# I. OVERVIEW OF THE FUNDING OPPORTUNITY

**Program Announcement 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: HT942524CRRPTRA**

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

**SUBMISSION AND REVIEW DATES AND TIMES**

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

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# II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

***This funding opportunity is intended for intramural applicants only.***

- An ***intramural applicant organization*** is defined as a Department of Defense (DOD) laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission: An application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.***

- An ***extramural applicant organization*** is defined as all those not included in the definition of intramural investigators, above. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD, and research institutes (e.g., intramural investigators submitting through a research foundation). Submissions from extramural investigators to this funding opportunity announcement will be withdrawn. ***Extramural Submission: An application submitted by a non-DOD organization to Grants.gov.***

Extramural applicants applying through extramural organizations should use the broad agency announcement, a separate funding opportunity announcement that is available through the electronic Biomedical Research Application Portal (eBRAP) at https://eBRAP.org/ under funding opportunity number HT9425S24CRRPTRA.

## II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Combat Readiness – Medical Research Program (CRRP) using delegated authority provided by United States Code, Title 10, Section 4001 (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 to deliver 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 to address 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 Translational Research Award (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 FY24 CRRP TRA Mechanism:***

- **This PA 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 PA may *not* be used to support fundamental basic research.** For this PA, 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 PA may *not* be used to support studies requiring an exception from informed consent (EFIC).**

**Funding from the PA may *not* be used to support larger of 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: S.C. 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.

Proposals/applications received in response to both the extramural FY24 CRRP TRA broad agency announcement and the intramural program announcement will be evaluated and considered for funding together. The government reserves the right to fund any combination of extramural and/or intramural proposals/applications.

The 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.

Awards made under this intramural program announcement will be managed through a direct funds transfer to the intramural organization. The award 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 FY24 CRRP TRA applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications 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

**II.C.1.a. Organization:** Applications for this program announcement may only be submitted by intramural organizations. Submissions from extramural applicants to this program announcement will be withdrawn. Intramural applicants are required to explain how their applications do not overlap with other funded efforts. Applicants from an extramural organization should apply through eBRAP under the funding opportunity number HT942524SCRRPTRA. These terms are defined above.

Awards are made to eligible ***organizations***, not to individuals. Refer to Appendix VII, Recipient Qualification and Restriction Information, for additional recipient 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 Principal Investigator (PI) in the application.

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

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

### II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

### II.C.3. Other

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

Refer to Section II.H.2, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or full application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

## II.D. Application and Submission Information

### II.D.1. Location of Application Package

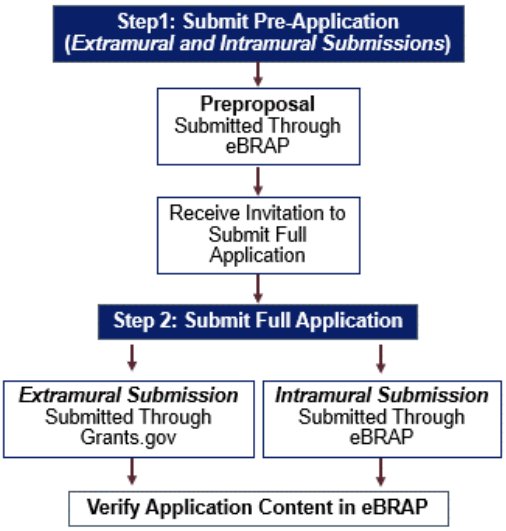
Submission is a two-step process requiring both a ***pre-application*** and a ***full application*** through eBRAP (eBRAP.org).

**eBRAP** (https://ebrap.org) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

***Intramural DOD Submission:***

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at eBRAP.org.

*Application Submission Workflow*




**Extramural Submission (Disallowed for this funding opportunity):** An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission. Extramural organizations should submit applications under funding opportunity HT942524SCRRPTRA, available from Grants.gov.

**Intramural Submission:** An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to eBRAP. Download application package components for HT942524CRRPTRA from the anticipated submission portal eBRAP (https://ebrap.org).

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection.

### II.D.2. Content and Form of the Application Submission

***Submitting applications 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).***

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 and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to Appendix XIII, National Policy Requirements.

FY24 CRRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

### II.D.2.a. Step 1: Pre-Application 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 Appendix V, Pre-Application Submission, for additional information):

***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-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-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 Submission

### II.D.2.b.i. Full Application Submission Type

**Intramural Submissions:** Intramural DOD organizations may submit full applications through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to Appendix VI, Full Application Submission for Intramural DOD Organizations, for considerations and detailed instructions regarding intramural DOD full application submission.

### II.D.2.b.ii. Full Application Submission Components

Each application submission must include the completed full application package for this program announcement. See Section II.H.3 of this program announcement for a checklist of the required application components.

**(a) Attachments:**

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in Appendix VIII, Formatting Guidelines.

- **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.

  ***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 that benefit military health and medicine as well as the general public.

- **Hypothesis or Objective:** State the hypothesis to be tested and/or the objective to be reached.

- **Specific Aims:** Concisely explain the project's specific aims. These aims should agree with the primary aims and associated tasks described in the Statement of Work (SOW). If the proposed work is part of a larger study, present only aims that the FY24 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 Practices (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 they are optimal for addressing the study aims and facilitate 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 Appendix X, Use of DOD or U.S. Department of Veterans Affairs Resources, 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 to demonstrate 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.***

  – **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.

- **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 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 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 the use of a commercially produced investigational drug, device, or biologic, provide a signed letter of commitment from the commercial entity to indicate 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 FY24 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 that describes 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 that involve 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 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 FY24 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 that recruit 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 that utilize 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 that proposes to include military personnel, refer to Appendix X, 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 to address 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 PA 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, FITBIR Requirements) 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 to obtain ongoing consent or to re-assess 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. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the Institutional Animal Care and Use Committee (IACUC) as the Animal Research Plan. 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: 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.

**(b) Research & Related Personal Data:** Refer to Section (c) in Appendix VI, Full Application Submission for Intramural DOD Organizations for detailed instructions.

**(c) Research & Related Senior/Key Person Profile (Expanded):** Refer to Section (d) in Appendix VI, Full Application Submission for Intramural DOD Organizations 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".

**(d) Research & Related Budget:** Refer to Section (d) in Appendix VI, Full Application Submission for Intramural DOD Organizations, for detailed instructions.

- **Budget Justification (no page limit):** Refer to the Budget Justification Instructions in Section (e) in Appendix VI, Full Application Submission for Intramural DOD Organizations.

**(e) Project/Performance Site Location(s) Form:** Refer to Section (f) in Appendix VI, Full Application Submission for Intramural DOD Organizations for detailed instructions.

### II.D.2.c. Applicant Verification of Full Application Submission in eBRAP

Independent of submission type, once the full application 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 submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement 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 responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

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

The applicant 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 through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

### II.D.4. Submission Dates and Times

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

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

### II.D.5. Funding Restrictions

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

The application's total costs budgeted for the entire period of performance should not exceed **$1.1M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. 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 may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **2** years.

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

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

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 FY24 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.6. Other Submission Requirements

Refer to Appendix VIII, Formatting Guidelines for detailed formatting instructions.

## II.E. Application Review Information

### II.E.1. Criteria

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

To determine technical merit, all applications 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 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 identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization.
  - If applicable, how well the application describes an appropriate intellectual and material property plan among participating organizations.
  - If applicable, how well the application 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, 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 Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.

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

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

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the Defense Health Program (DHP) 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 translational potential

### II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.health.mil/about/2tierRevProcess.

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 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. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

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

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

An applicant organization may review SAM and submit comments 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, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

## II.F. Federal Award Administration Information

### II.F.1. Federal Award Notices

Each applicant organization 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 and an information paper describing the funding recommendation and review process for the CRRP award mechanisms. The information papers 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 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 recipient organization.

***Only an appointed USAMRAA Grants Officer 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 Grants Officer is the official authorizing document, i.e., assistance agreement.***

***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 ***intragovernmental and intramural DOD organizations*** 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.

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. Refer to the Pre-Award Costs section in Appendix VI, Full Application Submission For Intramural DOD Organizations for additional information about pre-award costs.

***If there are technical reporting requirement delinquencies for any existing CDMRP-issued awards at the applicant organization, no new awards will be issued to the applicant 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 Section F in Appendix XIII, Administrative Information, 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 program announcement.

Refer to Appendix XIII, Administrative Information, for general information regarding administrative requirements.

Refer to Appendix XIV, National Policy Requirements, 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 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 (OHARO), prior to implementation. This administrative review requirement is in addition to the local IACUC, IRB, or Ethics Committee (EC) review. Refer to Appendix XII, Research Protections Review Requirements, for additional information.

