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: HT9425S24CRRPTRA

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application/Preproposal Submission Deadline:** 5:00 p.m. Eastern time (ET), September 4, 2024
- **Invitation to Submit a Proposal/Application**: October 25, 2024
- **Full Application/Proposal Submission Deadline:** 11:59 p.m. ET, December 5, 2024
- **End of Submission Verification Period:** 5:00 p.m. ET, December 10, 2024
- **Peer Review:** February 2025
- **Programmatic Review:** April 2025

This Broad Agency Announcement must be read in conjunction with the General Submission Instructions available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

This funding opportunity announcement is a Broad Agency Announcement (BAA) through the Fiscal Year 2024 (FY24) 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 the 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 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/offerors only. **For definitions and additional information, see** Section II.C.1, Eligible Applicants/Offerors**.** Intramural DOD organizations should use the parallel funding opportunity announcement that is available through the electronic Biomedical Research Application Portal (eBRAP) at https://eBRAP.org/ under funding opportunity number HT942524CRRPTRA to submit applications.

The North American Industry Classification System code for contracts under this announcement is 541715 - Research and Development in the Physical, Engineering, and Life Science (except nanotechnology and Biotechnology) with a small business size standard of 1,000 employees.

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications/proposals to the FY24 CRRP TRA using delegated authority provided by 10 USC 4001. The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the CRRP in 2019 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the CRRP from FY19 through FY23 totaled $50 million (M). The FY24 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; triage, 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, nutrition) 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 often translate to civilian care.

A 2009 Department of Defense (DOD) mandate established a policy that Warfighters should be provided with lifesaving care within 60 minutes of injury, a time span that is referred to as the "golden hour." Achieving this metric is supported through increased infrastructure enabling rapid transportation of battlefield casualties from the point of injury to forward surgical teams (Role of Care, Role 2) and combat support hospitals (Role 3), where medical assets and damage control capabilities could rapidly provide lifesaving treatment. Future combat scenarios may involve peer or near-peer adversaries in large-scale combat operations where evacuation capabilities are delayed or unavailable. 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. **The time-specific window of the golden hour may not be feasible for Warfighters in certain complex and/or austere operational environments. Therefore, it is essential to bring effective and efficient life-saving capabilities closer to the point of injury and sustain prolonged care (greater than 72 hours) where necessary.** Thus, innovations in technology and knowledge are critical to ensure front line provider skills sustainment to support rapid response in future operations. Advancement of clinical decision support tools and other automated technologies may support continued Force readiness and availability in combat environments and assist Warfighters in providing additional life-saving care where clinical 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 have potential for integration into civilian-based practices to address health security threats and support 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. FY24 CRRP Focus Areas

To meet the intent of the funding opportunity applicants ***must address at least one of the FY24 CRRP Focus Areas***. The priorities and specific research topics described in the FY24 congressional language for the CRRP are aligned to distinct Focus Areas which describe medical

priorities to improve readiness and for delivering frontline care in combat situations. Selection of the appropriate FY24 CRRP Focus Area is the responsibility of the applicant.

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

- **Battlefield diagnostics, triage, and decision aid tools:** Solutions to enhance delivery of care in point of injury, austere resuscitative and surgical care, prolonged casualty care, and en route care environments:
    - Telemedicine
    - Medical simulation technology
    - Infectious disease
    - Traumatic brain injury biomarkers
    - Blast sensor technology
    - Antibiotic susceptibility test development
- **Treatments:** Solutions to enhance delivery of care in point of injury, austere resuscitative and surgical care, prolonged casualty care, and en route care environments:
    - Freeze-dried plasma and platelets
    - Battlefield wound care technologies, including therapies and devices
    - Purified exosomal products to treat battlefield orthopedic injuries
    - Highly infectious disease treatment and transport
    - Hemorrhage field care
    - Infectious disease
- Solutions to address threats to Warfighter readiness in operational environments:
    - Combat medical skills sustainment training
    - Medical simulation technology
    - Sleep disorders
    - Eating disorders
    - Sarcoidosis
    - Valley fever

- Highly infectious disease treatment and transport
- Infectious disease

- Solutions addressing other threats to Warfighter readiness in nonoperational environments:
  - Myalgic encephalomyelitis/chronic fatigue syndrome
  - Hydrocephalus
  - Dietary interventions and noninvasive brain stimulation in support of post-traumatic stress disorder
  - Infectious disease

II.A.2. Award History

The CRRP TRA mechanism was first offered in FY23. Since then, 80 TRA applications have been received, and four have been recommended for funding.

II.B. Award Information

The intent of the FY24 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 Service Members, Veterans, their Families, and the American public.

