each submission 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 DOD 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](mailto: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 (<https://eBRAP.org/>). Because the invitation to submit a proposal/application is based on the contents of the pre-proposal/pre-application, investigators should not change the title or research objectives after the pre-proposal/pre-application is submitted.

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 applicant must contact the eBRAP Help Desk at [help@eBRAP.org](mailto: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](mailto:help@eBRAP.org) or 301-682-5507) and at the discretion of the USAMRAA Grants/Contracting/Agreements Officer.

PIs with an ORCID identifier should enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP.

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 application information includes assignment of primary and secondary research classification codes, which may be found at <https://ebrap.org/eBRAP/public/Program.htm>. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.



- **Tab 2 – Application Contacts**

Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the 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 Research & Related Form), and click on “Add Organizations to this Pre-application.” The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

It is recommended that applicants identify an Alternate Submitter in the event that assistance with 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 application.

[FY22 DMRDP BWMIR Award Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the eBRAP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

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

- **Tab 5 – Pre-Application Files**

**Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the focus area under which the application will be submitted as well as intended funding level. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions. An invitation to submit is *not* required.

- **Tab 6 – Submit Pre-Application**

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

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

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

Each proposal/application submission must include the completed full proposal/application package for this BAA. The full proposal/application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://grants.gov/>). See Table 1 below for more specific guidelines.

**II.D.2.b.i. Full Application 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 “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

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

**Table 1. Full Proposal/Application Submission Guidelines**

<b>Proposal/Application Package Location</b>
Download proposal/application package components for W81XWH-22-S-DMRDP-BWMIR from Grants.gov ( <a href="https://grants.gov/">https://grants.gov/</a> ) 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.
<b>Full Proposal/Application Package Components</b>
<b>SF424 Research &amp; Related Application for Federal Assistance Form:</b> 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: <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> </ul>

- [Project/Performance Site Location\(s\) Form](#)
- [Research & Related Subaward Budget Attachment\(s\) Form](#)

### **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 close 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 ID **prior to** the proposal/application submission deadline. ***Do not password protect any files of the application package, including the Project Narrative.***

### **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 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**

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

- **Attachments:**

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

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have 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 megabytes (MB), and the file size for the entire full proposal/application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (15-page limit for projects that include a clinical trial; 10-page limit for projects without a clinical trial [preclinical and clinical research]): 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 proposal/application.

- **Outline for the Project Narrative:** Describe the proposed project in detail using one of the two outlines below, depending on whether or not a clinical trial is proposed. Within the Project Narrative describe how the proposed research has the potential for broadly applicable advances benefiting military health and medicine as well as the general public.

*Outline for projects without a clinical trial (e.g. Funding Level 1 or Funding Level 2-clinical research only):*

- **Background:** Describe the problem, question, or knowledge gap related to at least one of the [FY22 DMRDP BWMIR Focus Areas](#) to be addressed by the proposed project. Present the scientific rationale on which the proposed work is based. Provide a critical review and analysis of relevant literature. Describe previous experience most pertinent to the project. Include relevant preliminary data that support proof of concept of the product or a prototype/preliminary version of the product; these data may be unpublished or from the published literature. Describe any existing resources that the proposed project will leverage. If the project is part of a larger study, articulate the information that establishes a framework for this study. The proposal/application must demonstrate logical reasoning and provide a sound scientific rationale for the proposed project.
- **Hypothesis or Objective:** State the hypothesis to be tested and/or the objective to be reached.

- **Specific Aims:** Concisely explain the project’s specific aims. These aims should agree with the primary aims and associated tasks described in the [Statement of Work \(SOW\)](#). If the proposed work is part of a larger study, present only aims that this DOD award would fund. Clearly communicate the objectives/specific aims of the proposed DMRDP BWMIR project.
  
- **Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for evaluation. Provide a well-developed, well-integrated research strategy that supports the translational feasibility and promise of the approach. Explain how the research strategy will meet the project’s goals and milestones within the proposed period of performance(s).
  - ❖ Define the specific study outcomes/endpoints and how they will be measured. Address potential problem areas and present alternative methods and approaches.
  - ❖ If applicable, describe resources available for the development of sufficient quantities of critical reagents under Good Manufacturing Practice (GMP).
  - ❖ If animal studies are proposed, briefly describe the key elements of the study/studies as they relate to the overall project. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and how it is optimal for addressing the study aims and facilitates translation of solutions for the Warfighter. Describe how animal research will be conducted in accordance with the ARRIVE guidelines 2.0 (<https://arriveguidelines.org/arrive-guidelines>). Further details of research involving animals will be required in [Attachment 8, Animal Research Plan](#), as applicable.
  - ❖ If human subjects or human biological samples will be used, briefly describe the study population and include a detailed plan for the recruitment of human subjects or the acquisition of samples. For clinical research, see [Attachment 7, Inclusion of Women and Minorities](#) for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study.
  - ❖ For clinical research studies, further details of clinical research components will be required in [Attachment 6, Human Subject Recruitment and Safety Procedures for Clinical Research](#), as applicable.
  