### II.F.4. Reporting

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

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see Section B in Appendix XIV, National Policy Requirements).

## II.G. Federal Awarding Agency Contacts

### II.G.1. eBRAP Help Desk

*Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission*

Phone: 301-682-5507

Email: help@eBRAP.org

## II.H. Other Information

### II.H.1. Program Announcement Version

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 901a.

### II.H.2. Administrative Actions

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

### II.H.2.a. Rejection

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

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

- Submission of an application for which a letter of invitation was not issued.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

***For 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.2.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.2.c. Withdrawal

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

- 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 or application processes including, but not limited to, concept design, application 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 fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications 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 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 from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD 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 includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Applications submitted by an intramural DOD organization with an extramural organization as the contracting organization.

- The invited application proposes a different research project than that described in the pre-application.
- The application does not demonstrate support for and access to relevant population(s) and/or resource(s).
- The 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.2.d. Withhold

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

### II.H.3. Full Application Submission Checklist

| Full Application Components | Uploaded |
|---|---|
| **Summary (Tab 1) and Application Contacts (Tab 2)** *(Intramural submissions only)* | ☐ |
| **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 *(if applicable)* – Attachment 7, upload as "HumSubProc.pdf" | ☐ |
| Animal Research Plan *(if applicable)* – Attachment 8, upload as "AnimRschPlan.pdf" | ☐ |
| Regulatory Strategy *(if applicable)* – Attachment 9, upload as "Regulatory.pdf" | ☐ |
| Transition Plan – Attachment 10, upload as "Transition.pdf" | ☐ |
| Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 11, 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_LastName.pdf) for each senior/key person | ☐ |
| **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 |
| AOR | Authorized Organizational Representative |
| CDE | Common Data Element |
| CDMRP | Congressionally Directed Medical Research Programs |
| CFR | Code of Federal Regulations |
| COC | Certificate of Confidentiality |
| CRRP | Combat Readiness – Medical Research Program |
| DHHS | U.S. Department of Health and Human Services |
| DOD | Department of Defense |
| DoDGARs | Department of Defense Grant and Agreement Regulations |
| DODI | DOD Instruction |
| DURC | Dual Use Research of Concern |
| 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 |
| GUID | Global Unique Identifier |
| HIPAA | Health Insurance Portability and Accountability Act |
| 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 |
| NINDS | National Institute of Neurological Disorders and Stroke |
| OHRO | Office of Human Research Oversight |
| ORCID | Open Researcher and Contributor ID |
| PDF | Portable Document Format |

| | |
|---|---|
| PI | Principal Investigator |
| PII | Personally Identifiable Information |
| RDT&E | Defense Health Program Research, Development, Test, and Evaluation |
| RM | Resource Management, Resource Manager |
| SAM | System for Award Management |
| SF424 (R&R) | Standard Form 424 (Research and Related) |
| SOW | Statement of Work |
| TBI | Traumatic Brain Injury |
| TRA | CRRA 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/

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/

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

Navy and Marine Corps Force Health Protection Command
https://www.med.navy.mil/Navy-and-Marine-Corps-Force-Health-Protection-Command/

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

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/

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

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 Directorate of Prevention, Resilience and Readiness
https://www.armyresilience.army.mil/

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

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

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

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

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

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.

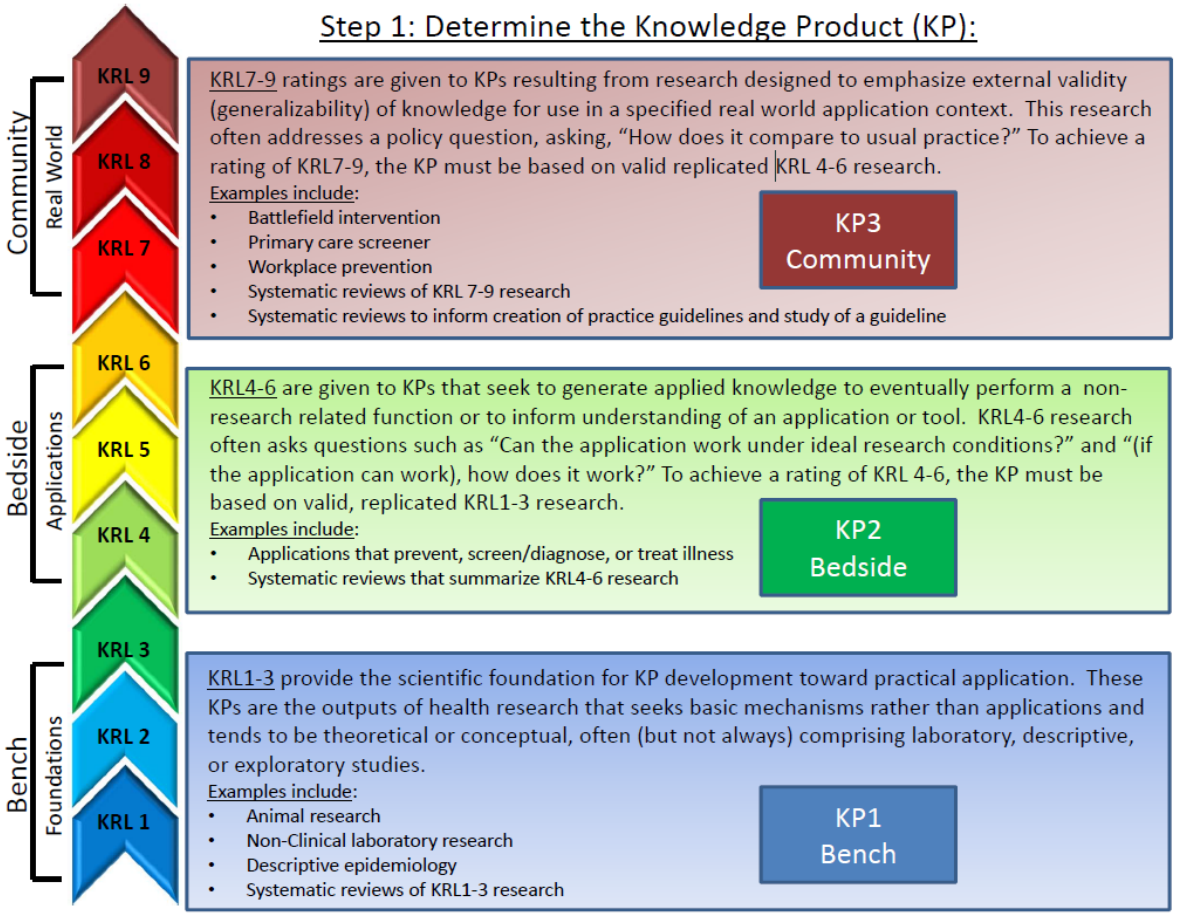
Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by researchers only. Data provided to FITBIR as part of you or your child's participation in this research study will be de-identified—i.e., you and/or your child's name will be separated from the data. However,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

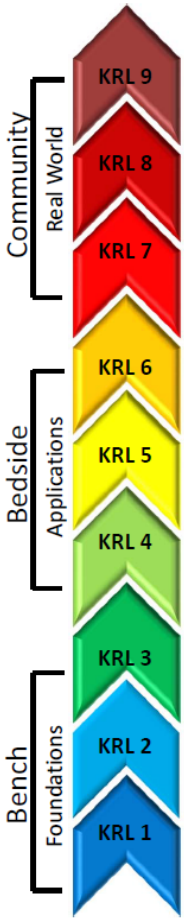
Finally, you should understand that we, the investigators, are also permitted to make voluntary disclosures with respect to information that is submitted to FITBIR, but do not plan to do so except in the event of severe threats to public health or safety. If, as part of your participation in this research 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://apps.dtic.mil/sti/pdfs/ADA418881.pdf).

***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: PRE-APPLICATION SUBMISSION

General information about eBRAP registration and pre-application submission is provided in this section. The eBRAP User Guide, found at https://ebrap.org/eBRAP/public/UserGuide.pdf, contains detailed instructions for these two processes.

### A. eBRAP Registration

All PIs must register in eBRAP to submit a pre-application.

***It is strongly recommended that PIs start the eBRAP registration process early to ensure sufficient time for completion prior to the submission deadline. There is no grace period.***

During eBRAP registration, the PI must request to be affiliated with their organization from the list of organizations already registered with eBRAP. If the PI's organization is not already registered with eBRAP, the PI must invite an Authorized Organizational Representative (Primary Organization Representative, AOR) to register the organization. The AOR does not need to complete the organization registration in eBRAP prior to the pre-application submission deadline in order for the pre-application to be submitted. ***However, the organization's eBRAP registration must be completed before the full application submission deadline to allow for processing, viewing, and modifying select components of the full application package during the application verification period.***

***Intramural Submissions:*** Applicants should ensure that the names and email addresses used during eBRAP registration are the same as the names and email addresses that will be provided when the full application package is submitted through eBRAP.