Applicants may leverage existing resources in translational research to address essential 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,"[1] 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.

[1]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.

Impact is a key component of this award mechanism. The potential impact of the research, both short term and long term, in addressing the FY24 CRRP Focus Area(s) should be clearly described. Successful high-impact research should lead to the accelerated 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 TRA Mechanism:

- **This BAA may be used to support applied, preclinical, clinical research, and/or small-scale clinical trials (e.g., first in human, phase 1/1b).**

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

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

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

Funding from this BAA may *not* be used to support larger or advanced clinical trials (e.g., phase 2/3, pivotal).

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) 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.

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

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

(1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition 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 assess 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 data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

Rigor of Experimental Design: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and 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/nature/journal/v490/n7419/full/nature11556.html). 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.

Women's Health: The CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

Relevance to Military Health: Relevance to the health care needs the Warfighter ahead of deployment and in operational environments is a key feature of this award.

Use of DOD or Department of VA Resources: Applications engaging investigators within the military Services and applications involving multidisciplinary collaborations among academia, industry, the military Services, the U.S. Department of Veterans Affairs (VA), and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. If the proposed research relies on access to unique 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.

Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of active-duty Service Members and their Families is encouraged. Such research could improve diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

The CDMRP intends that information, data, and research resources generated under awards funded by this program announcement be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large.

The funding instrument for awards made under this BAA will be assistance agreements, contracts, or Other Transactions. 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. The USAMRDC will also consider the use of Other Transactions (OTs) as a vehicle for award, in accordance with the conditions in 10 USC 4021 and 10 USC 4022.

An **assistance agreement** can take the form of a **grant** or **cooperative agreement**. The level of involvement on the part of the CDMRP during the project's period of performance is the key factor in determining whether to award a grant or cooperative agreement. If "no substantial involvement" on the part of the CDMRP is anticipated, a grant will be made (31 USC 6304). Conversely, if "substantial involvement" on the part of the CDMRP is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement means that, after award, CDMRP staff will assist, guide, coordinate, or participate in project activities.

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 (31 USC 6303).

An "Other Transaction" is appropriate to carry out certain prototypes, research, and production projects (10 USC 4021 and 10 USC 4022). Other Transaction authorities were created to provide the flexibility necessary to adopt and incorporate business practices that reflect commercial industry standards and best practices into its award instruments.

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

The anticipated total costs budgeted for the entire period of performance for an FY24 CRRP TRA Award should not exceed **$1.1M**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately $3.3M to fund approximately three CRRP TRA Awards. Funding of applications/proposals received is contingent upon the availability of federal funds for this program, the number of applications/proposals received, the quality and merit of the applications/proposals as evaluated by peer 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 FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants/Offerors

II.C.1.a. Organization

Applications/proposals for this BAA may only be submitted by extramural organizations, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities. Submissions from intramural DOD organizations to this BAA will be withdrawn.

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

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Applications/proposals with Principal Investigators (PIs) employed by intramural DOD organizations may be submitted extramurally through a research foundation. It is also permissible for an intramural DOD investigator to be named as a collaborator on an application/proposal submitted through an extramural organization. In this case, the submission must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

In accordance with DoDI 5000.77 and 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 as long as they are permitted under the sponsoring agreement between the federal government and the specific FFRDC.

Awards are made to eligible ***organizations***, not to individuals. Refer to the General Submission Instructions, Appendix 1, for additional awardee qualification requirements.

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 application/proposal.

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

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement for contracts or assistance agreements but may exist if research OT or prototype OT is the selected funding instrument. Cost-sharing requirements for OTs are stated in 10 USC 4021 for Research OTs and 10 USC 4022 for Prototype OTs.

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 striving to conduct business only with responsible organizations. The USAMRDC uses the "Exclusions" within the Performance Information functional area of the SAM and the "Responsibility and Qualifications" within the Entity Information functional area of the SAM to verify that an organization is eligible to receive federal awards. More information about SAM is available at https://sam.gov/SAM/. Refer to the General Submission Instructions, Appendix 1, for additional information.

Conflicts of Interest (COIs): Prior to award, applicants/offerors will be required to disclose all potential or actual COIs along with a plan to mitigate them. An award may not be made if it is determined by the USAMRAA Warranted Official that COIs cannot be adequately mitigated. Refer to the General Submission Instructions, Appendix 1, for additional information.

Review of Risk: The following areas may be reviewed in evaluating the risk posed by an applicant/offeror: 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.

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 19.7, Defense Federal Acquisition Regulation Supplement (DFARS) 219.7. A mutually agreeable plan will be developed during the award negotiation process and incorporated as part of the resultant contract.