- **Statistical Plan:** Describe the data management plan. Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, and identification of primary endpoints and secondary endpoints. Describe the data collection instruments (e.g., research questionnaires, assays, assessment measures) that will be used, and to what degree they are appropriate to support the statistical

significance of the proposed study. Clearly describe the statistical plan and rationale for the statistical methodology demonstrating that the proposed research is designed to achieve reproducible and rigorous results. Provide a sample size estimate and the method by which it was derived, including power analysis calculation, if applicable. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, or international regulatory agency, if applicable.

- **Research Team:** Describe how the background and expertise of the PI and other key personnel demonstrate their understanding of working in military populations or relevant trauma environments. Describe whether the composition of the research or study team is appropriate and complementary.

*Outline for projects with a clinical trial (e.g., Funding Level 2 - clinical trial. Note: The Project Narrative is not the formal clinical trial protocol. If recommended for funding, the clinical trial protocol will be requested.):*

- **Background:** Describe the problem, question, or knowledge gap related to at least one of the [FY22 DMRDP BWMIR Focus Areas](#) to be addressed by the proposed project. Present the scientific rationale on which the proposed work is based. Provide a critical review and analysis of relevant literature. Describe previous experience most pertinent to the project. Importantly, describe the studies showing proof of concept and efficacy in in vivo system(s) that led to the current proposed work. Provide a summary of relevant clinical trials and distinguish how the proposed study differs from other relevant ongoing or recently completed clinical trials. 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). If the proposed clinical trial was initiated using other funding prior to this 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 would be supported with funds from this award. 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. Describe any existing resources that the proposed project will leverage. If the project is part of a larger study, articulate the information that establishes a framework for this study. The proposal/application must demonstrate logical reasoning and provide a sound scientific rationale for the proposed project.
- **Hypothesis or Objective:** State the hypothesis to be tested and/or the objective to be reached.
- **Specific Aims:** Concisely explain the project's specific aims. These aims should agree with the primary aims and associated tasks described in the SOW. If the proposed work is part of a larger study, present only aims that this DOD award

would fund. Clearly communicate the objectives/specific aims of the proposed DMRDP BWMIR project.

- **Research Strategy (include only if laboratory research studies are proposed as a component of the application):**
  - ❖ Describe the laboratory research studies that will be performed under this award and how they are *clearly linked* to the clinical trial.
  - ❖ Describe the experimental design and methodology, including reagents, assay validation, statistical analysis, potential pitfalls, and alternative approaches. Where relevant, describe the availability of, and access to, necessary data and/or critical reagents (e.g., therapeutic molecules, human samples) necessary for the proposed research. If applicable, describe resources available for the development of sufficient quantities of critical reagents under GMP.
  - ❖ Provide a well-developed, well-integrated research strategy that supports the translational feasibility and promise of the approach. Address potential problem areas and present alternative methods and approaches. Define the specific study outcomes/endpoints and how they will be measured.
  - ❖ Define the specific study outcomes/endpoints and how they will be measured.
- **Clinical Trial (*only small-scale [first in human, phase 1/1b] clinical trials are allowed*):** Provide detailed plans for initiating, conducting, and completing the clinical trial during the period of performance. If the clinical trial is proposed in the DMRDP BWMIR Award proposal/application, the trial must be initiated no later than **month 9** of the initial period of performance. As appropriate, outline a plan for obtaining IND/IDE status (or other FDA approvals). Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate. Explain how the research strategy will meet the project's goals and milestones within the proposed period of performance(s).
  - ❖ Identify the intervention to be tested and describe the projected outcomes.
  - ❖ Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
  - ❖ Describe the availability of, and access to, critical reagents (e.g., therapeutic molecules) necessary for the clinical trial.
  - ❖ Describe how the clinical trial will inform the correlative clinical research, if applicable.

- ❖ 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). Provide information on the availability of, and access to, sufficient subjects to meet accrual goals for the clinical trial.
  - ❖ Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers). See [Attachment 7, Inclusion of Women and Minorities](#) for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study.
  - ❖ Further details of clinical trial components will be required in [Attachment 6, Human Subject Recruitment and Safety Procedures for Clinical Research](#), as applicable.
- **Statistical Plan:** Describe the data management plan. Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, and identification of primary endpoints and secondary endpoints. Specify the number of human subjects that will be enrolled. If multiple 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. Describe the data collection instruments (e.g., research questionnaires, assays, assessment measures) that will be used, and to what degree they are appropriate to support the statistical significance of the proposed study. Clearly describe the statistical plan and rationale for the statistical methodology demonstrating that the proposed research is designed to achieve reproducible and rigorous results. Provide a sample size estimate and the method by which it was derived, including power analysis calculation, if applicable. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, or international regulatory agency, if applicable.
  - **Clinical Team:** Describe how the background and expertise of the PI and other key personnel demonstrate their understanding of working in military populations or relevant trauma environments. Describe whether the composition of the research or study team is appropriate and complementary. If prospective clinical studies are included, the PI or research team must demonstrate appropriate expertise in conducting clinical studies.
- **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 equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If 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. 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 PI has the support or 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.

- **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 DMRDP BWMIR are subject to a federal purpose license. A term of the DMRDP BWMIR 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.

It is important to disclose/list any intellectual property (software, data, patents, etc.) that will be used in performance of the project or provide a statement that none will be used. If applicable, all proprietary information to be provided to the government should be stated and identified; the applicant should indicate whether a waiver of the federal purpose license will be required.