PIs are encouraged to utilize an Open Researcher and Contributor ID (ORCID) identifier and enter that information in the appropriate field in the "My Profile" tab in the "Account Information" section of eBRAP. Registration for a unique ORCID identifier can be done online at https://orcid.org/.

### B. Content and Form of Pre-Application Submission

***For specific instructions regarding content of the pre-application submission components, refer to section II.D.2.a., Pre-Application Submission, in the program announcement for the funding opportunity.***

***All pre-application components must be submitted through eBRAP by the deadline specified on the first page of the program announcement.***

To start a new pre-application, select the "New Pre-Application" link associated with the relevant program and award mechanism and follow the prompts in eBRAP. Select the appropriate submission type (intramural). Information used to identify the pre-application will be requested at this step, including application title, keywords, and research characteristics.

**Incorrect selection of submission type will delay processing.**

Once a new pre-application is created, eBRAP will assign a unique log number, i.e., the eBRAP log number. The eBRAP log number remains with the application through the entire application and review process, and throughout the life of the award if the project is recommended for funding. Applicants should use this log number when referencing the application.

The pre-application consists of the following components, organized in eBRAP by separate tabs:

**Summary:** Displays the information previously entered for the pre-application, such as application title, PI, Business Official, performing organization, contracting organization, etc. As the steps of the pre-application are completed, additional information will display on this tab.

**Tab 1 – Application Information:** This tab is prepopulated with information provided when creating a new pre-application. Prepopulated information can be changed in this tab, including the application submission type. Enter additional information as prompted.

**Tab 2 – Application Contacts:**

Enter/update contact information for the PI and the Business Official responsible for sponsored program administration. The Business Official must be either selected from the eBRAP list or invited to allow the pre-application to be submitted. If the Business Official cannot be found in eBRAP, an invitation must be sent to them to register in eBRAP. The invitation to register must be sent prior to the pre-application deadline, but the Business Official has until the full application deadline to complete the registration. This registration is required for the Business Official to view, modify, and verify the application in eBRAP after submission.

Select the performing organization (site/organization at which the PI will perform the proposed work) and the contracting organization (recipient organization financially responsible for the award). The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

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

**Tab 3 – Collaborators and Key Personnel:** Enter the name, organization, and role of all collaborators and key personnel associated with the application, including partnering PI(s), if applicable.

***No member of the Programmatic Panel may be named as a Collaborator or Key Personnel for the proposed research project, nor found to have assisted in the pre-application or application processes. Refer to the specific program announcement for a link to the list of Programmatic Panel members.***

**Tab 4 – Conflicts of Interest:** To avoid conflicts of interest during the screening and review processes, list all individuals, other than collaborators and key personnel, who may have a conflict of interest in the review of the application, including individuals with whom the PI has a personal or professional relationship.

**Tab 5 – Pre-Application Files:** Upload all components as individual PDF files as specified in the program announcement. Pre-applications where the components exceed the specified page limits may be rejected, or excess pages deleted from the file. Refer to the specific program announcement for detailed instructions. Documents should conform to the formatting guidelines outlined in Appendix VIII, Formatting Guidelines.

**Tab 6 – Submit Pre-Application:** Enter eBRAP password and click the "Submit" button. Click the "Confirm Submission" button to complete the pre-application submission. ***This finalizes the pre-application process.***

Following completion of pre-application submission, the status of the pre-application in eBRAP will change from "DRAFT" to "SUBMITTED," and a confirmation email will be sent to the PI and named Business Official.

***The pre-application is not submitted until Tab 6 is complete. Pre-applications not submitted remain in DRAFT status. An applicant with a pre-application in DRAFT status after the pre-application submission deadline is ineligible to submit a full application. There is no grace period.***

## APPENDIX VI: FULL APPLICATION SUBMISSION FOR INTRAMURAL DOD ORGANIZATIONS

### 1. Content and Form of Full Application Submission – eBRAP

### (a) eBRAP Full Application Package Components

The eBRAP full application package includes the following components, which are organized in eBRAP by separate tabs. **To access these tabs, go to "My Applications" and click on "Start Full Application"** for the log number under which the pre-application was submitted.

**Tab 1 – Summary:** Provides a summary of the application information and copies of standard application forms.

**Tab 2 – Contacts:** This tab will be populated by eBRAP. Add the name of the AOR.

**Tab 3 – Full Application Files:** Upload each application component in eBRAP as individual PDF files. Refer to Appendix VIII, Formatting Guidelines for detailed formatting guidelines.

**Tab 4 – Application and Budget Data:** Review and edit Proposed Project Start Date, Proposed End Date, and budget data pre-populated from the Budget Form.

**Tab 5 – Submit/Request Approval Full Application:** Once all components have been uploaded, and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will validate files against the program announcement requirements, and discrepancies will be noted. If no discrepancies are noted, press the "Confirm Submission" button to complete the application submission. eBRAP will notify your RM/Comptroller/Task Area Manager or equivalent Business Official by email to log into eBRAP to review and approve the full application package prior to the approval deadline.

### (b) Attachments

**Upload attachments to Tab 3 – Full Application Files.** Each attachment must be uploaded as an individual PDF unless otherwise stated. Do not password protect any files of the application package, including the Project Narrative.

***All documents that require signatures must be signed. Both electronic and hand signatures will be accepted. Any document that is signed by hand should be scanned at a resolution of 100-150 dots per inch.***

The following must be included as attachments unless otherwise stated in the funding opportunity:

***For specific instructions regarding additional attachments, attachment numbers, content, and page limits, refer to the program announcement. Attach each as a separate PDF, named as indicated in the announcement.***

**Attachment: Project Narrative: Attach as "ProjectNarrative.pdf".** The Project Narrative is the main body of the application. 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.

***Submission of a Project Narrative that exceeds the page limit specified in the program announcement will result in administrative rejection of the application.***

**Attachment: Supporting Documentation: Combine and attach as a single PDF named "Support.pdf".** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings.

Submitting material that is not requested may be viewed as an attempt to gain an unfair competitive advantage; such material will be removed, or the application may be administratively withdrawn. ***Letters of support not requested in the program announcement, such as those from members of Congress, will be removed from the application package.***

**DOD Data Management Plan:** DOD Data Management Plans have specific basic requirements as described in Section 3.c., Enclosure 3, DoD Instructions 3200.12, and therefore applicants should not simply upload a copy of the NIH Data Management and Sharing Plan. The DOD Data Management Plan should be no more than two pages and submitted under "Supporting Documentation" only if a separate Data Management Attachment is ***not*** required by the funding opportunity. ***Do not duplicate the Data and Research Resources Sharing Plan.*** The DOD Data Management Plan should include but is not limited to:

- The types of data, software, and other materials to be produced.
- How the data will be acquired.
- Time and location of data acquisition, if scientifically pertinent.
- How the data will be processed.
- The file formats and the naming conventions that will be used.
- A description of the quality assurance and quality control measures during collection, analysis, and processing.
- A description of dataset origin when existing data resources are used.
- A description of the standards to be used for data and metadata format and content.

- Appropriate timeframe for preservation.

The plan may consider the balance between the relative value of data preservation and other factors such as the associated cost and administrative burden. The plan will provide a justification for such decisions. ***Include a statement that the data cannot be made available to the public when there are controlled unclassified information concerns (e.g., "This data cannot be cleared for public release in accordance with the requirements in DOD Instruction 5230.09.").***

***For a complete list and descriptions of required Supporting Documentation, refer to the program announcement.***

**Attachment: Technical Abstract: Attach as "TechAbs.pdf".** Abstracts of all funded research projects will be posted on the CDMRP website at https://cdmrp.health.mil. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

**Attachment: Lay Abstract: Attach as "LayAbs.pdf".** Abstracts of all funded research projects will be posted on the CDMRP website at https://cdmrp.health.mil. ***Do not include proprietary or confidential information. Do not duplicate the technical abstract.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

**Attachment: SOW: Attach as "SOW.pdf".** The SOW is an outline of the proposed research project that includes the specific aims, proposed tasks, and project milestones that will be accomplished during the award period of performance. All study site locations should be listed, including the country(ies) where DOD-funded research will be performed. The SOW should contain sufficient detail to be informative as a stand-alone document, and there is no limit to the number of specific aims, tasks, or subtasks that are described within the SOW page limit. Applicants are strongly encouraged to use the suggested SOW format stated in the program announcement. Templates for SOW formats are available on the eBRAP "Program Announcement & Forms" page at https://ebrap.org/eBRAP/public/Program.htm. The SOW must be in PDF format prior to attaching.