Refer to Section II.H.1, Administrative Actions, for a list of administrative actions that may be taken if a pre-application /proposal or full application/proposal does not meet the administrative, eligibility, or ethical requirements defined in this BAA.

II.D. Application/Proposal and Submission Information

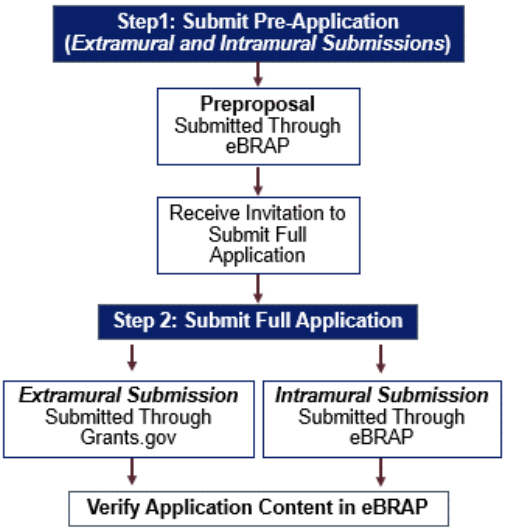
II.D.1. Location of Application/Proposal Package

Submission is a two-step process requiring both a ***pre-application/preproposal*** submitted via the eBRAP.org and a ***full application/proposal*** submitted through eBRAP.org or Grants.gov.

The CDMRP uses two portal systems to accept pre- and full application/proposal submissions.

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs and/or organizational representatives to receive communications from the CDMRP and submit their pre-applications/proposals. Additionally, eBRAP allows applicants/offerors to view and verify full applications/proposals submitted to Grants.gov.

Grants.gov (https://grants.gov) is a federal system that must be used by funding agencies to announce extramural grant opportunities. Full applications/proposals for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application/proposal through eBRAP.



Extramural Submission: An application/proposal submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural DOD organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application/proposal package components for HT942524SCRRPTRA from Grants.gov (https://grants.gov). Full applications/proposals from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission *(Disallowed for this funding opportunity)*: An application/proposal submitted by an intramural DOD organization for an investigator employed by that organization.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application/proposal components must be submitted by the deadlines stipulated on the first page of this BAA. There are no grace periods for deadlines; failure to meet submission deadlines will result in application/proposal rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant/offeror organization using system-to-system interfaces with Grants.gov.***

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

Applications/proposals that propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s)/proposal(s).

Unnecessary duplication of funding or accepting funding from more than one source for the same research, is prohibited. See the CDMRP's full position on research duplication at https://cdmrp.health.mil/funding/researchDup.

Including classified research data within the application/proposal and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application/proposal withdrawal. Refer to the General Submission Instructions, Appendix 7, Section B.

FY24 CRRP Programmatic Panel members should not be involved in any pre-application/proposal or full application/proposal. For questions related to panel members involvement, refer to Section II.H.1.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

II.D.2.a. Step 1: Pre-Application/Preproposal Submission

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

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the 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 application submission deadline.

II.D.2.a.i. Pre-Application Components

Pre-application submissions must include the following components (refer to the General Submission Instructions, Section II, for additional information on pre-application submission):

Note: Upload documents as individual PDF files unless otherwise noted.

- **Preproposal Narrative (three-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

  The Preproposal Narrative should include the following:

  - **Research Plan:** Concisely state the scientific rationale on which the proposed work is based. State the project's hypotheses, objectives, and specific aims, and briefly describe the experimental approach. If the proposed research includes a clinical trial, briefly state the clinical intervention, subject populations(s), and phase of the clinical trial.

  - **Personnel:** Briefly describe the qualifications of the PI and key personnel to perform the described research project.

  - **Impact and Relevance:** State explicitly how the proposed work will lead to translation of 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. Importantly, identify how the proposed work will address specific challenges encountered in priority environments identified by the DOD (i.e., frontline, prolonged, and/or en route care in austere and combat environments), as well as how the study outcomes will directly or indirectly benefit military Service Members and the general public.

  - **Alignment with Focus Areas:** Identify and explain how the proposed work addresses at least one FY24 CRRP Focus Area.

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:

  - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).

  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.

  - **Key Personnel Biographical Sketches (five-page limit per individual):** ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

II.D.2.a.ii. Pre-Proposal/Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the CRRP, pre-applications will be screened based on the following criteria:

- **Research Plan:** How well the scientific rationale, hypotheses, objectives, specific aims, and experimental approach are described.
- **Personnel:** To what extent the qualifications and experience of the PI and key personnel are appropriate to perform the proposed research project.
- **Impact and Relevance:** How well the proposed work will lead to translation of 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.
- **Alignment with Focus Areas:** To what extent the proposed work addresses at least one FY24 CRRP Focus Area.

