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

Combat Readiness – Medical Research Program

Translational Research Award

Announcement Type: Initial

Funding Opportunity Number: HT9425-23-S-CRRP

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), July 7, 2023

- **Proposal/Application Submission Deadline:** 11:59 p.m. ET, July 20, 2023

- **End of Proposal/Application Verification Period:** 5:00 p.m. ET, July 25, 2023

- **Peer Review:** September 2023

- **Programmatic Review:** December 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."

TABLE OF CONTENTS

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 2023 (FY23) Combat Readiness – Medical Research Program (CRRP) for the Translational Research Award (TRA). For the remainder of the announcement, this BAA will be referenced as the CRRP TRA. 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 CRRP 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](#).** The North American Industry Classification System (NAICS) code for contracts under this announcement is 541715 with a small business size standard of 1,000 employees. 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 HT9425-23-CRRP-TRA.

II.A. Program Description

Proposals/applications to the FY23 CRRP TRA are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by 10 USC 4001. The execution management agent for this BAA is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC).

The CRRP was initiated by Congress in FY19 with an appropriation of $15 million (M) to pursue solutions related to the medical needs of the Warfighter. Specifically, the CRRP focuses on forward-deployable solutions that can promptly address life-threatening injuries, medical threats, and treatments for Warfighters in deployed and battlefield settings. Appropriations for the CRRP from FY19 through FY22 totaled $45M. The FY23 appropriation is $5M.

The CRRP vision is to increase survivability and readiness of the Warfighter. The program seeks to develop innovative high-impact solutions to increase medical readiness, diagnose and treat life-threatening injuries, reduce morbidity and mortality, and promote positive long-term outcomes for the Warfighter. While the CRRP focuses on priorities related to frontline care, the program also considers how chronic disorders typically associated with pre-deployment readiness (e.g., sleep, gastrointestinal conditions, post-traumatic arthritis) may influence the delivery of care in deployed environments and contribute to injury susceptibility and recovery. Innovations developed by CRRP-supported research may be applied proactively to enhance medical readiness ahead of deployment, in operational settings at the point of injury, during periods of prolonged care, or during transport/en route between roles of care. These solutions will not only help to minimize the morbidity and mortality of combat-related injuries sustained by the Warfighter but will also often translate to civilian care.

Force strength and lethality is a primary mission of the Armed Forces; therefore, operational readiness must include the ability of health care 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.[1] 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 is referred to as the "golden hour." At the time, numerous multi-Service medevac assets, forward surgical teams (Role of Care, Role, 2), and combat support hospitals (Role 3) were made available across the battlefield environment. The available infrastructure mitigated the need for prolonged field care and enabled rapid transportation of casualties to Role 2 or 3 where medical assets and damage control capabilities allowed for life-saving treatment within the "golden hour."

The time-specific window of the "golden hour" may not accurately reflect current trauma care considerations and may not be feasible for Warfighters in some battlefield environments. Therefore, there is a need 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. Future combat scenarios may involve peer or near-peer adversaries in large-scale combat operations (i.e., multi-domain operations [MDO]) where evacuation capabilities are delayed or unavailable. The military must be prepared to conduct operations in all potential contested domains (land, air, sea, cyber, and space) with potential adversaries that may hinder or deter access to those domains. Combat operations may involve maneuvers in varied environments where medical and casualty care support for the Force is dispersed and sometimes isolated under difficult conditions (e.g., dense urban, subterranean, maritime, high-altitude, dust storm, and extreme environments). Access to highly skilled providers under such conditions may be limited. Utilization of clinical decision support tools, to include those integrated with biological sensors capable of physiological monitoring, and other automated technologies may inform continued Force readiness and availability in combat environments and assist Warfighters in providing additional life-saving care where clinical

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[1]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.

capabilities are limited or non-existent. Casualty care must address not only the scope of these challenges, but also the scale of casualties projected. Mass casualty events that overwhelm immediately available medical capabilities, to include personnel, supplies, and/or equipment, present a significant obstacle to providing damage control interventions closer to the point of need.

Trauma care in complex and austere environments is not unique to military contexts. Civilian emergency medical care provided in rural settings or during natural disasters, public health crises, and mass casualty events draws 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 CRRP expects the innovative approaches and technologies developed with CRRP funding to improve survivability of injuries sustained in both combat and civilian settings.

II.A.1. FY23 CRRP Focus Areas

The priorities and specific research topics described in the FY23 congressional language for the CRRP were organized into distinct Focus Areas. These Focus Areas broadly describe current priorities to improve readiness for delivering frontline care in combat situations. This includes delivering medical damage control capability, assets, and life-saving interventions during prolonged and en route care in austere and combat environments, including the acute and early management of combat-related trauma at the point of injury. **Proposals/applications submitted to the FY23 CRRP TRA _must_ address at least one of the FY23 CRRP Focus Areas listed below**. Selection of the appropriate FY23 CRRP Focus Area is the responsibility of the applicant.

Funding should be used for the research and development of one of the following Focus Areas:

- Solutions to enhance combat care delivery throughout the far-forward environment, such as:

  - Telemedicine solutions that enable medical capabilities at far-forward battlespace locations worldwide

  - Medical simulation technologies that support the sustainment of critical skills and medical decision-making

  - Blood products, including freeze-dried plasma and platelets

  - Ruggedized oxygen generation systems for medical use

  - Solutions for the assessment of mild traumatic brain injury, to include portable and hand-held detection devices

  - Initial treatment and transport of patients with highly transmissible infectious diseases

- Wound care solutions for complex trauma and tissue regeneration that span the operational medical care continuum or roles of care (e.g., acute through chronic care), such as:
  - Multi-modal wound care solutions that provide a combination of hemostasis, wound healing, infection prevention, and/or analgesia

- Solutions to enhance Warfighter readiness, such as solutions to address:
  - Sleep disorders
  - Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS)
  - Service-related post-traumatic arthritis
  - Eating disorders
  - Sarcoidosis
  - Valley fever
  - Complementary health measures to accelerate return to duty
  - Regenerative medicine

Areas of Encouragement related to the FY23 CRRP Focus Areas have been identified by the Department of Defense (DOD) and the FY23 CRRP Programmatic Panel as capabilities and knowledge gaps that are of high priority and programmatic relevance. Applicants are urged to read and consider these Areas of Encouragement (Appendix II) before preparing their applications. ***The information provided is not exhaustive. Applicants are not required to address an Area of Encouragement from this list; all submitted proposals/applications must demonstrate relevance to the program mission, vision, and FY23 CRRP Focus Areas.***

The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.