### (c) Research & Related Personal Data

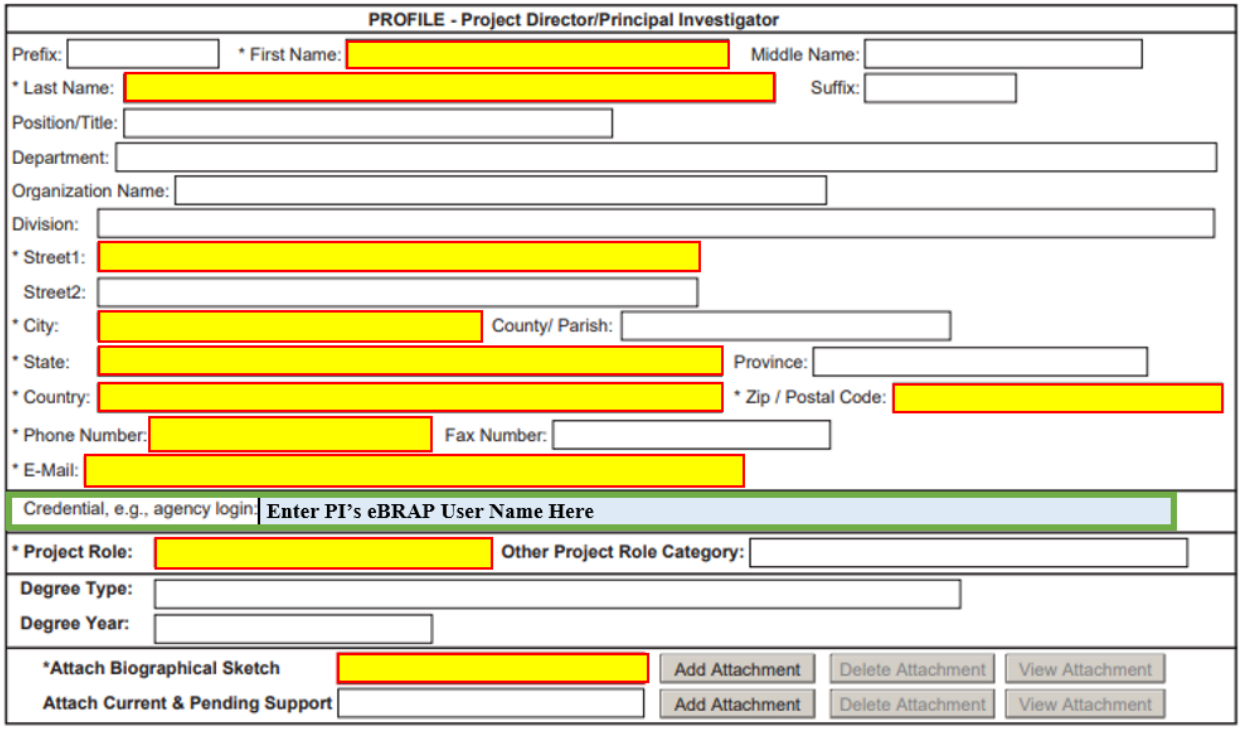
Each application must include this form with the name fields of the PD/PI and any Co-PD(s)/Co-PI(s) completed; however, provision of the demographic information in the form is voluntary. If completing the form for multiple individuals, each Co-PD/Co-PI can be added by selecting the "Next Person" button. The demographic information, if provided, will be used for statistical purposes only and will not be made available to reviewers. Applicants who do not wish to provide information should check or select the "Do not wish to provide" option.

Upload the Research & Related Personal Data Form as "PersonalData_LastName.pdf" to Tab 3 – Full Application Files.

### (d) Research & Related Senior/Key Person Profile (Expanded)

Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project, including the provision of degree information. All fields marked with an asterisk are required. For the application PI, in the "PROFILE – Project Director/Principal Investigator" section, enter the PI's User Name provided by eBRAP into the data field labeled "Credential, e.g., agency login" (Green Box, Figure 2). Additional senior/key persons can be added by selecting the "Next Person" button.

**Figure 2. PI's eBRAP User Name**




A biographical sketch and full description of the PI and each Senior/Key Person's previous/current/pending support information may be either attached to the Research & Related Senior/Key Person Profile (Expanded) Form or uploaded as individual files within Tab 3 – Full Application Files.

Upload the Research & Related Senior/Key Person Profile (Expanded) as "KeyPersonnel_LastName.pdf" to Tab 3 – Full Application Files.

- **Biographical Sketch:** This file must be titled "Biosketch_LastName.pdf" where "LastName" is the last name of the PI or Senior/Key Person.

  The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page at, https://ebrap.org/eBRAP/public/Program.htm in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format. Page limitations will be specified in the program announcement.

- **Previous/Current/Pending Support:** This file must be titled "Support_LastName.pdf" where "LastName" is the last name of the PI or Senior/Key Person.

  Provide support information for the PI and all senior/key personnel, including other individuals who will contribute to the scientific development or execution of the proposed research project in a substantive, meaningful way, independent of whether they request salaries or compensation. Compensation could take many forms including cash, research funding, complimentary foreign travel, honorific titles, career advancement opportunities, promised future compensation, or other types of remuneration or consideration, including in-kind compensation. Include the total or estimated dollar amount for research, resource, or other project support.

  Consistent with National Security Presidential Memoranda-33, individuals are required to disclose grants and contracts associated with participation in programs sponsored by foreign governments, instrumentalities, or entities, including foreign government-sponsored talent recruitment programs. Further, if individuals receive direct or indirect support that is funded by a foreign government-sponsored talent recruitment program, even where the support is provided through an intermediary and does not require membership in the foreign government-sponsored talent recruitment program, that support must be disclosed. Individuals must also report other foreign government sponsored or affiliated activity. ***Foreign government-sponsored talent recruitment program" is defined as an effort organized, managed, or funded by a foreign government, or a foreign government instrumentality or entity, to recruit science and technology professionals or students (regardless of citizenship or national origin, or whether having a full-time or part-time position) as noted in the Guidance for Implementing National Security for United States Government-Supported Research and Development, page 23***.

  If there is no previous, current, or pending support, enter "None." An updated previous, current, and pending support document will be required if an award is recommended for funding.

  **Research Support:** For all previous (award period of performance ending within the past 5 years), current, and pending (includes all proposals currently under review or pending award) research support, include the following:

  - Title of the project
  - Project number
  - Level of effort (percentage or calendar months)
  - Performance period (month/day/year – month/day/year)
  - Funding amount
  - Supporting agency
  - Supporting agency POC (name and contact information)

- Specific aims/tasks
- Brief description of the project's goals
- Description of any actual or potential overlap with the proposed research project. ***Clearly state if there is no overlap.***

**Positions and Appointments:** List all positions and scientific appointments, both domestic and foreign (including affiliations with foreign entities or governments), held by the PI and all senior/key personnel. This includes titled academic, professional, or institutional appointments, independent of whether remuneration is received and/or whether the position/appointment is full time, part time, or voluntary (including adjunct, visiting, or honorary). Selection to a foreign "talents" or similar-type program must be reported.

**Resources:** Report all other support including resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of monetary value. This includes but is not limited to foreign financial support, research or laboratory personnel, lab space, scientific materials such as high-value materials that are not freely available (biologics, chemical, model systems, technology, etc.), or other foreign or domestic research support.

**Other Projects and Activities:** Report all current projects and activities that involve the PI and all senior/key personnel, even if the support received is only in-kind (e.g., office/laboratory space, equipment, supplies, employees). This includes resource and/or financial support from all foreign and domestic entities, including but not limited to, gifts provided with terms or conditions, financial support for laboratory personnel, and participation of student and visiting researchers supported by other sources of funding. Information must be provided for all current support for ongoing projects, whether such support is provided through the applicant organization, through another domestic or foreign organization, or is directly provided to an individual who supports the senior/key personnel's research efforts.

### (e) Budget Form

The total proposed research project cost, with a breakdown of all cost categories for each year of the project, must be submitted. Complete a separate "Suggested Intragovernmental/Intramural Budget Form" that covers all years of the period of performance for each research site involved in the project (including subaward sites) and upload to Tab 3 – Full Application Files as a single document titled **IGBudget.pdf**. The "Suggested Intragovernmental/Intramural Budget Form" is available for download on the eBRAP "Funding Opportunities and Forms" web page at https://eBRAP.org. For limits on funding amounts, types of costs, and period of performance, refer to the program announcement. ***A budget justification for the entire period of performance that includes a Federal Financial Plan must be appended to the "Suggested Intragovernmental/Intramural Budget Form."*** The budget and budget justification should include sufficient detail for the government to determine whether the proposed costs are allowable, allocable, and reasonable for the proposed research. The government reserves the right to request a revised budget and budget justification and/or additional information.