II.D.2.a.iii. Notification of Pre-Proposal/Pre-Application Screening Results

Following the pre-application screening, PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section I, Overview of the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

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

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

Full applications/proposals ***must*** be submitted through Grants.gov Workspace. Full applications/proposals from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Submission Instructions, Section IV, for considerations and detailed instructions regarding full application/proposal submission.

II.D.2.b.ii. Full Application/Proposal Submission Components

Each submission must include the completed full application/proposal package for this BAA. See Section II.H.2 of this BAA for a checklist of the required components.

(a) SF424 Research & Related Application for Federal Assistance Form: Refer to the General Submission Instructions, Section IV.B.(a), for detailed information.

(b) Attachments:

Each attachment to the full application/proposal 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 2.

- **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 that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application/proposal.

  For applications/proposals including a clinical trial, the Project Narrative is NOT the formal clinical trial protocol. All essential elements of the proposed clinical trial necessary for scientific review must be included as directed in Attachment 1 (the Project Narrative) and Attachments 6, 7, 9, and 10 described below.

  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 FY24 CRRP Focus Areas 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 this 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.

- If the proposed research involves access to active-duty military and/or VA patient populations and/or DOD or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Include a plan for obtaining any required data sharing, memorandum of understanding, or other agreements required to access and publish data. Refer to the General Application Instructions, Appendix 4, for additional considerations.

- For clinical research studies, further details of clinical research components will be required in Attachment 7, Human Subject Recruitment and Safety Procedures, as applicable.

- For clinical trials, describe the rationale for the proposed clinical trial. Provide a description of the intervention, and the endpoints to be measured. Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.

Statistical and Data Management Plans: 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 U.S. Food and Drug Administration (FDA), or international regulatory agency, if applicable.

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

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. 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 application/proposal.

  References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.

  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 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.

  DOD Data Management Plan (two-page limit is recommended): Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instructions 3200.12. Do not duplicate the Data and Research Resources Sharing Plan. Refer to General Submission Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.

  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 the BAA, such as those from members of Congress, do not impact application/proposal review or funding decisions.

Letters of Collaboration *(if applicable)* (one-page limit per letter is recommended): Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application/proposal submitted through an extramural organization, the submission must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing 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 the 2 CFR 200.315, "Intangible Property."

- **Background and Proprietary Information:** Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. All software and data first produced under this the CRRP TRA are subject to a federal purpose license. Therefore, it is important to disclose/list any intellectual property (software, data, patents, etc.) that will be used in performance of the project. If applicable, all proprietary information to be provided to the government should be stated and identified; the applicant/offeror should indicate whether a waiver of the federal purpose license will be required.

- **Intellectual and Material Property Plan *(if applicable)*:** Provide a plan for resolving intellectual and material property issues among participating organizations.

Data and Research Resources Sharing Plan: Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants.

For proposals/applications involving FITBIR-eligible Traumatic Brain Injury (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 CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about the CDMRP's expectations for making data and research resources publicly available.

Quad Chart: Provide a quad chart for the proposed project. The format for the quad chart is available on the eBRAP "Funding Opportunities & Forms" web page at (https://ebrap.org/eBRAP/public/Program.htm).

Use of DOD Resources *(if applicable)*: Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.

Use of VA Resources *(if applicable)*: Provide a letter of support signed by 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. If the VA-affiliated non-profit corporation is not identified as the contracting organization 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.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed

  Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

  Background: Present the scientific rationale behind the proposed research project.

  Hypothesis/Objective(s): State the hypothesis to be tested and/or objective(s) to be reached.

  Specific Aims: State the specific aims of the study.

Study Design: Describe the study design, including appropriate controls.

Impact and Translation: Describe the innovative qualities of the proposed work. State the FY24 CRRP Focus Area(s) 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, and addresses issues of particular interest to the affected community. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

  Lay abstracts should address the points outlined below ***in a manner that will be readily understood by readers without a background in science or medicine***. Avoid overuse use of scientific jargon, acronyms, and abbreviations.

  Describe the objectives and theoretical reasoning behind the proposed work.

  State the FY24 CRRP Focus Area(s) that the research addresses and describe how it is addressed.

  Describe the problem or question to be addressed and the ultimate applicability to Warfighter health 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, their Families, and 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".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested SOW format and recommended strategies for assembling the SOW.