- **Intellectual and Material Property Plan:** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community.

Refer to the General Submission Instructions, Appendix 2, Section L, for more information about CDMRP expectations for making data and research resources publicly available.

- **Quad Chart:** Provide a Quad Chart for the proposed project. The format for the quad chart is available on the eBRAP “Funding Opportunities & Forms” web page at (<https://ebrap.org/eBRAP/public/Program.htm>).
- **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.
- **Use of VA Resources (if applicable):** Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the 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 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.
- **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.

***Programmatic reviewers rely on the technical abstract for appropriate description of the project's key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.***

The technical abstract should include the following elements:

- **Background:** Describe the idea and rationale behind the proposed work.
  - **Objective/Hypothesis:** State the objective to be reached/hypothesis to be tested. Provide evidence or rationale that supports the hypothesis(es)/objective(s).
  - **Specific Aims:** State concisely the specific aims of the study.
  - **Study Design:** Briefly describe the study design, including appropriate controls. For studies enrolling human subjects, describe the population and enrollment targets. For animal studies, include a description of the animal model.
  - **Impact and Translation:** Identify the [FY22 DMRDP BWMIR Focus Area\(s\)](#) that the research addresses. Indicate how the proposed work will lead to improvements in prevention and care of combat traumatic wound injuries and/or anticipated changes in clinical practice guidelines.
- **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.

- Describe the objectives and rationale for the research in a manner that will be readily understood by readers without a background in science or medicine.
- Identify the [FY22 DMRDP BWMIR Focus Area\(s\)](#) to be addressed.
- Describe the potential research and clinical applications, benefit, and risks.
- Describe the projected timeline to achieve any potential patient-related outcomes.
- Describe how the proposed project will benefit Service Members, and/or the American public.

- **Attachment 5: Statement of Work (three-page limit if no clinical trial is proposed; six-page limit if a clinical trial is proposed): Upload as “SOW.pdf”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>.

For the DMRDP BWMIR Award mechanism, refer to the “*Suggested SOW Strategy Generic Research*” document for Funding Level 1 or the “*Suggested SOW Strategy Clinical Research*” for Funding Level 2, and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

- **Attachment 6: Human Subject Recruitment and Safety Procedures for Clinical Research (required for all studies recruiting human subjects; no page limit): Upload as “HumSubProc.pdf”.** The Human Subject Recruitment and Safety Procedures for Clinical Research 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 USAMRDC OHARO to ensure that DOD regulations have been met.*

- **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). 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/gender. *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.

- **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, healthcare provider identification).
  - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
  - If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan.
  - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.
  
- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects. *This BAA may not be used to support studies requiring EFIC.*
  - *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 re-assessing capacity over the course of a long-term study, and describe any relevant procedures to assure continued consent.
  - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. *Note:* In compliance with 10 USC 980 (<https://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf>), the proposal/application must describe a clear intent to

benefit for human subjects who cannot give their own consent to participate in the proposed clinical study. If applicable, 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 local IRB to identify the conditions necessary for obtaining assent.
- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. **Note:** Some screening procedures may require a separate consent or a two-stage consent process.
- **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 clinical 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:**
    - ❖ 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: Inclusion of Women and Minorities (required for applications that propose clinical research, including clinical trials; four-page limit): Upload as “Inclusion.pdf”.** 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/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The Public Health Service (PHS) Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.
- **Attachment 8: Animal Research Plan (required for all studies utilizing animals; five-page limit): Upload as “AnimRschPln.pdf”.**

When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. In accordance with the ARRIVE guidelines 2.0 (<https://arriveguidelines.org/arrive-guidelines>), the Animal Research Plan should address the following points for each proposed animal study:

- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study’s relevance to human biology.
- For studies using non-gyrencephalic (lissencephalic) animal models of traumatic brain injury, include justification for their use.
- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.

- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s)/ outcome measure(s).
- Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- **Attachment 9: Regulatory Strategy (required for applications that propose clinical trials; no page limit): If submitting multiple documents, start each document on a new page, combine, and upload as a single file named “Regulatory.pdf”.** Address the following items and provide supporting documentation as applicable. Evidence of IND or IDE application submission or authorization without clinical hold status must be included in the FY22 DMRDP BWMIR Award proposal/application.
  - State the product/intervention name.
  - If applicable, state how many months into the award the anticipated clinical trial would be initiated after the award begins, taking into account any required advanced preclinical work (e.g., GMP production, pharmacokinetics, and toxicity testing) and/or clinical trial preparation (IRB and DOD OHRO approval). *Clinical trials proposed in the DMRDP BWMIR Award proposal/application must be initiated no later than **month 9** of the period of performance.*

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

- For investigator-sponsored regulatory exemptions (e.g., IND, IDE) provide evidence of institutional support. Provide evidence that the clinical trial does not require regulation by the FDA. If the clinical trial will be conducted at international sites, provide equivalent information relevant to the host country(ies) regulatory requirements. No further information for this attachment is required.