***If the budget fails eBRAP validation, the PI will receive an error message and will be required to correct the budget within the existing application prior to the full application submission deadline. Any additional modifications to the budget must also be completed prior to the full application submission deadline.***

**Budget Regulations and Restrictions:**

- **Administrative and Cost Principles:** Recipients will be required to comply with the following, as applicable:
    - "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR 200), as implemented by Chapter XI of Title 2 CFR
    - Provisions of Chapter I, Subchapter C of Title 32, CFR, "DOD Grant and Agreement Regulations," Parts 26, 28, 34.16; and Title 2, CFR Parts 1100-1199
    - FAR Part 31

***It is prohibited to charge a fee or profit to an assistance agreement, either by the recipient/awardee or subrecipient/subawardee.***

- **Cost of Preparing Applications:** The cost of preparing applications in response to a program announcement is not considered an allowable direct charge to any resultant award. However, the cost of preparing applications may be an allowable cost that can be included in the indirect/F&A cost as specified in the organization's applicable cost principles.
- **Currency:** All costs must be entered in U.S. dollars.
- **Timelines:** Programs are funded via Defense Health Program Research, Development, Test, and Evaluation (RDT&E) appropriations. RDT&E funds must be obligated or allocated to a specific award or purpose within 24 months from the start of the fiscal year in which the funds were appropriated (e.g., FY24 funds must be obligated no later than 30 September 2025). In addition to obligation deadlines, RDT&E funds will be available for use for a limited time period and expire for disbursement 5 years after the obligation deadline. Expired (i.e., undisbursed) funds return to the U.S. Treasury at the end of the 5-year disbursement period (e.g., FY24 funds expire for disbursement to performers by 30 September 2030).
- **Funding:** The USAMRDC's RM office will "direct fund" Intragovernmental/Intramural Organizations utilizing either the Project Order Statute (41 USC 6307) or the Economy Act Statute (31 USC 1535), as appropriate. Where applicable, the Project Order Statute is the preferred transactional authority that will be used for intramural DOD organizations. Funds will be sent by the authorized method through the MIPR, FAD, or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals.

Intragovernmental and intramural DOD organizations must be prepared to accept the entirety of the requested budget for the site in the fiscal year funds aligned with the funding opportunity. CSI appropriations for a given topic or program are not part of the requested DOD budget and are not guaranteed in the future. Intragovernmental and intramural DOD investigators are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support any external collaborators. Intragovernmental and intramural DOD investigators and collaborators are reminded to coordinate receipt and commitment of funds through their respective RM/Task Area Manager/Comptroller or equivalent Business Official.

- **Pre-Award Costs:** An institution of higher education, hospital, other nonprofit, or for-profit organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award if such costs (1) are necessary to conduct the project and (2) would be allowable under the award, if awarded. If specific expenditures would otherwise require prior approval, the recipient must obtain the Grants Officer's approval before incurring the cost. Government prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new award.

  The incurrence of pre-award costs in anticipation of an award imposes no obligation on the government either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred or in the absence of appropriations. The government expects the recipient to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the organization's ability to accomplish the project objectives within the approved timeframe or in any way adversely affect the conduct of the project.

**Intragovernmental/Intramural Budget Form Instructions:**

Begin by entering the organization name, PI name, and eBRAP Log number, in the fields at the top.

- **Name:** Beginning with the PI, list all key personnel who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all collaborating investigators, research associates, individuals in training, mentor (if applicable), and support staff who will contribute significantly to the proposed research project.

  ***DOD Civilian and Military Personnel: Personnel involved in the project should be listed in this section; however, this award is not intended to provide salary support for any federal employee. Generally, RDT&E funds may only be requested to support civilian salaries for those individuals who are in reimbursable positions. These circumstances will be discussed during award***

***negotiations and will require substantial justification in the budget justification section.***

- **Role/Key Personnel:** Identify the role of each participant listed. Describe their specific functions in the proposed research in the budget justification.

- **Title/Position/Rank:** Identify the title, position, or rank for each individual.

- **Annual Base Salary:** Enter the annual organizational base salary (based on a full-time appointment) for each individual requesting salary reimbursement listed for the project. If no reimbursement is requested, leave the annual base salary section blank.

- **Effort on Project:** List the percentage of each appointment to be spent on this project for all staff members including unpaid personnel.

- **Salary Requested:** Enter the salary for each position for which funds are requested. This is calculated automatically from the data provided.

- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines.

- **Totals:** Calculated automatically from the salaries and fringe benefits data provided. Ensure the totals are correctly auto-calculated.

- **Consultant Costs:** List the total costs for any consultant fees/services.

- **Equipment:** Provide the cost of proposed equipment. Equipment is tangible personal property (including information technology systems) having a useful life of more than 1 year and a per unit acquisition cost that equals or exceeds the lesser of (a) $5,000 or (b) the recipient's or the subrecipient's capitalization threshold for financial statement purposes. Applicant organizations are encouraged to provide all equipment necessary to conduct the proposed research project.

- **Materials and Supplies:** "Materials and Supplies" means all tangible property, including a computing device, acquired under an award that does not meet the definition of equipment.

- **Military and Federal Civilian Travel Costs:** Applicants are responsible for budgeting all costs associated with travel, including airfare, hotel, etc., associated with the trip. Anticipated travel costs should be built into the budget at current or projected DOD per diem rates. Note, military and federal civilian travel costs, unless funded via a project order, cannot not be subjected to fees/indirect costs.

- **Contractor Travel Costs:** For contractor personnel, indicate all travel costs associated with travel, including airfare, hotel, etc., associated with the trip. Anticipated travel costs should be built into the budget at current or projected DOD per diem rates.

- **Other Direct Costs:** Itemize other anticipated direct costs such as research-related subject cost, publication and report costs, equipment rental (provide hours and rates), communication costs, and organizationally provided services. Estimate the costs of publishing and reporting research results, including direct charges for clerical services, illustrations, reprints, and distribution. Organizationally provided services should be supported by the organization's current cost/rate schedule. These items should be described in detail and clearly justified.

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

- **Total Direct Costs:** Calculated automatically from the data provided for the initial budget period and for the entire proposed period of support.

***The primary award (including the direct and indirect costs of any subawardees/subcontractors, if applicable) should not exceed the cost limit stated in the program announcement.***

- **Total Indirect Costs:** If funds for indirect costs are requested, sufficient justification must be provided in the Justification section. The government reserves the right to disallow any indirect costs not sufficiently justified. No budget will be approved by the government using an indirect rate exceeding the organization's negotiated rate.

- **Total Direct and Indirect Costs:** This section is calculated automatically from the data provided.

- **Required Information (last page of the form):**

    - Indicate the name and contact information for the Resource Management, Business Official, and any parties who should be included on budgetary matters.

    - Indicate the last date the institution can accept current fiscal year funds.

    - The authorized organization representative must (1) attest that the organization has a system in place to accept funds; (2) acknowledge that receipt of funds may occur within the last 6 months of the current fiscal year; and (3) sign the document.

**Budget Justification Instructions:**

Provide a clear budget justification for the entire period of performance for each item in the budget. ***Append the Budget Justification to the "Suggested Intragovernmental/Intramural Budget Form" and upload as a single document.*** It is recommended that the headings of the cost categories in the budget justification match the cost categories in the Suggested Intragovernmental/Intramural Budget Form. Itemize direct costs for all years of the award. Organizations must provide sufficient detail and justification so the government can determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort. Applicants performing research outside of the United States should also include the cost in local currency, the rate used for converting to U.S. dollars, and

justification/basis for the conversion rate used. Foreign currency exchange rates for applicants performing research outside of the United States will be determined at the time of application submission.

**Personnel:** Identify the role of each senior/key person listed and describe their specific functions in the budget justification. Identify and explain any proposed adjustments to labor rates or salaries.

**Equipment:** If equipment is requested, provide a detailed list showing the cost of each item and a rationale for the stated costs. The budget justification for any requested equipment must describe, as applicable: (a) special test equipment to be fabricated for specific research purposes and its cost; (b) standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately; and (c) existing equipment to be modified to meet specific research requirements, including modification costs. Do not include as special test equipment those items of equipment that, if purchased by the recipient with recipient funds, would be capitalized for federal income tax purposes.

**Travel:** If travel costs are requested to attend scientific/technical meetings, include the meeting name, purpose, location, and date, if known. International travel may be requested but must be justified with additional documentation and is subject to approval by the Program Office. The justification should clearly confirm that the requested travel costs meet any travel requirements and/or restrictions stated in the program announcement.