For the CRPR TRA mechanism, refer to "Example: Assembling a Generic Statement of Work," for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit the SOW as a PDF file.

- **Attachment 6: Military Relevance/Impact 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 FY24 CRRP Focus Area(s). If research is cross-cutting, describe how it may have the potential to benefit multiple DOD medical research program areas.

  Describe how the proposed research will significantly improve the readiness of the Force in varied military 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 large-scale combat operations 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.

  - **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 an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. The enrollment table(s)

should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement. ***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***. 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 4, for more information.***

Inclusion/Exclusion Criteria: List the inclusion and exclusion criteria for the proposed clinical study. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

Description of the Recruitment Process: Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, 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. Address the availability of human subjects for the clinical study at each enrollment site. 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. 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 any ongoing clinical studies that may compete for the same population and how they may impact the enrollment progress.

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 III) for sample consent language.***
  - Applicants are also strongly encouraged to include language in consent forms to allow for optional passive follow-up via electronic health record.
- 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), if the research will include an intervention or interaction with subjects for the primary purpose of obtaining data regarding the effect of the intervention or interaction, the proposal/application must describe a clear intent to benefit for all human subjects who cannot give their own consent to participate in the proposed clinical study. If applicable, refer to the General Submission Instructions, Appendix 6, 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:**

  - Appropriate to the study's level of risk, describe how safety monitoring and reporting to the IRB and Regulatory Agency (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".**

  If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. 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. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the Institutional Animal Care and Use Committee (IACUC). The Animal Research Plan should address the following points to achieve reproducible and rigorous results 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.

  - 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).

- **Attachment 9: Regulatory Strategy (no page limit): (*Attachment 9 is only applicable and required for applications proposing clinical research/trials that involve products regulated by the FDA or international equivalent*). If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".** Address the following and provide supporting documentation as applicable.

  For FY24 CRRP TRA applications proposing clinical research/trials involving regulated products:

  - 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 a Regulatory Agency:

  Provide evidence that the product/intervention does not require regulation by a Regulatory Agency. Note that this request includes, but is not limited to software applications, algorithms, nutraceuticals, or behavioral health interventions. ***Submissions providing "not applicable," "none," or similar responses do not satisfy this request and may be administratively withdrawn.*** 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:

  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. Clearly identify whether a member of the study team holds the regulatory exemption.

  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 FY24 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 IV). 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 Good Clinical Practice (GCP) guidelines, if appropriate. For clinical research involving FDA-regulated products or that 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/offerors 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 8, Section B, Representations.

- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form," available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The ***total*** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Submission Instructions, Section IV.B, for additional information and considerations.

(c) Research & Related Personal Data: Refer to the General Submission Instructions, Section IV.B.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): Refer to the General Submission Instructions, Section IV.B.(d), for detailed instructions.

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

(e) Research & Related Budget: Refer to the General Submission Instructions, Section IV.B.(e), for detailed instructions.

- **Budget Justification (no page limit):** Refer to General Submission Instructions, Section IV.B.(e), Budget Justification Instructions.

(f) Project/Performance Site Location(s) Form: Refer to the General Submission Instructions, Section IV.B.(f), for detailed instructions.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable)*: Refer to the General Submission Instructions, Section IV.B.(g), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 12.

II.D.2.c. Verification of Full Application/Proposal Submission in eBRAP

Once the full application/proposal is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application/proposal submission. Verification is strongly recommended but not required. eBRAP will validate full application/proposal files against the specific BAA requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's/offeror's responsibility to review all application/proposal components and ensure proper ordering as specified in the BAA. ***The Project Narrative and Research & Related Budget Form cannot be changed after the full application/proposal submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application/proposal package must be submitted prior to the full application/proposal submission deadline.*** Other application/proposal components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the submission verification period. The full application/proposal cannot be modified once the submission verification period ends.

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

The applicant/offeror organization must be registered as an entity in SAM (https://www.sam.gov/content/home) and receive confirmation of an "Active" status before submitting an application/proposal through Grants.gov. Organizations must include the UEI generated by SAM in submission to this funding opportunity.

II.D.4. Submission Dates and Times

The pre-application/proposal and full application/proposal 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.

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity.

II.D.5. Intergovernmental Review

Not applicable.

II.D.6. Funding Restrictions

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

The application's/proposal'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. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the direct costs of the primary award.

The applicant/offeror 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 Central Florida Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Research subject compensation and reimbursement for trial-related out-of-pocket costs (e.g., travel, lodging, parking, costs associated with caregiving, and resources/equipment to enable participation).
- Special purpose equipment
- Travel in support of multi-institutional collaborations
- 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 to scientific/technical meetings should be to present project information or disseminate project results from the CRRP TRA.