***For products 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 in the DMRDP BWMIR Award proposal/application period of performance, evidence of the IND or IDE application submission or authorization without clinical hold status must be included in the 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 trial. ***Provide the date of submission, the application number, and a 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 an amendment is needed to include the proposed trial, describe the type and nature of the amendment(s) ***and provide evidence of the submission within the proposal/application.*** Indicate whether the amendment increases the risk of the intervention.
- 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, Good Laboratory Practice (GLP), and Good Clinical Practice (GCP) guidelines.
- If the clinical trial 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).
- If a drug is to be used in the proposed clinical trial, 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).

- If a device is to be used in the proposed clinical trial, 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.
- If the 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 is not required. If the investigational product is a device, 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 from the IRB of record or the FDA if an IDE is not required or if the device qualifies for an abbreviated IDE. The government reserves the right to withhold or withdraw funding if an IND or IDE is necessary to conduct the clinical trial during the period of performance but has not been *obtained* within 6 months of the award date.
- **Attachment 10: Transition Plan (three-page limit): Upload as “Transition.pdf”.**

Describe the methods and strategies proposed to enable the product or knowledge outcomes to move to the next phase of development (e.g., clinical trials, partnership with DOD advanced developers, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Estimate the target technology readiness level/knowledge readiness level (TRL/KRL) upon completion of the proposed research ([Appendix III](#)). For clinical trials, demonstrate how the proposed product is currently at a minimum of TRL4. 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, DOD advanced developers, and/or other funding agencies to facilitate moving the product into the next phase of development. The transition plan should include the components listed below.

- Details of the funding strategy to transition the product(s) to the next level of development and/or commercialization (e.g., specific potential industry partners, specific funding opportunities to be applied for). Include a description of collaborations and other resources that will be used to provide continuity of development.
- A brief schedule and milestones for transitioning the product(s) to the next phase of development (e.g., next-phase clinical trials, transition to industry, delivery to the civilian and/or military market, incorporation into clinical practice, and/or approval by the FDA).
- For proposals/applications that *do not* propose a clinical trial, describe the current and planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication (e.g., Target Product Profile).

- Describe in detail the FDA regulatory strategy, including the number and types of studies proposed to reach approval, licensure, or clearance; the types of FDA meetings to be held; the submission filing strategy; and considerations for compliance with GMP, GLP, and GCP guidelines, if appropriate. For clinical trials, see [Attachment 9](#) for the required regulatory strategy appropriate to the objectives of the study.
- 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 clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications.
  - 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.
  - If prior federally funded Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) data supports the proposed development effort, describe the connection between the prior SBIR/STTR and the current project and explain all active SBIR/STTR data rights.
  - A risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 11: Impact and Military Benefit Statement (two-page limit): Upload as “Impact.pdf”.** The Impact Statement should be written with a broad audience in mind, including readers without a background in science or medicine.
- **Short-Term Impact:** Describe the anticipated short-term outcome(s) that will have the potential to optimize survival and recovery from combat traumatic wounds in austere environments and when access to definitive medical care is delayed or unavailable.
  - **Long-Term Impact:** Describe the anticipated research outcomes or long-term vision that will impact the development of medical solutions for Service Members and the public. Describe how the proposed materiel or knowledge product represents an improvement to currently available pharmacologic agents, devices, or clinical guidance (as applicable).
  - **Military Benefit:** Describe how the proposed research can be applied in far-forward roles of care (e.g., combat, at the point of injury, en route) and other operational environments to optimize survival and recover during future MDOs.
  - **Public Purpose:** Concisely describe how this research can benefit the general public.
  - **Challenges:** Describe potential issues that might limit the impact of the proposed research and strategies that may be employed to overcome those issues.

- **Attachment 12: Representations: Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Submission Instructions, Appendix 5, Section B, Representations.
- **Attachment 13: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using “Suggested Collaborating DOD Military Facility Budget Format”, available for download on the eBRAP “Funding Opportunities & Forms” web page <https://ebrap.org/eBRAP/public/Program.htm>, including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & 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 DOD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in 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.

- PI Biographical Sketch (six-page limit): Upload as “Biosketch\_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.
- PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.
- Key Personnel Biographical Sketches (six-page limit each): Upload as “Biosketch\_LastName.pdf”.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.

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

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

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

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

- **Intramural DOD Collaborator(s):** Complete a separate DOD military budget, using the “Suggested Collaborating DOD Military Facility Budget Format” (available for download on the eBRAP “Funding Opportunities & Forms” web page [<https://ebrap.org/eBRAP/public/Program.htm>]), and upload to Grants.gov Attachment Form as [Attachment 13, Suggested Collaborating DOD Military Facility Budget Format](#). (Refer to the General Submission Instructions, Section III.A.8, for detailed information.)

### **II.D.3. Unique Entity Identifier (UEI) and System for Award Management**

The applicant organization must be registered as an entity in SAM (<https://www.sam.gov/SAM/>) and receive confirmation of an “Active” status before submitting a proposal/application through Grants.gov. As published in the Federal Register, July 10, 2019, (<https://www.federalregister.gov/documents/2019/07/10/2019-14665/unique-entity-id-standard-for-awards-management>), the 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, cooperative agreements, and OTAs will use the UEI.** USAMRDC 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: <https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/iae-information-kit/unique-entity-identifier-update>.) 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 Grants.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**

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-proposal/pre-application and proposal/application submissions are required. The pre-proposal/pre-application and proposal/application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

#### **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 DMRDP BWMIR Award 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 DMRDP BWMIR. ***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 prior to the proposal/application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the proposal/application submission deadline.*** 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 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.