**Materials and Supplies:** Include a general description of expendable material and supplies for each year. If animals are to be purchased, state the species, strain (if applicable), number to be used, cost per animal and total costs, proposed vendor, and a copy of the animal per diem cost/rate agreement. If human cell lines are to be purchased, state the source, cost, and description. If a computer/software purchase is requested, include a detailed explanation for why purchase of computer/software is required to complete the proposed research project. Include a statement verifying that the requested computer/software is not currently available for use.

**Consultant Services:** Independent of whether funds are requested for any proposed consultant services, include the name(s) and organizational affiliation(s) of all consultants, and include the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.

**Service Costs and User Fees:** List proposed equipment or facility rental/user fees, including data processing fees. Include information regarding estimated hours/units required for the proposed research project and the provider's service rates.

**Alterations and Renovations:** Provide a description of the existing facility and detailed description of the requested changes. Include a justification outlining how changes directly support the proposed research. ***Costs for the construction of facilities are not allowable.***

**Other Expenses:** Describe and justify any other anticipated direct costs.

**Indirect Costs:** Provide details of the direct cost base (modified total direct costs, salary and wage, or other). Identify any costs that have been excluded from the base (in accordance with the approved rate agreement). Also indicate if the rate(s) is an on-site or off-site rate(s). If more than one rate is applicable, provide a breakdown of the calculation.

**Federal Financial Plan: The** CDMRP funding is directed by Congress on a yearly basis for each program and obligated up-front for each award as there is no guarantee of future program appropriations. Funds are available for obligation for 2 years from the beginning of the fiscal year of appropriation. **For applications involving an intragovernmental or intramural DOD organization, include a federal financial plan in the budget justification. The plan must address how all funds transferred to the intragovernmental or intramural DOD organization will be obligated before their** expiration for obligation**, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, if applicable.** ***Unless otherwise stated in the funding opportunity, the CDMRP does not intend to use funds from future fiscal year(s), if appropriated, to support the award.***

**Foreign Collaboration Justification:** Applications that propose consultant, subaward, consortium, or contractual arrangements with foreign organizations or collaborators employed by foreign organizations/governments are required to demonstrate how one or more of the following conditions have been met:

- The foreign organization or individual(s) employed by foreign organizations/governments contributes unique expertise, organizational capability, facilities, data resources, and/or access to a geographic location or population not generally available to investigators based in the U.S. (or which would require significant effort or time to duplicate) or would potentially significantly advance the health sciences in the United States.
- The foreign organization, individual(s) employed by foreign organizations/governments, or project offers significant unique health research opportunities to advance U.S. Military medicine and benefit Service Members, Veterans, and their Families.

### (f) Project/Performance Site Location(s) Form

Indicate the primary site where the work will be performed. If a portion of the work will be performed at any other site(s), include the name and address for each collaborating location in the data fields provided. Add more sites as necessary using the "Next Site" button. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach it to this form. Each additional research site requesting funds will require a subaward budget.

Upload the Project/Performance Site Location(s) Form as "Performance.pdf" to Tab 3 – Full Application Files.

### 2. Applicant Verification of Full Application Submission in eBRAP

Upon application submission, the organizational RM/Comptroller/Task Area Manager or equivalent Business Official will receive an email instructing them to log into eBRAP to review and approve the full application submission. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. Verification of application content is strongly recommended but not required. Modifications to application components may only be made after the Business Official has set the status to "Return to PI" for the PI to make changes, or "Draft" for the Business Official to make changes.

***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.***

Other application components, including subaward budget(s) and subaward budget justification(s) may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends. The RM/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

***The full application submission deadline and the end of the application verification period are stated on the first page of the specific program announcement (Section I, Overview of the Funding Opportunity).***

## APPENDIX VII: RECIPIENT QUALIFICATION AND RESTRICTION INFORMATION

### Recipient Qualification

To protect the public interest, the federal government ensures the integrity of federal programs by conducting business with qualified recipients only. According to the standards of DoDGARs 22.415, a potential qualified recipient must: (1) have the management capability and adequate financial and technical resources, given those that would be made available through the grant or cooperative agreement, to execute the program of activities envisioned under the grant or cooperative agreement; (2) have a satisfactory record of executing such programs or activities, if it is a prior recipient of an award; (3) have a satisfactory record of integrity and business ethics; and (4) be otherwise qualified and eligible to receive a grant or cooperative agreement under applicable laws and regulations (see DoDGARs 22.420[c]).

The federal government will not provide funds to support scientists from countries meeting the criteria for designation as a State Sponsor of Terrorism (https://www.state.gov/j/ct/list/c14151.htm).

The USAMRDC utilizes the Exclusions Within the Performance Information functional area of SAM to identify individuals and organizations unqualified to receive federal awards. More information about Exclusions reported in SAM is available at https://www.sam.gov/SAM/. Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold as defined in 2 CFR 200.1 over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

### J-1 Visa Waiver

Each organization, including organizations located outside of the United States, is responsible for ensuring that the personnel associated with any application recommended for funding are able to complete the work without intercession by the DOD for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.

Additional information on J-1 Visa Waivers can be located at the following Department of State website: https://travel.state.gov/content/travel/en/us-visas.html.

### Post-Employment Restrictions

There are certain post-employment restrictions on former federal officers and employees as defined in 18 USC 207. Post-employment restrictions may exist if a former federal officer or employee participates in the proposed project. The situation should be addressed with the USAMRDC Office of the Staff Judge Advocate at Fort Detrick (https://home.army.mil/detrick/index.php/my-fort/all-services/legal-assistance-office) prior to expending time and effort in preparation of an application.

## APPENDIX VIII: FORMATTING GUIDELINES

All pre-application and application documents must be legible and should conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ among the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF as viewed on a computer screen.

- **Document Format:** Each attachment to the full application forms must be uploaded as an individual file in the format specified in the program announcement. All contributors to the application must use matching compatible versions of Adobe software for all PDF documents when editing and preparing application components. The use of different software versions will result in corruption of the submitted file.
- **Font Size:** 12 point, not condensed.
- **Font Type:** Times New Roman.
- **Spacing:** Single space or no more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- **Margins:** At least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).
- **Color, High-Resolution, and Multimedia Objects:** Project narratives and pre-application files may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF; however, these objects should not exceed 15 seconds in length and a size of 10 MB. Photographs and illustrations must be submitted in JPEG format; bitmap and TIFF formats are not allowed. Please note that these types of objects are not allowed in the technical and public abstracts.
- **Scanning Resolution:** 100 to 150 dots per inch.
- **Internet URLs:** URLs, or web addresses, directing reviewers to websites that contain additional information about the proposed research are not allowed in the application or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. However, links to publications referenced in the application are encouraged.
- **Language:** All documents must be submitted in English, unless otherwise specified in the program announcement (e.g., foreign transcripts submitted with English translations).
- **Headers and Footers:** Should not be used. Pre-existing headers and footers on required forms are allowed.
- **Page Numbering:** Should not be used.
- **Recommended Attachment Size:** Individual attachments should be no larger than 20 MB.

## APPENDIX IX: APPEALS AND INQUIRY REVIEW PROCESS

Although not required by law or assistance regulation, the CDMRP offers the Inquiry Review Process (IRP) as a courtesy to all applicants to CDMRP funding opportunities and other USAMRDC funding opportunities administered by the CDMRP to maintain the high integrity of its review processes. If an application is not recommended for funding and the applicant believes a factual or procedural error occurred during the review of the application, the organization or PI may submit an inquiry through the eBRAP Help Desk at help@eBRAP.org within 15 business days after the notification letter is sent. Inquiries submitted after 15 business days will not be considered.

To be considered, the inquiry must identify and address a specific perceived factual or procedural error, as defined below:

- Factual Error: An error in the review (peer or programmatic) that is restricted to, or based on, fact. Differences of opinion between reviewers or between reviewer(s) and an applicant are not factual errors.

- Procedural Error: An error in the review (peer or programmatic) that is restricted to review process adherence. The review process did not follow the procedures in the program announcement that describe peer and programmatic review (e.g., documents requested in the program announcement and submitted with the original application were inadvertently left out of the peer or programmatic review package).

The purpose of the IRP is to assess whether an error occurred during application review. Inquiries that provide a point-by-point rebuttal to multiple weaknesses in the summary statement without clearly identifying and addressing specific perceived factual or procedural error(s) in the review will not be considered. Inquiries that misrepresent comments in the summary statement or notification letter, such as not referencing the full text of a comment or changing the language of a comment, will also not be considered.

A CDMRP IRP panel will determine whether an error occurred in either peer or programmatic review and, if so, recommend corrective action when appropriate.

***The determination of an error in the review process is not a guarantee of re-review or funding.***

The IRP decision and any associated funding decisions are considered final and are not subject to appeal. Questions related to the IRP prior to or after submitting an inquiry should be directed to the eBRAP Help Desk at help@eBRAP.org.