For this award mechanism, direct costs must not be requested for:

- Costs for travel to scientific/technical meeting(s) beyond the limits stated above
- Equipment
- Tuition

II.D.7. Other Submission Requirements

Refer to the General Submission Instructions, Appendix 2, for detailed formatting guidelines.

II.E. Application/Proposal Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications/proposals will be individually 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 strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research. 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.
    - To what extent the research can be completed within the proposed period of performance.
    - 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.

- **Military Relevance/Impact**

  - How well the proposed work represents an accelerated and relevant approach aligned to the FY24 CRRP Focus Area(s).

  - To what extent the proposed research will significantly improve the readiness of the Force.

  - 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, if applicable.

  - 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 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 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 and confidentiality of study records are appropriately considered.
- To what degree the processes for seeking informed consent are appropriate and whether safeguards are in place for vulnerable populations.

- **Regulatory Strategy and Transition Plan**
  - If applicable, whether evidence that the product/intervention does not require regulation by a Regulated Agency is provided and reasonable.
  - If applicable, how the overall regulatory strategy and product development plan will support the planned product indication or product label change.
  - As appropriate, whether the application/proposal includes evidence that the IND or IDE application (or international equivalent) has been submitted to the appropriate Regulatory Agency.
  - For investigator-sponsored investigational product regulatory exemptions (e.g., IND, IDE), whether there is evidence of appropriate institutional support.
  - Whether plans to comply with current GLP, GMP, and GCP guidelines are appropriate.
  - Whether a member of the study team is the regulatory sponsor and holds the investigational product regulatory exemption (e.g., IND/IDE) for the proposed indication.
  - Whether the overall strategy described to transition the research to commercialization or clinical use is reasonable and achievable.
  - Whether the schedule and milestones for transitioning the research to a clinical product are achievable.
  - Whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
  - How well the application/proposal identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization.
  - If applicable, how well the application/proposal describes an appropriate intellectual and material property plan among participating organizations.
  - If applicable, how well the application/proposal addresses any impact of intellectual property issues on product development and the government's ability to access such products or technologies in the future.

- **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.
    - How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).

In addition, the following criteria will also contribute to the overall evaluation of the application/proposal, but will not be individually scored and are therefore termed **unscored criteria**:

- **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.
- **Budget**
    - Whether the budget is appropriate for the proposed research.
- **Application/Proposal Presentation**
    - To what extent the writing, clarity, and presentation of the submission components influence the review.

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s)/proposal(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 priorities of the Defense Health Program and FY24 CRRP, as evidenced by the following:
    - Adherence to the intent of the funding opportunity
    - Program portfolio composition
    - Relevance to military health
    - Relative impact and translation potential

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

All applications/proposals are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications/proposals against established criteria to determine technical merit, where each application/proposal is assessed for its own merit, independent of other applications/proposals. The second tier is **programmatic review**, a comparison-based process in which applications/proposals 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 applications/proposals 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.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of confidentiality can result in the dissolution of a panel(s) and other corrective actions. In addition, personnel at the applicant/offeror 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 application/proposal. Violations by panel members or applicants/offerors 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 a third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

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

An applicant/offeror organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. The federal awarding agency will consider any comments by the applicant/offeror, in addition to

other information in the designated integrity and performance system, in making a judgment about the applicant's/offeror's integrity, business ethics, and record of performance under federal awards when determining an awardee's qualification prior to award, according to the qualification standards of the DoDGARs, Section 22.415.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each organizational representative and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application/proposal and an information paper describing the funding recommendation and review process for the CRRP award mechanisms. The information paper and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application/proposal is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the awardee organization.

Only an appointed USAMRAA Warranted Official may obligate the government to the expenditure of funds to an extramural organization. No commitment on the part of the government should be inferred from discussions with any other individual. ***The award document signed by the USAMRAA Warranted Official is the official authorizing document.***

Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to support ***intragovernmental and intramural DOD*** subawards/subcontracts will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

For assistance agreement awards, an 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.

For contract awards and OTs, an organization may request and negotiate pre-contract/pre-agreement costs prior to award.

Refer to the General Submission Instructions, Section IV.B.(e), Pre-Award Costs section, for additional information about pre-award costs.

If there are technical reporting requirement delinquencies for any existing CDMRP-issued awards at the applicant/offeror organization, no new awards will be issued to the applicant/offeror organization until all delinquent reports have been submitted.

II.F.2. PI Changes and Award Transfers

Unless otherwise restricted, changes in PI or organization will be allowed on a case-by-case basis, 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 7, Section F, for general information on organization or PI changes.