Verify that subaward budget(s) with budget justification 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.

### **II.D.5. Intergovernmental Review**

This BAA is not subject to Executive Order (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 are not required under this BAA.

### **II.D.6. Funding Restrictions**

*The requested funding level should be aligned with the scope of the research proposed and the funding level descriptions. The government reserves the right to fund a proposal/application at a lower funding level.*

#### **Funding Level 1:**

- The maximum period of performance is **3** years.
- The anticipated total costs (direct and indirect) budgeted for the entire period of performance will not exceed **\$1.2M**. Indirect costs are to be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the government exceeding **\$1.2M** total costs or using an indirect rate exceeding the organization’s negotiated rate.

#### **Funding Level 2:**

- The maximum period of performance is **4** years.
- The allowable range of total costs (direct and indirect) budgeted for the entire period of performance is **\$2.2M**. Indirect costs are to be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the government exceeding **\$2.2M** total costs or using an indirect rate exceeding the organization’s negotiated rate.

#### **For Both Funding Levels:**

- All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum (3 years for Funding Level 1; 4 years for Funding Level 2).

For this award mechanism, direct costs must be requested for:

- Travel costs for the PI to present project information or disseminate project results at a DOD-sponsored meeting (e.g., progress review meeting or Military Health System Research Symposium) in year 2 of the award. For planning purposes, it should be assumed that the meeting will be held in the Central Florida Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all inclusive):

- Special purpose equipment
- Travel in support of multidisciplinary collaborations
- Travel costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the DMRDP BWMIR Award

Must not be requested for:

- Equipment (other than special purpose equipment)
- Tuition

Awards made to extramural organizations will consist of contracts, assistance agreements (grants and cooperative agreements) or OTs. For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DOD or other federal agency is not allowed except under very limited circumstances. Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer. Participating intramural sites receiving direct funds are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators. It is the responsibility of intramural research site to ensure intramural funds are obligated by the deadlines associated with the fiscal year of funds.

Regardless of location, any work that is to be performed through an intramural investigator must be limited to work performed under existing support vehicles, and resource sharing should be accomplished through Cooperative Research and Development Agreements or Material Transfer Agreements. The government reserves the right to administratively withdraw any application that does not meet these eligibility criteria. ***Applications that require research at intramural sites to be performed by a non-DOD organization under a new support vehicles will not be considered for funding.***

Refer to the General Submission Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. ***For federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in the General Submission Instructions, Section III.A.5.***

#### **II.D.7. Other Submission Requirements**

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



## **II.E. Proposal/Application Review Information**

### **II.E.1. Criteria**

#### **II.E.1.a. Peer Review**

To determine technical merit, all proposals/applications will be evaluated according to the following **scored criteria**, of which are listed in decreasing order of importance.

- **Research Strategy and Feasibility**
  - How well the scientific rationale supports the project and its translational feasibility as demonstrated by a critical review and analysis of published literature, logical reasoning, and preliminary data, if applicable.
  - How well the hypothesis, objectives, specific aims, experimental design, methods, and analyses are developed.
  - How well the proposal/application describes study outcomes/endpoints and how they will be measured.
  - How well the proposal/application acknowledges potential problem areas and addresses alternative methods and approaches.
  - How well the animal study is (or studies are) designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used, and facilitate development of solutions for the Warfighter (if applicable).
  - How well the applicant demonstrates access to the relevant study resources, necessary data, and/or critical reagents (e.g., therapeutic molecules, human samples).
  - For research conducted with human subjects (clinical research and clinical trials), how well the application demonstrates the availability of, and access to, the appropriate patient populations(s), as well as the ability to accrue a sufficient number of subjects.
  - For research conducted with human subjects (clinical research and clinical trials), to what extent the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed clinical research.
  - To what extent the intellectual and material property plan is appropriate (if applicable).
  - To what extent the research can be completed within the proposed period of performance.
- **Clinical Trial Strategy (*for proposals/applications that include a clinical trial*)**
  - To what extent the type of clinical trial (e.g., prospective, randomized, controlled) proposed is appropriate to meet the project's objectives.

- To what extent the clinical trial is designed with appropriate study variables, controls, and endpoint.
- How well the application sufficiently demonstrates the clinical trial can be initiated by **month 9** of the award.
- How well potential challenges and alternative strategies are appropriately identified.
- **Impact**
  - To what extent the short-term outcome(s) of the proposed research has the potential to optimize survival and recovery from combat-related or trauma-induced injury in austere environments when access to definitive medical care is delayed or unavailable.
  - To what extent the anticipated research outcome(s) or long-term vision of the proposed research may impact the development of medical solutions for Service Members and the public.
  - To what degree the proposed materiel or knowledge product represents an improvement to currently available pharmacologic agents, devices, or clinical guidance (as applicable).
- **Regulatory Strategy and Transition Plan**
  - How the regulatory strategy and the development plan to support the proposed product label are appropriate and well-described (if applicable).
  - As appropriate, whether the application includes documentation that the study is exempt from FDA or other international agency regulation, or that the IND or IDE application and/or international equivalent has been submitted to the FDA and/or relevant international regulatory agency or authorized without clinical hold status.
  - For clinical trials, how well the documentation provided supports the feasibility of acquiring an active IND or IDE and/or international equivalent covering the proposed trial (if applicable).
  - For clinical trials with investigator-sponsored regulatory exemptions (e.g., IND, IDE, other international equivalent), whether there is evidence of appropriate institutional support.
  - For clinical trials, whether plans to comply with GMP, GLP, and GCP guidelines are appropriate.
  - Whether the identified next level of development and/or plan for commercialization is realistic (if applicable).
  - Whether the proposed target TRL or KRL is realistic and appropriate.