II.A.2. Award History

The CRRP TRA mechanism is being offered for the first time in FY23.

II.B. Award Information

The CRRP seeks to increase pre-hospital survivability of the Warfighter by enabling individuals, of varying expertise, to address casualties of the battlespace and closer to the point of injury. The intent of the FY23 CRRP TRA is to support high-impact translational research that will accelerate innovative ideas into clinical applications, including health care products, technologies, and/or practice guidelines. Research funded under this award mechanism will be hypothesis-driven, high-impact applied research that is relevant to active-duty Service Members, Veterans, other military beneficiaries, and the American 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: An investigator basing a research project on existing resources in order to amplify potential gains in knowledge or accelerate technical maturity.*** Research of interest may include knowledge products, "knowledge resulting from research with the potential to improve individual or public health,"[2] 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.

Impact is a key component of this award mechanism. The potential impact of the research, both short term and long term, in addressing the FY23 CRRP Focus Area(s) should be clearly described. Successful high-impact research should lead to the rapid development and translation of applicable advances for improving medical readiness, mitigating fatalities, optimally treating life-threatening injuries, and promoting positive long-term outcomes for military health and medicine, as well as the general public.

Key aspects of the CRRP Translational Research Award Mechanism:

- **This BAA may be used to support applied, preclinical, and/or clinical research.**

- ***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.***

- **Preliminary data are required:** Inclusion of preliminary data relevant to the proposed study is required.

- **Statistical Analysis and Data Management Plans:** The application should include a clearly articulated statistical analysis plan; a power analysis reflecting sample size projections that will answer the objectives of the study; and a data management plan and use of an appropriate database to safeguard and maintain the integrity of the data.

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,

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[2]Engel CC, Silberglitt 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.

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.

Funding from this BAA may *not* be used to support studies requiring an exception from informed consent (EFIC).

Clinical research encompasses research with patient samples, data, and interaction with patients that may or may not be considered a clinical trial. ***For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research.*** Clinical research is observational in nature and includes: (1) Research that does <u>not</u> seek to evaluate the effects of interventions. Research conducted with human subjects (or on material of human origin such as data, tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects, but does not seek to assess the effects of an intervention, qualifies as clinical research. Patient-oriented research may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.
(2) Epidemiologic and behavioral studies that do not seek to study the safety, effectiveness, and/or efficacy outcomes of an intervention. (3) Outcomes research and health services research that do not fit under the definition of clinical trial. Excluded from the definition of clinical research are in vitro studies that utilize human tissues that cannot be linked to a living individual.
Note: Studies that meet the requirements for exemption under [§46.104(d)(4) of the Common Rule](#) are not considered clinical research as defined by CDMRP. Exemption category 4 refers to secondary research for which consent is not required.

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 a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. Clinical trials are not allowed under this funding opportunity announcement.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

The period of performance of the CRRP TRA will be 2 years. The anticipated ***total costs*** budgeted for an FY23 CRRP TRA should not exceed **$1.1M**.

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

Awards will be made no later than September 30, 2024. For additional information refer to [Section II.F.1, Federal Award Notices](#).

The CDMRP expects to allot approximately $4.4M to fund approximately four CRRP Translational Research 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. 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. It is anticipated that

awards made from this FY23 funding opportunity will be funded with FY23 funds, which will expire for use on September 30, 2029.

Proposals/applications received in response to both the extramural FY23 CRRP TRA BAA and the intramural program announcement will be evaluated and considered for funding. 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 Data, Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human data, human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of application submission is *not* required; however local IRB/EC approval is necessary prior to OHRO review. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of *all required and complete* documents to the OHRO. Refer to the General Submission Instructions, Appendix 1, and the OHARO web page https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo for additional information.

As of January 20, 2020, U.S. institutions engaged in non-exempt cooperative research *must* rely on a single IRB to review and approve the portion of the research conducted at domestic sites in accordance with Code of Federal Regulations, Title 45, Part 46.114(b) (45 CFR 46.114[b]). If the proposed, non-exempt research involves more than one U.S.-based 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. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 (https://www.nature.com/articles/nature11556). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Projects that include research on animal models are required to submit Attachment 8, Animal Research Plan, as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) 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 and/or VA patient populations and/or DOD or VA resources or databases, the 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 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 FY23 CRRP TRA 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.

Federal Interagency Traumatic Brain Injury Research (FITBIR) Data Sharing: The DOD requires that awardees make any traumatic brain injury (TBI) focused research data generated by this award mechanism available to the research community through the FITBIR Informatics System. The FITBIR Informatics System is a free resource designed to accelerate research progress by allowing the storage, reanalysis, integration, and rigorous comparison of multiple datasets. Currently, FITBIR-eligible research includes all studies generating prospectively collected human TBI subject data (e.g., clinical, demographic, phenotypic, imaging and genetic). Consult the FITBIR website at https://fitbir.nih.gov for additional information. Elements that must be included in the proposed research can be found in Appendix IV.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.

Organizations eligible to apply include national, international, non-profit, for-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 HT9425-23-CRRP-TRA. 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 award 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 is not an eligibility requirement.

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): 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 and the "Responsibility and Qualifications within the Entity Information" functional area of SAM to verify that an organization is eligible to receive federal awards. More information about Exclusions reported in SAM is available at https://www.sam.gov/SAM/. 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

Inclusion of classified research data within the application and/or proposing research of which the anticipated outcomes may be classified or deemed sensitive to national security concerns

may result in application withdrawal. Refer to the General Submission Instructions Appendix 2, Section E.

II.D.1. eBRAP and Grants.gov

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs to submit their pre-proposal/pre-applications, view and verify extramural full 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. eBRAP also allows intramural organizations to submit full applications following pre-proposal/pre-application submission.