## APPENDIX X: USE OF DOD OR U.S. DEPARTMENT OF VETERANS AFFAIRS (VA) RESOURCES

Access to certain DOD or VA patient populations, resources, or databases may only be obtained by collaboration with a DOD or VA investigator who has a substantial role in the research and may not be available to a non-DOD or non-VA investigator if the resource is restricted to DOD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DOD or non-VA investigator collaborating with the DOD and/or VA. If access cannot be confirmed at the time of application submission, the government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s).

**For clinical research or trials proposing inclusion of military populations for research,** see the guidance document, "A Primer for Conducting Department of Defense (DOD) Funded Human Research With Military Populations," on the CDMRP website.

## APPENDIX XI: RESEARCH BIOSAFETY REQUIREMENTS

**Safety and Environment Requirements:** In certain instances, safety and environment compliance review may require submission of additional documentation prior to the awarding of any assistance agreement. Such instances may include use of Army-provided infectious agents or toxins, Biological Select Agents or Toxins (https://www.selectagents.gov/sat/list.htm), specific chemical agent(s) (https://www.cwc.gov/cwc_treaty_chemicals_schedules.html), or pesticides outside of an established laboratory. ***Applicants do not need to address these requirements in the initial application*** unless instructed otherwise in the program announcement. PIs and organizational representatives will receive award-specific instructions if/when the application is recommended for funding.

Additional information is available at https://mrdc.health.mil/index.cfm/resources/researcher_resources/safety.

If applicants have questions, they may call the Surety and Environmental Manager at 301-619-2004.

**Research Involving Recombinant or Synthetic Nucleic Acid Molecules:** For research that is recommended for funding involving recombinant or synthetic nucleic acid molecules, the recipient must assure that all work will be in compliance with guidance provided in NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules – Office of Science Policy (nih.gov).

**Dual Use Research of Concern (DURC):** For research that is recommended for funding that can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security, the recipient must assure that the work will be performed in compliance with United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern with appropriate reporting and oversight.

More information on DURC policy and oversight can be found at https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab0/.

## APPENDIX XII: RESEARCH PROTECTIONS REVIEW REQUIREMENTS

The USAMRDC OHARO ensures that research conducted, contracted, sponsored, supported, or managed by the DOD and involving animals, human subjects, human data, human anatomical substances, and/or human cadavers is conducted in accordance with federal, DOD, Army, USAMRDC, and international regulatory requirements. PIs and applicant organizations **may not commence performance** of research involving any of the above until regulatory documents are submitted **and** approved by the respective USAMRDC OHARO office(s) to ensure that DOD regulations are met. All expectations described below are consistent with DOD Instruction (DODI) 3216.01, "Use of Animals in DoD Programs," and DODI 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research."

Organizational protocol approvals (e.g., IACUC or IRB approval) are not required at time of application submission, unless otherwise noted in the program announcement. PIs and organizational representatives will receive award-specific instructions if/when the application is recommended for funding. Applicants are encouraged to review the "Guide for Funded Investigators" that is found on eBRAP at https://ebrap.org/eBRAP/public/Program.htm, and the other referenced websites below for additional information about post-award processes and requirements.

For additional information about OHARO visit https://mrdc.health.mil/index.cfm/collaborate/research_protections.

### Animal Care and Use Review Office (ACURO)

All DOD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHARO ACURO, in addition to the local IACUC of record, prior to using DOD funds to start work with animals. This includes reviewing and approving amendments to ongoing projects that will use DOD funds. When requested, PIs must submit the institutionally approved animal use protocol, documentation of IACUC approval of that protocol, and the completed ACURO Appendix. PIs should ***allow 3 to 4 months for the ACURO review and approval processes.***

**Site Visits:** The ACURO conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of USAMRDC as a part of their responsibility to protect animals in research.

For current information about ACURO policies, detailed guidance, and the ACURO Appendix, visit https://mrdc.health.mil/index.cfm/collaborate/research_protections/acuro. ***Allow at least 3 to 4 months for regulatory review and approval processes for animal studies.***

Send questions via email to the ACURO (usarmy.detrick.medcom-usamrdc.other.acuro@health.mil).

## Office of Human Research Oversight

All DOD-funded research involving new and ongoing research with human subjects, data, specimens, and/or cadavers must be reviewed and approved by the USAMRDC OHARO, Office of Human Research Oversight (OHRO), prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee review. PIs should ***allow up to 3 months to complete the OHRO regulatory review and approval process following submission of all required and complete documents to the OHRO.*** Studies taking place in international settings may require additional time for completion of OHRO reviews.

For current information about OHRO policies, detailed guidance, and submission forms, visit https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo.

Questions regarding applicable research protection regulations, policies, and guidance should be directed to the local IRB or the OHRO (usarmy.detrick.medcom-usamrmc.other.hrpo@health.mil).

### A. Human Subjects Research

Applicants should keep in mind the following key requirements as they plan any DOD-funded human subjects research. Additional information is provided in the "Information for Investigators – Human Subjects Research" guidance document on the OHRO website.

- **Assurance of Compliance:** Each institution engaged in non-exempt human subjects research must have a current DHHS Office for Human Research Protection Federalwide Assurance or DOD Assurance (Intramural DOD institutions only).
- **Informed Consent Language:** The following must appear in the consent form:
    - A statement that the DOD is providing funding for the study.
    - A statement that representatives of the DOD are authorized to review research records.
    - In the event that HIPAA authorization is required, the DOD must be listed as one of the parties to whom protected health information may be disclosed.
- **10 USC 980 Waiver:** If the applicant proposes to conduct a trauma clinical trial or other planned emergency research under the 21 CFR 50.24 provisions for exception from informed consent, the applicant should plan for 3-6 months of additional time for the OHARO OHRO to review the submission and request the Army Surgeon General or DOD for approval of a waiver of the requirements of 10 USC 980, a DOD-unique statute involving use of DOD funds.

### B. Research Involving the Secondary Use of Human Data and/or Human Anatomical Substances

ALL USAMRDC-supported research involving the secondary use of human data and/or human anatomical substances, i.e., specimens, must be reviewed for compliance with federal and DOD

human subjects protection requirements and approved by the OHRO prior to using DOD funds for any such research. ***Research involving the use of human data and/or human anatomical substances not otherwise subject to IRB review (e.g., "exempt" research) still requires PIs to submit the DOD-funded human data/specimens research to the IRB to obtain a determination letter (e.g., stating that the project does not constitute "human subjects research" or can be considered "exempt human subjects research") from the IRB confirming this status.***

Detailed guidance and instructions on OHRO review of DOD-funded research activities involving access, use, and analysis of human data and/or human anatomical substances is provided in the "Information for Investigators – Research with Data/Specimens" guidance document on the OHRO website. This guidance document also includes a detailed discussion on the types of human data, cell lines, specimens, etc., that do an do not require OHRO review and approval.

### C. Use of Unique or Regulated Sample Types

**Fetal Tissue:** OHRO submission and review is required for research using fetal tissue and cell lines derived from fetal tissue. Note that use of cord blood or materials derived from placenta are not considered fetal tissue. Due to state and federal laws that govern research use of fetal tissue, the OHRO will confirm that the institutional review determined:

- the written consent of the mother was obtained;
- the fetus can be used for research;
- the use of fetal material is required for the research and other materials cannot be substituted;
- and the source of the materials is documented (institution, clinical providers, nonprofit repositories, etc.)

Additional approvals are required for research with fetal tissues in accordance with DOD Instruction 3216.02. Investigators should allow for additional time to receive OHRO and higher-level approval.

**Human embryonic stem cell lines:** The OHRO adheres to the NIH policy requirements and requires submission and review of research on existing human embryonic stem cell lines and derivation of new human embryonic stem cell lines. Due to the ethical issues related to research use of embryonic stem cells, OHRO recommends investigators who plan to conduct research with embryonic stem cells consult the OHRO.

### D. Use of Human Cadavers or Human Anatomical Substances Obtained from Human Cadavers

RDT&E, education, or training activities involving human cadavers or human anatomical substances obtained from cadavers (postmortem samples) shall not begin until the USAMRDC OHARO grants approval in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training (https://mrdc.health.mil/assets/docs/orp/Army_Policy_

for_Use_of_Human_Cadavers.pdf). The USAMRDC OHARO is the Action Office for this Army policy. **Additional requirements apply to use of cadaveric specimens obtained from outside the U.S. and activities involving exposure of cadavers to impacts, blasts, ballistics testing, crash testing, and other destructive forces.**

### E. Large-Scale Genomic Data (LSGD) Collected from DOD-Affiliated Personnel

Disclosure of DOD-affiliated personnel's LSGD may pose a national security risk; accordingly, such research (including the secondary use or sharing of identified or de-identified data or specimens) requires inclusion of administrative, technical, and physical safeguards commensurate with risk. LSGD efforts must undergo security review and additional approvals by the USAMRDC OHARO, USAMRDC Headquarters, and DOD Office of Human Research Protections to ensure the adequacy of the proposed administrative, technical, and physical safeguards. These requirements do not apply to incidental participation of DOD-affiliated personnel in research that enrolls a broader population and does not extend to research on targeted genes, genotypes, or phenotypes that are non-large-scale. DOD-affiliated personnel include Service Members, Reserve Service Members, National Guard members, DOD civilians, and DOD contractors. DOD-funded research involving LSGD collected from DOD-affiliated personnel may require that the performer obtain a NIH Certificate of Confidentiality (https://grants.nih.gov/policy/humansubjects/coc.htm). If selected for funding, performers must take these additional requirements into consideration when developing timelines and milestones.