- Whether the schedule and milestones for bringing the anticipated product(s) to the next level of development (clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice, or approval by the FDA) are achievable.
- Whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
- Whether the funding strategy described to bring the product(s) to the next level of development (e.g., specific potential industry partners, specific funding opportunities to be applied for) is realistic and reasonable.
- Whether the proposed collaborations and other resources for providing continuity of development of knowledge products, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications are established and/or achievable (if applicable).
- **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.
  - How well the level of risk to human subjects is minimized and how the safety monitoring and reporting plan is appropriate for the level of risk.
  - For clinical trials, whether the population selected to participate in the trial stands to benefit from the knowledge gained.
  - To what degree privacy issues are appropriately considered.
  - To what degree the processes for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
- **Statistical and Data Analysis Plan**
  - 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 adequate the statistical plan, including sample size projections and power analysis, is for achieving the study objectives and is appropriate to type and phase of study.
  - How well the application identifies sampling methods to gain a representative sample from the population(s) of interest (if applicable).

- To what degree the research data collection instruments, are appropriate to support statistical significance of the proposed study.

- **Research Team**

- To what degree the background, experience, and expertise of the PI and other key personnel demonstrate their ability to perform the proposed work.
- To what degree the levels of effort by the PI and other key personnel are appropriate to ensuring the successful conduct of the project.
- How the PI's record of accomplishment demonstrates their ability to accomplish the proposed work.

- **Environment**

- How the scientific environment is appropriate for the proposed research.
- How the quality and extent of organizational support are appropriate for the proposed research.
- How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).

In addition, the following **unscored criteria** will also contribute to the overall evaluation of the proposal/application:

- **Budget**

- Whether the **total** costs exceed the allowable total costs as published in this BAA.
- Whether the budget is appropriate for the proposed research.

- **Proposal/Application Presentation**

- To what extent the writing, clarity, and presentation of the proposal/application components influence the review.

### **II.E.1.b. Programmatic Review**

To make funding recommendations and select the proposal(s)/application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY22 DMRDP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Relevance to military health
  - Relative impact and translatability

### **II.E.2. Proposal/Application Review and Selection Process**

All proposals/applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation 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 programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. *The highest-scoring proposals/applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section II.E.1.b, Programmatic Review](#).* Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.health.mil/about/2tierRevProcess>. An information paper describing the funding recommendations and review process for the DMRDP BWMIR will be provided to the PI and posted on the CDMRP website.

All CDMRP 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 and approval 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 and approval 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 is a crime in accordance with 18 USC 1905.

### **II.E.3. Integrity and Performance Information**

Prior to making an assistance agreement 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 FAPIIS.

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a federal awarding agency previously entered and is currently available in FAPIIS.

The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the DoDGARs, Section 22.415.

#### **II.E.4. Anticipated Announcement and Federal Award Dates**

All proposal/application review dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. 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**

Awards supported with FY22 funds are anticipated to be made no later than September 30, 2023. Refer to the General Submission Instructions, Appendix 2, for additional award administration information.

After email notification of proposal/application review results through eBRAP, and if selected for funding, a representative from the USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

**Pre-Award Costs (Assistance Agreements Only):** An institution of higher education, hospital, or non-profit organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Submission Instructions, Section III.A.5.

***Only an appointed USAMRAA Grants/Contracting/Agreements Officer may obligate the government to the expenditure of funds.*** No commitment on the part of the government should be inferred from discussions with any other individual. **The award document signed by the Grants/Contracting/Agreements Officer is the official authorizing document.**

**Federal Government Organizations:** Funding made to federal government organizations (to include intramural DOD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants

and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

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

The organizational transfer of an award supporting a clinical trial under an assistance agreement is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer. The organizational transfer of an award supporting a clinical trial under a contract or OTA will not be allowed.

Unless otherwise restricted, changes in PI or organization will be allowed at the discretion of the USAMRAA Grants/Contracting/Agreements Officer, provided the intent of the award mechanism is met.

An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Submission Instructions, Appendix 2, Section B, for general information on PI or organization changes.

#### **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](#); the [USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions](#); and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#), for further information.

**New Requirement:** 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 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**

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.***

Annual progress reports and quad charts as well as final progress reports and quad charts will be required. The Award Terms and Conditions will specify if more frequent reporting is required.

**Award Expiration Transition Plan:** An Award Expiration Transition Plan must be submitted with the first annual report. Use the one-page template “Award Expiration Transition Plan,” available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) under the “Progress Report Formats” section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

**PHS Inclusion Enrollment Reporting Requirement (*only required for clinical research studies*):** Enrollment on the basis of sex/gender, race, and/or 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 (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP.