II.F.3. 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 outlined in Appendix III.

Refer to the General Submission Instructions, Appendix 7, for general information regarding administrative requirements.

Refer to the General Submission Instructions, Appendix 8, for general information regarding national policy requirements.

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

Applications/proposals recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight, prior to implementation. This administrative review requirement is in addition to the local IACUC, IRB, or Ethics Committee review. Refer to the General Submission Instructions, Appendix 6, for additional information.

II.F.4. Reporting

Annual technical progress reports and quad charts as well as a final technical progress report with quad chart will be required. Annual and final technical reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

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

The Award Terms and Conditions will specify whether additional and/or more frequent reporting is required.

Awards resulting from this BAA may entail additional reporting requirements related to awardee integrity and performance matters. Awardee 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 awardees are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Submission Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions regarding BAA content or submission requirements as well as technical assistance related to pre-application/proposal submission:

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace:

Phone: 800-518-4726; International 1-606-545-5035

Email: support@grants.gov

II.H. Other Information

II.H.1. Administrative Actions

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

II.H.1.a. Rejection

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

- Preproposal Narrative exceeds page limit
- Preproposal Narrative is missing

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

- Submission of an application/proposal for which a letter of invitation was not issued
- 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 Project Narrative.
- Documents not requested will be removed.

II.H.1.c. Withdrawal

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

- An FY24 CRRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application/proposal or full application/proposal processes including, but not limited to, concept design, application/proposal development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation. ***A list of the FY24 CRRP Programmatic Panel members can be found at https://cdmrp.health.mil/crrp/panels/panels24.***
- The application/proposal 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.
- Applications/proposals that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, 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).

- Personnel from applicant/offeror 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.

- Applications/proposals from extramural organizations, including non-DOD federal agencies, received through eBRAP.

- Applications/proposals submitted by an extramural (non-DOD) federal government organization may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.

- Application/proposal includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.

- Applications/proposals submitted by an intramural DOD organization as the contracting organization.

- The invited application proposes a different research project than that described in the pre-application.

- 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

Applications/Proposals 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 Warranted Official for a determination of the final disposition of the application/proposal.

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

Full Application/Proposal Components	Uploaded
SF424 Research & Related Application for Federal Assistance	☐
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐
Military Relevance/Impact Statement – Attachment 6, upload as "Impact.pdf"	☐
Human Subject Recruitment and Safety Procedures for clinical research – Attachment 7, upload as "HumSubProc.pdf"	
Animal Research Plan – Attachment 8, upload as "AnimRschPln.pdf"	
Regulatory Strategy – Attachment 9, upload as "Regulatory.pdf"	
Transition Plan – Attachment 10, upload as "Transition.pdf"	
Representations – Attachment 11, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 12, upload as "IGBudget.pdf"	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐
Attach Previous/Current/Pending Support (Support_LastName.pdf) for each senior/key person	☐
Research & Related Budget Include budget justification	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐

APPENDIX I: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
BAA	Broad Agency Announcement
CDE	Common Data Element
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CRRP	Combat Readiness – Medical Research Program
DHA	Defense Health Agency
DHHS	U.S. Department of Health and Human Services
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FITBIR	Federal Interagency Traumatic Brain Injury Research
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
KRL	Knowledge Readiness Level
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
PDF	Portable Document Format
PI	Principal Investigator
SAM	System for Award Management
SOW	Statement of Work
TBI	Traumatic Brain Injury
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	U.S. Department of Veterans Affairs

APPENDIX II: DOD AND VA WEBSITES

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

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

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

Armed Forces Radiobiology Research Institute
https://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.health.mil/

U.S. Air Force 59th Medical Wing
https://www.airforcemedicine.af.mil/

Military Operational Medicine Research Program
https://momrp.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-Center/

Navy and Marine Corps Force Health Protection Command
https://www.med.navy.mil/sites/nmcphc/Pages/Home.aspx

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

Office of the Under Secretary of Defense for Acquisition and Sustainment
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. Army Aeromedical Research Laboratory
https://www.usaarl.health.mil/

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

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

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

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

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

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

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

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

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

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

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

APPENDIX III: 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 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 https://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 NIH, 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 DOD and the NIH 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 FITBIR informatics system. FITBIR is a biomedical informatics system and data repository created by the Department of Defense and NIH—part of the 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 FITBIR informatics system. FITBIR is a biomedical informatics system and data repository created by the DOD and the NIH—part of the 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.