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-proposal/pre-application content and forms and full application packages (which must be submitted under funding opportunity number HT9425-23-CRRP-TRA 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 Application Guidelines for full proposal/application submission guidelines.

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 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 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 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.

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

The applicant organization and associated PI identified in the pre-proposal/pre-application should be the same as those intended for the subsequent 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 or 301-682-5507.

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-proposal/pre-application to be submitted.

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

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

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

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

  FY23 CRRP Programmatic Panel members should not be involved in any pre-proposal/pre-application or application. For questions related to panel members and pre-proposal/pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at 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-Proposal/Pre-Application Files**

  Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the FY23 CRRP focus area under which the application will be submitted. 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 a full application is NOT provided after LOI submission and applicants are not required to have such an invitation in order to proceed to submitting a full application.*

- **Tab 6 – Submit Pre-Proposal/Pre-Application**

  This tab must be completed for the pre-proposal/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

Proposal/Application Package Location
Download proposal/application package components for HT9425-23-S-CRRP from Grants.gov (https://grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the proposal/application components and routing of the proposal/application package through the applicant organization for review prior to submission.
Full Proposal/Application Package Components
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Submission Instructions, Section III.A.1, for detailed information.
Descriptions of each required file can be found under Full Proposal/Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • 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): 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.

  Describe the proposed project in detail using the outline below.

  - **Background:** Describe the problem, question, or knowledge gap related to at least one of the FY23 CRRP Focus Areas and, if applicable, any relevant FY23 CRRP Area(s) of Encouragement to be addressed by the proposed project. Present the scientific rationale on which the proposed work is based. Provide a literature review and describe the preliminary studies and/or preclinical data that led to the development of the proposed research. 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. Throughout the Project Narrative, describe how the proposed research is translational and has the potential for broadly applicable, cross-cutting advances benefiting military health and medicine as well as the general public.

  - **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 the CRRP TRA would fund.

  - **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.

    - 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 rapid development and 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.

- For clinical research studies, further details of clinical research components will be required in Attachment 6, Human Subject Recruitment and Safety Procedures, 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 experience 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 for the proposed work and complementary.

○ **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 (one-page limit per letter is recommended):** 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, one-page limit per letter is recommended):** 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 signed 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 signed 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 CRRP TRA are subject to a federal purpose license. A term of the CRRP TRA requires the recipient to grant the government all necessary and appropriate licenses, which could include licenses to background and proprietary information that have been developed at private expense. Refer to the General Submission Instructions, Appendix 2, Sections C and D, for more information about disclosure of proprietary information.

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

  ▪ **Intellectual and Material Property Plan:** 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. For proposals/applications involving FITBIR-eligible TBI research:

  ▪ Identify and describe the planned common data elements (CDEs), alignment to FITBIR data elements and forms, and timelines for integrating data to the FITBIR Informatics System.

  ▪ For unique data elements (UDEs), provide a justification as to why existing CDEs are not applicable or appropriate.

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

– **Enrollment Table (required, for studies enrolling human subjects):** Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The 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.

– **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 signed 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/Specific Aims:** State the objective to be reached/hypothesis to be tested. Provide evidence or rationale that supports the hypothesis(es)/objective(s). State concisely the specific aims of the study.

– **Study Design:** Briefly describe the study design.

– **Impact and Translation:** Describe the innovative qualities of the proposed work. State the FY23 CRRP Focus Area(s) and, if applicable, any relevant FY23 CRRP Areas of Encouragement that the research addresses. Indicate how the proposed work will lead to the translation of advances for improving medical readiness, mitigating fatalities, optimally treating life-threatening injuries, and promoting positive long-term outcomes for Service Members, as well as the general public.

○ **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***. ***Do not duplicate the technical abstract.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

- Describe the objectives and theoretical reasoning behind the proposed work in a manner readily understood by readers without a background in science or medicine.

- State the FY23 CRRP Focus Area(s) and, if applicable, any relevant FY23 CRRP Areas of Encouragement that the research addresses and describe how it is addressed.

- Describe the problem or question to be addressed and the ultimate applicability and impact of the research.

  - How does the research increase medical readiness, mitigate fatalities, optimally treat life-threatening injuries, and/or promote positive long-term outcomes?

  - How will the research improve delivery of medical damage control capability, assets, and life-saving interventions?

  - What are the potential clinical applications, benefits, and risks?

- Describe how the proposed project will benefit Service Members, Veterans, military beneficiaries, and/or the American public.

  - How will the research increase survivability and readiness of the Warfighter in diverse operational settings?

○ **Attachment 5: Statement of Work (three-page limit): 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 CRRP TRA mechanism, refer to the ***"Suggested SOW Strategy Generic Research"*** and use the blank SOW format titled "Suggested SOW Format". The SOW must be in PDF format prior to attaching.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined step-by-step as they relate to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this proposal/application and, as applicable, should also:

- Include the following information for each study site/subaward site: Organization; organization address; investigator(s), collaborator(s), consultant(s); description of research with animals, human anatomical substances, and/or human subjects or cadavers to be conducted at the site; and key personnel responsible for each major task and each subtask to be performed at the site.

- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. As applicable, estimated times to complete each task should include time for local and USAMRDC regulatory review and approval, as shown below. Refer to the General Submission Instructions, Appendix 1for additional information regarding regulatory review.

- For studies involving human subjects, include a subtask that allows at least 2 to 4 months for regulatory review and approval by the USAMRDC OHRO; this does not include the additional time required for local IRB review and approval.

- For animal studies, include a subtask that allows at least 3 to 4 months for regulatory review and approval by the USAMRDC ACURO; this does not include the additional time required for local IACUC review and approval.

- **Attachment 6: Impact/Military Relevance 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.

  - Explain in detail how the research represents an accelerated and relevant approach for existing research and technologies, aligned to the FY23 CRRP Focus Area(s) and, if applicable, any relevant FY23 CRRP Areas of Encouragement. Describe how the research is cross-cutting with the potential to benefit multiple DOD medical research program areas.