Awards resulting from the DMRDP BWIR 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 \$10M 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 content or submission requirements in the DMRDP BWMIR BAA as well as questions related to the pre-proposal/pre-application or intramural proposal/application submission 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. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

### **II.G.2. Grants.gov Contact Center**

Questions related to extramural proposal/application submission through 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](mailto:support@grants.gov)

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

## **II.H. Other Information**

### **II.H.1. Administrative Actions**

After receipt of pre-proposals/pre-applications or proposals/applications, the following administrative actions may occur:

#### **II.H.1.a. Rejection**

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

- Pre-Application (LOI) was not submitted

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

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

***For proposals/applications involving animal research:***

- [Attachment 8, Animal Research Plan](#), is missing.

***For proposals/applications recruiting human subjects:***

- [Attachment 6, Human Subject Recruitment and Safety Procedures for Clinical Research](#), is missing.
- [Attachment 7, Inclusion of Women and Minorities](#), is missing.

***For proposals/applications proposing clinical trials:***

- [Attachment 9, Regulatory Strategy](#), is missing.

#### **II.H.1.b. Modification**

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Proposal/Application Project Narrative.
- Documents not requested will be removed.

#### **II.H.1.c. Withdrawal**

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

- An FY22 DMRDP BWMIR Programmatic Panel member is named as being involved in the research proposed or is 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. ***A list of the FY22 DMRDP BWMIR Programmatic Panel members can be found at <https://cdmrp.health.mil/dmrp/panels/bwmirapanel22>.***
- 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).

- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted proposals/applications. For FY22, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.health.mil/about/2tierRevProcess>). Proposals/applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Proposals/applications submitted by an intramural DOD organization as the contracting organization.
- The invited proposal/application proposes a different research project than that described in the pre-proposal/pre-application.
- The application does not address at least one of the [FY22 DMRDP BWMIR Focus Areas](#).
- The proposed research includes a phase 2 or phase 3 clinical trial.
- The proposal/application requiring IND/IDE (or international equivalent) during the period of performance does not include documentation of submission or authorization without clinical hold status in the Regulatory Strategy ([Attachment 9](#)).
- The proposal/application involves research at intramural sites to be performed by a non-DOD organization under a new support vehicle.

#### **II.H.1.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 Grants/Contracting/Agreements Officer for a determination of the final disposition of the proposal/application.

## II.H.2. Proposal/Application Submission Checklist

Proposal/Application Components	Action	Completed
SF424 Research & Related 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 for Clinical Research: Upload as Attachment 6 with file name "HumSubProc.pdf" if applicable	
	Inclusion of Women and Minorities: Upload as Attachment 7 with file name "Inclusion.pdf" if applicable	
	Animal Research Plan: Upload as Attachment 8 with file name "AnimRschPln.pdf" if applicable	
	Regulatory Strategy: Upload as Attachment 9 with file name "Regulatory.pdf" if applicable	
	Transition Plan: Upload as Attachment 10 with file name "Transition.pdf"	
	Impact and Military Benefit Statement: Upload as Attachment 11 with file name "Impact.pdf"	
	Representations: Upload as Attachment 12 with file name "RequiredReps.pdf"	
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 13 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

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

## APPENDIX I: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
ARRIVE	Animal Research: Reporting <i>In Vivo</i> Experiments
BAA	Broad Agency Announcement
BWMIR	Battlefield Wound Management and Infection Research
CCCRP	Combat Casualty Care Research Program
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CICA	Competition in Contracting Act
COI	Conflict of Interest
DFARS	Defense Federal Acquisition Regulation Supplement
DHA	Defense Health Agency
DHP	Defense Health Program
DMRDP	Defense Medical Research and Development Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
EFIC	Exception from Informed Consent
EO	Executive Order
ET	Eastern Time
FAD	Funding Authorization Document
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
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
JPC	Joint Program Committee
KP	Knowledge Product

KRL	Knowledge Readiness Level
LAR	Legally Authorized Representative
LOI	Letter of Intent
M	Million
MB	Megabytes
MDO	Multi-Domain Operation
MIDRP	Military Infectious Diseases Research Program
MIPR	Military Interdepartmental Purchase Request
NDC	Non-Traditional Defense Contractor
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OHARO	Office of Human and Animal Research Oversight
OHRO	Office of Human Research Oversight
ORCID	Open Researcher and Contributor ID, Inc.
OT	Other Transaction
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RDT&E	Research, Development, Test and Evaluation
SAM	System for Award Management
SBIR	Small Business Innovation Research
SF	Standard Form
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
STTR	Small Business Technology Transfer
TCCC	Tactical Combat Casualty Care
TRA	Technology Readiness Assessment
TRL	Technology Readiness Level
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs

## APPENDIX II: DOD AND VA WEBSITES

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

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

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

Armed Forces Radiobiology Research  
Institute  
<https://afri.usuhs.edu/home>

Combat Casualty Care Research Program  
<https://cccrp.health.mil/>

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

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

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

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

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

Military Health System Research  
Symposium  
<https://mhsrs.amedd.army.mil/SitePages/Home.aspx>