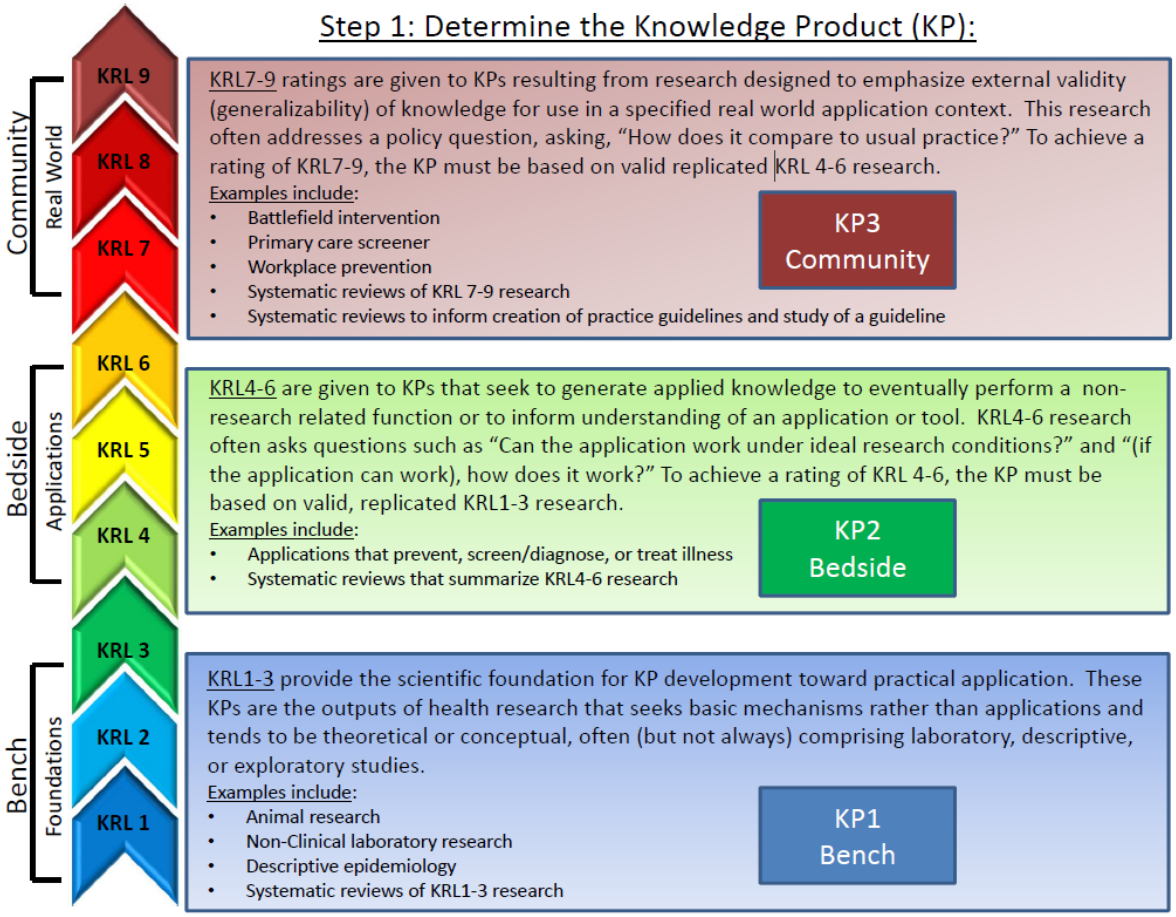
Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by researchers only. Data provided to FITBIR as part of you or your child's participation in this research study will be de-identified—i.e., you and/or your child's name will be separated from the data. However, 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.

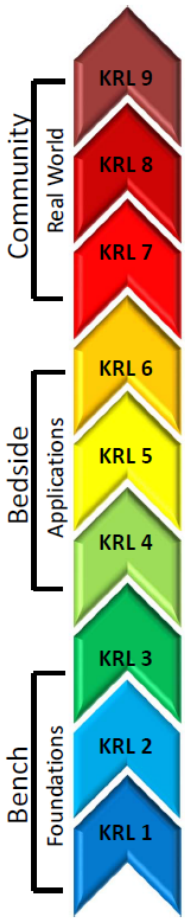
Finally, you should understand that we, the investigators, are also permitted to make voluntary disclosures with respect to information that is submitted to FITBIR, but do not plan to do so except in the event of severe threats to public health or safety. If, as part of your participation in this research 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 IV: 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 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 Technology Readiness Assessment Deskbook (July 2009, https://discover.dtic.mil/).

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 2: Determine the Knowledge Readiness Level (KRL)

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.)

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.)

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.)

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.

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.

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).

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)

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.

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 V: 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