  - Describe how the proposed research will significantly improve the readiness of the Force in combat and frontline trauma environments. Clearly articulate how the proposed research can be applied in far-forward roles of care (e.g., in combat, at point of injury, en route) to optimize survival and recovery during future MDO that feature delayed evacuation and austere environments.

  - Describe how the anticipated outcomes will be translated into clinical practice and decrease morbidity and mortality of the Warfighter. Expand on how the outcomes will be utilized and implemented in far-forward roles of care and/or austere environments, if applicable. Describe any potential issues or anticipated challenges that might limit the impact.

  - Describe how the anticipated outcomes of the proposed project will advance operational performance, medical readiness, or quality of life of Service Members or Veterans. In addition, describe how the proposed research will benefit their families, caregivers, and the American public, as applicable. Include the timeline to realize the anticipated short-term and long-term outcomes of the research. Explain how the knowledge, technologies, or products gained from the research could be implemented in a dual-use capacity to benefit the civilian population and address the health care needs of military Service Members, Veterans, and/or their beneficiaries, as appropriate.

- ○ **Attachment 7: Human Subject Recruitment and Safety Procedures for clinical research (no page limit), if applicable; required for all studies recruiting human subjects: Upload as "HumSubProc.pdf".** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below, where applicable.

  Applicants and collaborating organizations may not use, employ, or subcontract for the use of any human participants, including the use of human anatomical substances, human data, and/or human cadavers until applicable regulatory documents are reviewed and approved by the USAMRDC OHRO 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.

  – **Women and Minorities in the Study:** Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Describe the strategy for the inclusion of women and minorities in the clinical research 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. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

–   **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care 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. FITBIR-eligible proposals/applications should include FITBIR consent language (see [Appendix IV](#)) for sample consent language.***

  ▪   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 8: Animal Research Plan (if applicable; 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. 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 TBI, 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 (no page limit): (*Attachment 9 is only applicable and required for applications proposing clinical research that involves FDA-regulated products*). If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".** Answer the following questions and provide supporting documentation as applicable.

For FY23 CRRP TRA applications proposing clinical research:

– State the product/intervention name.

  ▪ If none, state how the proposed study meets the definition of clinical research as defined in Section II.B, Award Information.

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

– For investigator-sponsored regulatory exemptions (e.g., investigational new drug, IND, investigational device exemption, IDE) provide evidence of institutional support. Provide evidence that the clinical study does not require regulation by the FDA. If the clinical study 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.

– ***If an IND or IDE is required for the work proposed in the FY23 CRRP TRA period of performance, the IND/IDE application must be submitted to the FDA prior to the proposal/application submission deadline.*** 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 clinical study, describe the type and nature of the amendment(s) and the timeline for submission. Indicate whether the amendment increases the risk of the intervention.

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

○ **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. Demonstrate how the proposed product or knowledge outcome is currently at a minimum technology readiness level (TRL) or knowledge readiness level (KRL) of 3, and estimate the target TRL/KRL level upon completion of the proposed research (Appendix V). Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to determine the TRL/KRL levels and 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, and/or incorporation into clinical practice).

- 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

research involving FDA-regulated products or may lead to FDA-regulated 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.

– A risk analysis for cost, schedule, manufacturability, and sustainability.

○ **Attachment 11: 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 12: 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 (NIH) 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 12, 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 an application through Grants.gov. *As of April 2022, all federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI generated through SAM.gov.* 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 CRRP TRA 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 CRRP TRA. *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 is not required under this BAA.

II.D.6. Funding Restrictions

The maximum period of performance is **2** years.

The application's total costs budgeted for the entire period of performance should not exceed **$1.1M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate.

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 **2** years.

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 Heath 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 CRRP TRA.

Must not be requested for:

- Clinical trial costs

- Equipment (other than special purpose equipment)

- Tuition

Awards made to extramural organizations will consist of contracts, assistance agreements (grants and cooperative agreements), or OTAs. 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. Intramural collaborators 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.

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**, 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.

  ○ How well the hypothesis and/or objectives, specific aims, experimental design, methods, and analyses are developed.

  ○ How well the application describes study outcomes/endpoints and how they will be measured.

  ○ How well the research strategy will meet the project's goals and milestones within the proposed period of performance.

  ○ How well the application acknowledges potential problem areas and addresses alternative methods and approaches.

  ○ If applicable, 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 rapid development and solutions for the Warfighter.

- How well the applicant demonstrates access to the relevant study resources.

- For research conducted with human subjects (clinical research), how well the application demonstrates the availability of, and access to, the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects.

- For research conducted with human subjects, whether the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.

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

- To what extent the research can be completed within the proposed period of performance(s).

- How well the data and resources plan feasibly allows for data sharing. For FITBIR-eligible applications:

    - How well the study utilizes TBI CDEs and describes processes and timelines for integrating data to the FITBIR Informatics System.

    - If UDEs are utilized, how well the application justifies the rationale for UDE collection.

- **Impact/Military Relevance**

    - How well the proposed work represents an accelerated and relevant approach aligned to the FY23 CRRP Focus Area(s) and, if applicable, any relevant FY23 CRRP Areas of Encouragement.

    - To what extent the proposed research will significantly improve the readiness of the Force in combat and frontline trauma environments.

    - How well the project outcomes will impact clinical practice and decrease morbidity and mortality of the Warfighter.

    - To what extent the proposed research can be utilized in far-forward roles of care or austere environments.

    - To what degree the anticipated outcomes of the proposed project will lead to improved operational performance, medical readiness, or quality of life for Service Members or Veterans.

    - To what degree the anticipated outcomes could be implemented in a dual-use capacity to benefit the civilian population and address the health care needs of military Service Members, and/or their beneficiaries, if applicable.

- **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.

  ○ If applicable, how well the application identifies sampling methods to gain a representative sample from the population(s) of interest.

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

- **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.

  ○ Whether the population selected to participate in the clinical research stands to benefit from the knowledge gained.

  ○ To what degree privacy issues are appropriately considered.

  ○ To what degree the processes for seeking informed consent are appropriate and whether safeguards are in place for vulnerable populations.