Military Infectious Diseases Research  
Program  
<https://midrp.health.mil/>

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

Naval Health Research Center  
<https://www.med.navy.mil/Naval-Medical-Research-Center/R-D-Commands/Naval-Health-Research-Center/>

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

Naval Medical Research Center  
<https://www.med.navy.mil/Naval-Medical-Research-Center/>

Navy and Marine Corps Public Health  
Center  
<https://www.med.navy.mil/sites/nmcphc/Pages/Home.aspx>

Office of Naval Research  
<https://www.nre.navy.mil/>

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

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

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

U.S. Air Force 59<sup>th</sup> Medical Wing  
<https://www.59mdw.af.mil/>



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

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

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

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

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

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

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

U.S. Army Sharp, Ready and Resilient  
Directorate  
<https://www.armyresilience.army.mil/>

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>

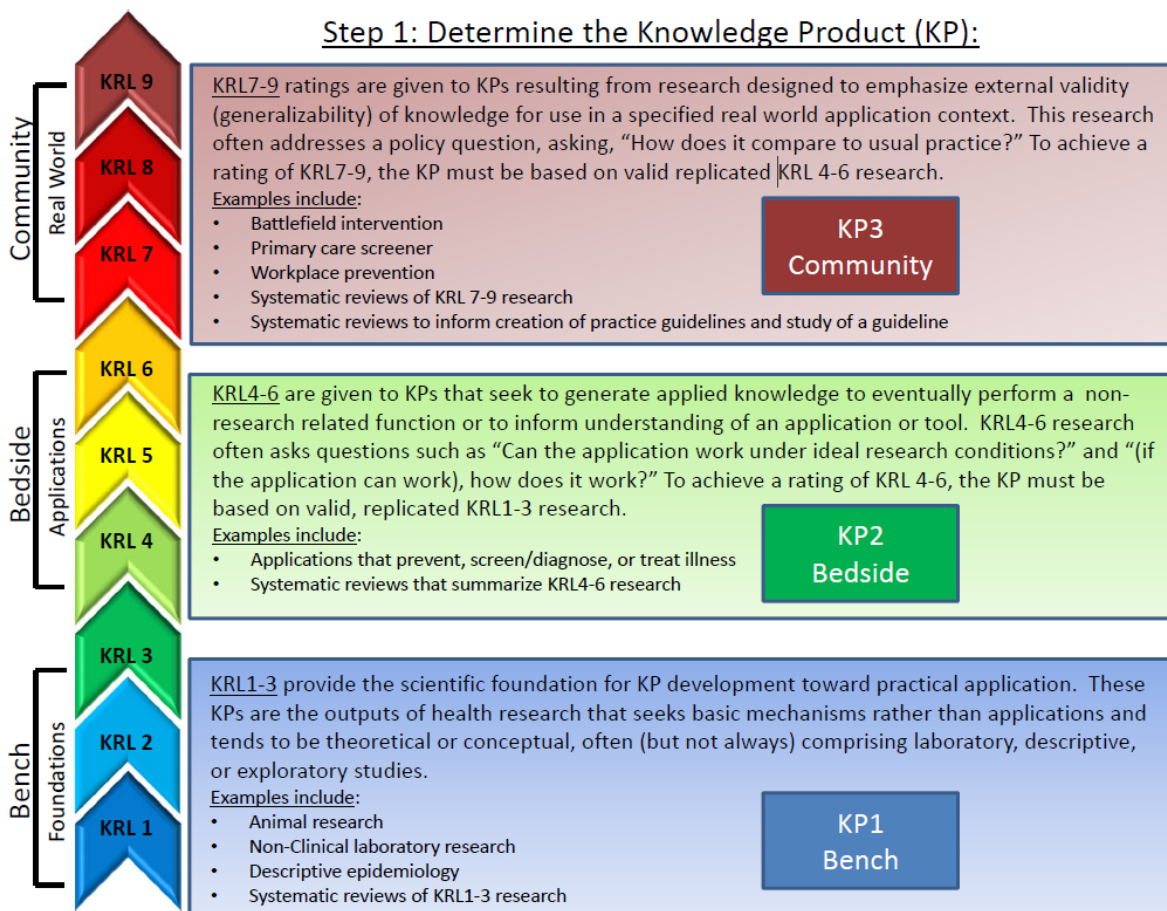
U.S. Naval Research Laboratory  
<https://www.nrl.navy.mil>

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

## APPENDIX III: TECHNOLOGY READINESS LEVELS AND KNOWLEDGE READINESS LEVELS

**Technology Readiness Levels:** TRLs are used to categorize the product maturity of materiel solutions. The DOD’s 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 that account for regulatory context for technology maturity and *intended context of use*. Information on Biomedical TRLs can be found in Appendix E of the DOD TRA Deskbook (July 2009, <https://apps.dtic.mil/docs/citations/ADA524200>).

**Knowledge Readiness Levels:** The scientific maturity of knowledge products resulting from biomedical research is not assessed in the same manner as that of materiel solutions. At the request of the USAMRDC, 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 ([https://www.rand.org/pubs/research\\_reports/RR2127.html](https://www.rand.org/pubs/research_reports/RR2127.html)). The figures below represent a quick reference guide for assessing KRLs for knowledge products.



## Step 2: Determine the Knowledge Readiness Level (KRL)