- **Research Team**

  ○ To what degree the background and experience 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 application:

- **Budget**

    ○ Whether the **total** costs exceed the allowable total costs as published in the program announcement.

    ○ 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 Defense Health Program and FY23 CRRP, as evidenced by the following:

    ○ Adherence to the intent of the award mechanism

    ○ Program portfolio composition

    ○ Relevance to military health

    ○ Relative impact and translation potential

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 CRRP TRA 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 SAM.

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

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

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 FY23 funds are anticipated to be made no later than September 30, 2024. 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, non-profit or for-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

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 additional FAR and DFARS clauses as found in Appendix VI.

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 and the USAMRAA General Research Terms and Conditions: Addendum to the DoD R&D General Terms and Conditions for further information.

Certification Regarding Disclosure of Funding Sources. The proposing entity must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI 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 will be required.

If the award made under this funding opportunity announcement is a contract or OTA, additional reporting requirements may apply.

The Award Terms and Conditions will specify if additional and/or 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 CRRP TRA 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 SAM 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 CRRP TRA 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

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

Sign up on Grants.gov for "send me change notification emails" by following the link on the "Synopsis" page for the CRRP TRA or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov proposal/application 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 proposal/application:

- Pre-proposal/pre-application (letter of intent) was not submitted.

- 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 7, Human Subject Recruitment and Safety Procedures 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 FY23 CRRP 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 FY23 CRRP Programmatic Panel members can be found at https://cdmrp.health.mil/crrp/panels/panels23.*

- 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 FY23, 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 proposal/application includes research data that are classified and/or proposes research of which the anticipated outcomes may be classified or deemed sensitive to national security will be considered for proposal/application withdrawal.

- The application does not address at least one of the FY23 CRRP Focus Areas.

- The proposed research includes a clinical trial.

- The proposal/application does not demonstrate support for and access to relevant population(s) and/or resource(s).

- The proposal/application requiring IND/IDE (or international equivalent) during the period of performance does not include documentation of submission in the Regulatory Strategy (Attachment 9).

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"	
	Impact/Military Relevance Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Human Subject Recruitment and Safety Procedures for Clinical Research: Upload as Attachment 7 with file name "HumSubProc.pdf" if applicable	
	Animal Research Plan: Upload as Attachment 8 with file name "AnimRschPln.pdf" if applicable	
	Regulatory Strategy: Upload as Attachment 9 with the final name "Regulatory.pdf"	
	Transition Plan: Upload as Attachment 10 with file name "Transition.pdf"	
	Representations: Upload as Attachment 11 with file name "RequiredReps.pdf"	
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 12 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

Proposal/Application Components	Action	Completed
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

ACURO   Animal Care and Use Review Office

ARRIVE   Animal Research: Reporting *In Vivo* Experiments

BAA   Broad Agency Announcement

CDC   Centers for Disease Control and Prevention

CDE   Common Data Element

CDMRP   Congressionally Directed Medical Research Programs

CFR   Code of Federal Regulations

CRADA   Cooperative Research and Development Agreement

CRRP   Combat Readiness – Medical Research Program

DIL   Delayed/Disconnected, Intermittently Connected, and/or Low-Bandwidth

DOD   Department of Defense

DoDGARs   Department of Defense Grant and Agreement Regulations

DoDI   DoD Instruction

DTIC   Defense Technical Information Center

eBRAP   Electronic Biomedical Research Application Portal

EC   Ethics Committee

EFIC   Exception from Informed Consent

ET   Eastern Time

FAD   Funding Authorization Document

FDA   Food and Drug Administration

FITBIR   Federal Interagency Traumatic Brain Injury Research

FWA   Federal wide Assurance

FY   Fiscal Year

GCP   Good Clinical Practice

GLP   Good Laboratory Practice

GMP   Good Manufacturing Practice

GUID   Global Unique Identifier

HIPAA   Health Insurance Portability and Accountability Act

HRPO   Human Research Protection Office

IACUC   Institutional Animal Care and Use Committee

IDE   Investigational Device Exemption

IND   Investigational New Drug

IRB   Institutional Review Board

KP	Knowledge Product
KRL	Knowledge Readiness Level
LAR	Legally Authorized Representative
M	Million
MB	Megabytes
MDO	Multi-Domain Operation
MIPR	Military Interdepartmental Purchase Request
mTBI	Mild Traumatic Brain Injury
NAICS	North America Industrial Classification System
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
NPC	Non-Profit Corporation
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
ORCID	Open Researcher and Contributor ID, Inc.
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
PII	Personally Identifiable Information
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TBI	Traumatic Brain Injury
TRA	Technology Readiness Assessment
TRA	Translational Research Award
TRL	Technology Readiness Level
UDE	Unique Data Element
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: FY23 CRRP AREAS OF ENCOURAGEMENT

The following Areas of Encouragement are related to the FY23 CRRP Focus Areas and have been identified by the Department of Defense (DOD) and the FY23 CRRP Programmatic Panel as capabilities and knowledge gaps that are of high priority and programmatic relevance. ***The information provided is not exhaustive. While applicants are not restricted to submitting applications that address an Area of Encouragement on this list, proposals/applications must demonstrate relevance to the program mission, vision, and FY23 CRRP Focus Areas.***

Infectious Diseases and Highly Infectious Disease Treatment and Transport

- Research and development of broadly active therapeutics for infectious diseases with simplified dosing to prevent multiple endemic disease threats in far-forward, austere environments.

- Research and development of novel medical countermeasures and innovative treatment approaches for multidrug-resistant organisms in combat wound infections and/or biofilm formation, maintenance, or propagation.

- Research relating to delivery and effectiveness of current standard of care for traumatic wounds to inform clinical practice guidelines.

Sleep Disorders

- Research on the prevention and/or mitigation of insomnia, hypersomnia, and somnolescence due to high military operational-tempo sleep restriction related to sustained combat operations, particularly associated with long aeromedical evacuation flights for both clinical team members and patients.

Service-Related Post-Traumatic Arthritis

- Research relating to prevention and treatment of post-traumatic arthritis to promote readiness.

Telemedicine and Medical Simulation Technologies

- Research and development of solutions that support medical systems communications capabilities in delayed/disconnected, intermittently connected, and/or low-bandwidth (DIL) environments.

- Research and development of solutions to maximize Warfighter capability by extending the operational reach, speed, and capacity to balance medical support. Solutions include point-of-injury treatment and evacuation of casualties to definitive care, proportionally with large-scale combat operations.

- Research and development of autonomous and/or semi-autonomous medical technologies to amplify "human-based" capabilities in far forward environments and/or situations of DIL communication.

- Research to promote and optimize the learning and training effectiveness of medical and non-medical military providers. Solutions may include low-cost materiel and knowledge products to improve of acquisition, retention, and application of gained knowledge, skills, and abilities.

Freeze-Dried Plasma and Platelets

- Research supporting development of alternatives to optimize logistics and administration of blood products to the Warfighter, including logistics of storage.

- Research supporting development of blood-type agnostic solutions.

Ruggedized Oxygen Generation Systems

- Research and development of solutions that are portable and easy to use with enhanced safety profiles.

Eating Disorders

- Research supporting development of evidence-based recommendations supporting Warfighter readiness.

- Research that contributes to improved understanding of eating and weight management behaviors and characteristics linked to physical performance, weight status, and relation to body composition standards needed for military screening.

Head Injury and Handheld Detection Devices for Traumatic Brain Injury (TBI)/Portable Neurological Devices in Support of Mild Traumatic Brain Injury (mTBI) Assessment

- Development of technologies that can be used for objective assessment, diagnosis, and prognosis of mTBI in far-forward environments.

Rapidly Deployable All-in-One Acute and Chronic Care Therapy to Address Complex Trauma and Start Tissue Regeneration

- Research and development of wound decontamination solutions (e.g., fourth-generation chemicals) and extracellular materials for wound care therapies to stabilize wounds, accelerate healing, and prevent complications.

- Research that may lead to cost-effective, sound care solutions.

- Research and development of innovative damage control surgical and non-surgical capabilities, especially interventions to be used in an austere environment by non-physician providers.

APPENDIX III: 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://afrri.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.health.mil

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

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

Naval Health Research Center
https://www.med.navy.mil/Naval-Medical-Research-Command/R-D-Commands/Naval-Health-Research-Center/med.navy.afpims.mil/Nurse-Corps/

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

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

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

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

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

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

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

U.S. Air Force 59th 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/ccdc

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

U.S. Army Research Institute of Environmental Medicine
https://www.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/index.cfm/collaborate/research_protections/hrpo

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 IV: FITBIR REQUIREMENTS

In order to share data with FITBIR, three elements ***must be included*** in the proposed research:

1. Updated informed consent language that includes FITBIR data sharing. Sample consent language is included below.

2. FITBIR Global Unique Identifier (GUID): The FITBIR GUID is a subject ID that allows researchers to share data specific to a study participant without exposing Personally Identifiable Information (PII) and makes it possible to match participants across laboratories and research data repositories. In order to generate a GUID for a subject, the following PII must be collected in the proposed research (this PII is never sent to the FITBIR system):

    *   Complete legal given (first) name of subject at birth

    *   Complete legal additional name of subject at birth (if subject has a middle name)

    *   Complete legal family (last) name of subject at birth

    *   Day of birth

    *   Month of birth

    *   Year of birth

    *   Name of city/municipality in which subject was born

    *   Country of birth

    Note that this PII is never sent to the FITBIR system. PII cannot be extracted from the GUID. Information on GUID compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations can be found at https://fitbir.nih.gov/content/global-unique-identifier.

3. National Institute of Neurological Disorders and Stroke (NINDS) TBI CDEs: Research data elements ***must be reported*** using the NINDS TBI CDEs or entered into the FITBIR data dictionary as new, unique data elements (UDEs). For the most current version of the NINDS TBI CDEs, go to https://www.commondataelements.ninds.nih.gov. Assistance will be available to help the researchers map their study variables to specific CDEs and ensure that the formats of the CDEs collected are compatible with the FITBIR Informatics System. Use of the TBI CDEs is required as applicable in an effort to create standardized definitions and guidelines about the kinds of data to collect and the data collection methods that should be used in clinical studies of TBI. Applicants are strongly required to review TBI CDEs and associated form structures during the development of the study collection methods. ***If approved CDEs are not incorporated, justification is required and subject to program approval.***

While there is no direct charge to users of the FITBIR Informatics System, a project estimation tool is available to help estimate costs and manpower needs that may be associated with data submission.

Sample Consent Language

Data from this study may be submitted to the Federal Interagency Traumatic Brain Injury (FITBIR) informatics system. FITBIR is a computer system run by the National Institutes of Health that allows researchers studying traumatic brain injury to collect and share information with each other. With an easier way to share, researchers hope to learn new and important things about traumatic brain injury more quickly than before.

During and after the study, the researchers will send information about you or your child's health and behavior and in some cases, you or your child's genetic information, to FITBIR. However, before they send it to FITBIR, they will remove information such as name, date of birth, and city of birth, and replace that information with a code number. Other researchers nationwide can then file an application to obtain access to your study data for research purposes. Experts who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You or your child may not benefit directly from allowing your information to be shared with FITBIR. The information provided to FITBIR might help researchers around the world treat future children and adults with traumatic brain injury so that they have better outcomes. FITBIR will report on its website about the different studies that researchers are conducting using FITBIR data; however, FITBIR will not be able to contact you or your child individually about specific studies.

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

Language to be used to describe certificates of confidentiality (three versions):

1.   Language for new studies that will be consenting subjects for the first time or for ongoing studies that will be re-consenting subjects because they are applying for a Certificate of Confidentiality (COC) for the study

To help protect you and/or your child's privacy the investigators of this study [have applied for]/[have obtained] a Certificate of Confidentiality from the National Institutes of Health, part of the U.S. Department of Health and Human Services (DHHS), an agency of the U.S. Government.

With this Certificate, we, the investigators, cannot be forced (e.g., by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Be aware that disclosure of you and/or your child's identity may be found necessary, however, upon request of DHHS for the purpose of audit or evaluation.

You should also understand that a Confidentiality Certificate does not prevent you or a member of your family from **voluntarily** releasing information about your child, yourself, or your involvement in this research. Note however, that if an insurer or employer learns about you and/or your child's participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

We are also asking your consent to provide research data and related findings to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system. FITBIR is a biomedical informatics system and data repository, created by the Department of Defense and the National Institutes of Health to assist biomedical researchers working to develop a better understanding of traumatic brain injury and/or to develop more effective methods to diagnose, treat and prevent traumatic brain injuries.

Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by qualified researchers only. Data provided to FITBIR as part of you and/or your child's participation in this research study will be de-identified—i.e., you and/or your child's name will be separated from the data. However, since this institution and others submitting data to FITBIR will retain individually identifying information related to the data they provide, NIH has issued a legislatively authorized "Certificate of Confidentiality" that will help FITBIR and participating institutions avoid being forced to disclose information that may identify you as a FITBIR participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Finally, you should understand that we, the investigators, are not prevented from taking steps, including reporting to authorities, to prevent serious harm to you, your child, or others. With respect to you and/or your child's participation in FITBIR, we do not plan to make voluntary disclosures except if there were severe threats to the public health or safety.

2. Language for studies that already have a Certificate and will be re-consenting subjects about FITBIR

With your consent, this study will collect and provide research data and related findings to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system. FITBIR is a biomedical informatics system and data repository created by the Department of Defense and National Institutes of Health—part of the U.S. Department of Health and Human Services (DHHS), an agency of the U.S. Government—to assist biomedical researchers working to develop a better understanding of traumatic brain injury and/or to develop more effective methods to diagnose, treat and prevent traumatic brain injury.

Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by researchers only. Data provided to FITBIR as part of you and/or your child's participation in this research study will be de-identified—i.e., you and/or your child's name will be separated from the data. However, since this institution and others submitting data to FITBIR will retain individually identifying information related to the data they provide, NIH has issued a legislatively authorized "Certificate of Confidentiality" to help FITBIR and participating institutions avoid being forced (e.g., by court subpoena) to disclose information that may identify you as an FITBIR participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Be aware that disclosure of you and/or your child's identity may be found necessary, however, upon request of DHHS for the purpose of audit or evaluation.

As you know, we have obtained a Certificate of Confidentiality from NIH that enables us to keep the individually identifiable information that you provide as a research subject private. With this Certificate, we, the investigators cannot be forced to disclose research information collected in this study that may identify you in any federal, state, or local civil, criminal, administrative,

legislative, or other proceedings. This protection will continue to protect you and/or your child's privacy even though we are providing de-identified data to FITBIR.

You should also understand that a Confidentiality Certificate does not prevent you or a member of your family from **voluntarily** releasing information about your child, yourself, or your involvement in this research. Note however, that if an insurer or employer learns about you and/or your child's participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Finally, as we explained when we told you about this privacy protection before, we, the investigators, are not prevented from taking steps, including reporting to authorities, to prevent serious harm to you and/or your child or others based on information they learn during this study. With respect to you and/or your child's participation in FITBIR, we do not plan to make voluntary disclosures except if there were severe threats to the public health or safety.

3. **Language for studies without a Certificate of their own**

With your consent, this study will collect and provide research data and related findings to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system. FITBIR is a biomedical informatics system and data repository created by the Department of Defense and the National Institutes of Health—part of the U.S. Department of Health and Human Services (DHHS), an agency of the U.S. Government—to assist biomedical researchers working to develop a better understanding of traumatic brain injury and/or to develop more effective methods to diagnose, treat and prevent traumatic brain injury.

Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by researchers only. Data provided to FITBIR as part of you or your child's participation in this research study will be de-identified—i.e., you and/or your child's name will be separated from the data. However, since this institution and others submitting data to FITBIR will still retain individually identifying information related to the data provided, the NIH has issued a legislatively authorized "Certificate of Confidentiality" to help FITBIR and participating institutions avoid being forced (e.g., by court subpoena) to disclose information that may identify you as an FITBIR participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Finally, you should understand that we, the investigators, are also permitted to make voluntary disclosures with respect to information that is submitted to FITBIR, but do not plan to do so except in the event of severe threats to public health or safety. If, as part of your participation in this research study itself, we learn about serious harm to you, your child or someone else, we would take steps to prevent that harm including notifying appropriate authorities like the police or child welfare.

APPENDIX V: 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). The figures below represent a quick reference guide for assessing KRLs for knowledge products.

Step 1: Determine the Knowledge Product (KP):

KRL7-9 ratings are given to KPs resulting from research designed to emphasize external validity (generalizability) of knowledge for use in a specified real world application context. This research often addresses a policy question, asking, "How does it compare to usual practice?" To achieve a rating of KRL7-9, the KP must be based on valid replicated KRL 4-6 research.
Examples include:
- Battlefield intervention
- Primary care screener
- Workplace prevention
- Systematic reviews of KRL 7-9 research
- Systematic reviews to inform creation of practice guidelines and study of a guideline

KP3 Community

KRL4-6 are given to KPs that seek to generate applied knowledge to eventually perform a non-research related function or to inform understanding of an application or tool. KRL4-6 research often asks questions such as "Can the application work under ideal research conditions?" and "(if the application can work), how does it work?" To achieve a rating of KRL 4-6, the KP must be based on valid, replicated KRL1-3 research.
Examples include:
- Applications that prevent, screen/diagnose, or treat illness
- Systematic reviews that summarize KRL4-6 research

KP2 Bedside

KRL1-3 provide the scientific foundation for KP development toward practical application. These KPs are the outputs of health research that seeks basic mechanisms rather than applications and tends to be theoretical or conceptual, often (but not always) comprising laboratory, descriptive, or exploratory studies.
Examples include:
- Animal research
- Non-Clinical laboratory research
- Descriptive epidemiology
- Systematic reviews of KRL1-3 research

KP1 Bench

Step 2: Determine the Knowledge Readiness Level (KRL)

Community / Real World

KRL 9

KRL9 research replicates or reviews well-designed KRL7 and KRL8 studies (e.g., cost analyses to achieve desired effect; comparative effectiveness studies to aid context specific policy development or intervention decisions; systematic review to estimate effect size with average participants in a real world context, assess **"Does the application work?"** in a context, or determine for which participants or time period the application works in an identified context.)

KRL 8

KRL8 research expands on or replicates KRL7 studies to directly assess **"Does the application work in the context of interest?"** It uses valid designs with emphasis on external validity (generalizability) for an intended context. (e.g., multi-site to obtain average effects; generalizable analyses of real world, (e.g., administrative) data; usual or standard care (not placebo or contact time) controls; and average (not ideal) participants.)

KRL 7

KRL7 research comprises early studies adapting applications supported by KRL4-6 research for use in a military health context. (e.g., adaptation from a longer screener, feasibility and standardization for post-deployment use of a brief screener; initial multi-modal tests of combined KRL4-6 supported interventions to achieve improved outcomes in primary care; adaptation and initial study in military mental health settings of KRL4-6 support therapy for PTSD; adaptation and initial study of KRL4-6 supported protective gear for preventing TBI during deployment.)

Bedside / Applications

KRL 6

KRL6 research replicates well-designed KRL5 studies. It adds nuance to answers from completed studies (e.g., not just "Can it work" and "How," but also "For whom," "Under what conditions," or "With what frequency?") It validates hypotheses that may suggest important application contexts (e.g., battlefield, primary care, emergency rooms, post-deployment screening). It includes systematic reviews of KRL4-5 studies to address "Can it work?" and "How?" questions.

KRL 5

KRL5 research tests *a priori* (pre-specified) hypotheses using rigorous scientific designs (e.g., RCTs for intervention efficacy) to directly assess "Can it work" and "If so, how?" It expands on or replicates a KRL4 finding and/or improves on the design of one or more KRL4 studies.

KRL 4

KRL4 research generates initial knowledge regarding a human health-related application or use. KRL4 findings require subsequent replication (e.g., descriptive human epidemiology or preliminary human studies, human studies that test a clinical hypotheses, pilot tests of an intervention, screening or diagnostic tool, and development of instrumentation needed to test an intended application (e.g., outcome measure).

Bench / Foundations

KRL 3

KRL3 research validates hypotheses and hints at future applications, research that replicates or systematically reviews well-designed KRL1-2 studies or theory, descriptive studies, particularly involving animal research (e.g., tool for prediction, prognosis, screening, diagnosis, treatment, prevention)

KRL 2

KRL2 research expands on or replicates a KRL1 finding, including systematic review of KRL1 studies to formulate a theoretical model (e.g., animal studies that test a hypothesis or are the first true experiment on a nascent theory and human studies not based on animal study findings that are descriptive or hypothesis generating.

KRL 1

KRL1 research generates initial or very early scientific knowledge without regard to or indication of a specific health use. Its purpose is inferential, with the intention to generalize. Its findings require replication. (e.g., descriptive animal studies, or those that are hypothesis generating rather than hypothesis testing.)

APPENDIX VI: FAR 7 DFARS CLAUSES APPLICABLE TO CONTRACTS REQUIREMENTS

FAR/DFARS Provisions/Clauses: For purposes of illustration, the following provisions and clauses may be applicable to procurement contracts resulting from this Broad Agency Announcement. Additional clauses apply based upon contract type. USAMRAA reserves the right to include all relevant and current FAR or DFARS clauses in the final contract award.

# Provision	Clause
52.204-7	System for Award Management
52.204-13	System for Award Management Maintenance
52.204-16	Commercial and Government Entity Code Reporting
52.204-21	Basic Safeguarding of Covered Contractor Information Systems
52.204-24	Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment
52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment
52.204-26	Covered Telecommunications Equipment or Services-Representation
52.209-9	Updates of Publicly Available Information Regarding Responsibility Matters
52.215-20	Requirements for Certified Cost and Pricing Data and Data Other than Certified Cost and Pricing Data
52.215-16	Facilities Capital Cost of Money
52.215-22	Limitations on Pass Through Charges - Identification of Subcontract Effort
52.216-1	Type of Contract
52.216-27	Single or Multiple Awards
52.217-4	Evaluation of Options Exercised at time of Contract Award
52.217-5	Evaluation of Options
52.217-9	Option to Extend the Term of the Contract
52.222-24	Preaward On-Site Equal Opportunity Compliance Evaluation (Applies if Exceeds $10M)
52.222-50	Combating Trafficking in Persons
52.222-56	Certification Regarding Trafficking in Persons Compliance Plan
52.223-6	Drug Free Work Place
52.226-2	Historically Black College or University and Minority Institution Representation
52.230-7	Proposal Disclosure - Cost Accounting Practice Changes
52.232-15	Progress Payments Not Included
52.233-2	Service of Protest
52.252-1	Solicitation Provisions Incorporated by Reference
52.252-3	Alterations in Solicitation
52.252-5	Authorized Deviations in Provisions
252.203-7005	Representation Relating to Compensation of Former DoD Officials
252.204-7004	Alternate A, System for Award Management
252.204-7008	Compliance with Safeguarding Covered Defense Information Controls
252.204-7012	Safeguarding Covered Defense Information and Cyber Incident Reporting

# Provision	Clause
252.204-7018	Prohibition on the Acquisition of Covered Defense Telecommunications Equipment or Services
252.215-7003	Requirements for Submission of Data Other than Certified Cost or Pricing Data - Canadian Commercial Corporation
252.204-7000	Disclosure of Information
252.204-7019	Notice of NIST SP 800-171 DoD Assessment Requirements
252.204-7020	NIST SP 800-171 DoD Assessment Requirements
252.219-7000	Advancing Small Business Growth
252.225-7048	Export Controlled Items
252.225-7055	Representation Regarding Business Operations with the Maduro Regime
252.225-7057	Preaward Disclosure of Employment of Individuals Who Work in the People's Republic of China
252.225-7058	Postaward Disclosure of Employment of Individuals Who Work in the People's Republic of China
252.225-7060	Prohibition on Certain Procurements from the Xinjiang Uyghur Autonomous Region