### F. Additional Information/Requirements

**OHRO Submission:** Any protocol submitted for OHRO review must include only those activities funded by the DOD, as referenced in the approved SOW. If the DOD-funded activities have been added to an ongoing/existing protocol that is not DOD-funded, OHRO will require the PI to write a stand-alone protocol that is limited to those activities supported under the DOD award.

***Any protocol submitted for OHRO review must include only those activities funded by the DOD, as referenced in the approved SOW.***

**Single IRB Requirement:** As of January 20, 2020, U.S. institutions engaged in non-exempt cooperative research must rely on a single IRB to review and approve the portion of the research conducted at domestic sites in accordance with 45 CFR 46.114(b). ***This includes certain types of work with human data and/or human specimens if that work has not been/will not be deemed exempt.*** If the proposed, non-exempt research involves more than one U.S.-based institution, a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single POC for regulatory submissions and requirements.

**Research Involving FDA-Regulated Products:** Research evaluating the safety or effectiveness of drugs, devices, or in vitro diagnostics requires IRB review in accordance with 21 CFR 50 and 21 CFR 56 and 21 CFR 312 and/or 21 CFR 812, as applicable.

**Site Visits:** The OHRO conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of USAMRDC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner to protect the confidentiality of subject information.

**Clinical Trial Registry:** PIs are required to register applicable clinical trials (ACTs) individually on https://clinicaltrials.gov/ using a Secondary Protocol ID number designation of "CDMRP-eBRAP Log Number" (e.g., CDMRP-PC22####). If several protocols exist under the same application, the Secondary Protocol ID number must be designated "CDMRP-eBRAP Log Number-A, -B, -C, etc." (e.g., CDMRP-PC22####-A). Clinical trials must be registered prior to enrollment of the first subject. All trials that meet the definition, of an ACT are required to register, i.e., controlled clinical investigations (other than phase 1 investigations) of any FDA-regulated drug or biological product for any disease or condition and certain studies of FDA-regulated medical devices, excluding small clinical trials to determine feasibility and certain clinical trials to test prototype devices, but including FDA-required pediatric post-market surveillances of a device product. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds as per U.S. Public Law 110-85. PIs conducting phase 3 clinical trials shall submit results of analyses of group differences on the basis of sex/gender, race, and/or ethnicity to clinicaltrials.gov at the time of final report submission. If final analyses of sex/gender and race/ethnicity are not available at the time of the final technical report, a justification and plan ensuring completion and reporting of the analyses must be submitted to USAMRAA.

**Posting of Informed Consent Forms:** For each study that meets the definition of a **clinical trial**, i.e., a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes, conducted or supported by a federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee conducting the trial on a publicly available federal website. The recommended location is clinicaltrials.gov. The informed consent form must be posted on the federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

**Research Involving Use of Fetal Tissue:** OHRO submission and review is required for research using fetal tissue and cell lines derived from fetal tissue. Note that use of cord blood or materials derived from placenta is not considered fetal tissue. Due to state and federal laws that govern research use of fetal tissue, the OHRO will confirm that the institutional review determined: the written consent of the mother was obtained; the fetus can be used for research; the use of fetal material is required for the research and other materials cannot be substituted; and the source of the materials is documented (institution, clinical providers, non-profit repositories, etc.). Additional approvals are required for research with fetal tissues in accordance with DoD Instruction 3216.02. The OHRO will coordinate these reviews; investigators should allow for additional time to receive OHRO approval.

## APPENDIX XIII: ADMINISTRATIVE INFORMATION

### A. Disclosure and Marking of Proprietary Information

Do not include proprietary information in a pre-application or abstract. Proprietary information should only be included in a full application if necessary for evaluation. Applicants should conspicuously and legibly mark any proprietary information that is included in the full application.

All applications recommended for funding will be subject to public release under the Freedom of Information Act (FOIA), to the extent that they are incorporated in an award document. Applications that are not selected for funding will not be subject to public release.

### B. Classified Information, Data, or Outcomes

In accordance with 32 CFR, Section 2002.4, inclusion of classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns is disallowed and may result in application withdrawal. Classified is defined as information that has been determined pursuant to Executive Order 13526 to require protection against unauthorized disclosure and is marked to indicate its classified status when in documentary form (to include electronic copies).

### C. Sharing of Application Information

The USAMRDC shares application information with other federal funding agencies (e.g., NIH, National Science Foundation, VA) to inform funding priorities and decisions, and to increase transparency. In addition, award data are made available to the public through the CDMRP website and to other organizations such as the International Cancer Research Partnership. By sharing and leveraging this information, coordination is enhanced and duplication of effort can be avoided, maximizing the impact of federal funds. The CDMRP believes that such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health. Updates on CDMRP-funded awards, including awardee information and published results, are shared on the Defense Technical Information Center (DTIC).

### D. Demographic and Career Information

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] et seq.), the DOD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. The Research & Related Personal Data form will be used by DOD as the source of demographic information, such as gender, race, ethnicity, and disability information, for the PD/PI and all other persons identified as Co-PD(s)/Co-PI(s). The Research & Related Senior/Key Person Profile (Expanded) form will be used by the DOD as the source for career information including Degree Type and Degree Year.

## E. Pre-Award Meeting

At the government's discretion, the PI and other personnel may be requested to participate in a pre-award meeting at the government's expense.

## F. Post-Award Organization and PI Changes

Awards are made to eligible ***organizations***, not to individuals.

**Transfer of Award to New Organization:** Unless restricted by the specific program announcement, a change in organizational affiliation will be considered on a case-by-case basis. If approved, the PI's original organization will be required to agree to relinquish the award. The new organization will be required to resubmit the entire application on behalf of the PI, including regulatory documentation. Extended times for transfer may put the award funding at risk. A transfer will not, unless under extraordinary circumstances, be allowed for any organization that includes a clinical trial at its location. Organization transfers are not allowed in the last year of the performance period.

**Change in PI:** Unless restricted by the specific program announcement, changes in PI will be considered on a case-by-case basis.

## G. FOIA Requests

The FOIA (5 USC 552) provides a statutory basis for public access to official government records. The definition of "records" includes documentation received by the government in connection with the transaction of public business. Records must be made available to any person requesting them unless the records fall under one of nine exceptions to the Act (https://www.justice.gov/oip).

When a FOIA request asks for information contained in a successful application that has been incorporated into an award document, the submitter will be contacted and given an opportunity to object to the release of all or part of the information that was incorporated. A valid legal basis must accompany each objection to release. Each objection will be evaluated by USAMRDC in making its final determination concerning which information is or is not releasable. If information requested is releasable, the submitter will be given notice of USAMRDC's intent to release and will be provided a reasonable opportunity to assert available action.

## H. Information Release

A recipient of an award will be required to agree to the release of information pertaining to the research and development supported by the federal agency. "Information" includes but is not limited to news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings, and symposia.

The following statements must be included in all information releases:

(1) All releases shall identify the award number and include a statement acknowledging the federal sponsoring agency. The release shall also contain a statement that the opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the DOD. The requirement with specific language will be included in the award notice. Below is an example:

"This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs and the Defense Health Agency J9, Research and Development Directorate, or the U.S. Army Medical Research Acquisition Activity at the U.S. Army Medical Research and Development Command, in the amount of (*insert total costs*), through the (*insert program name*) under Award No. (HT9425241XXXX). Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense."

(2) "In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture." Include required assurances, approvals, documents and information specified on the ACURO website. (https://mrdc.health.mil/index.cfm/collaborate/research_protections/acuro).

(3) "In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules." (https://www.nih.gov/)

(4) "In the conduct of research involving hazardous organisms or toxins, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories." (https://www.cdc.gov/safelabs/resources-tools/biosafety-resources-and-tools.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fsafelabs%2Fresources-tools.html)

***Failure to include the above statements and adhere to the above regulations, when required, may result in loss of funding.***

## I. Contracted Fundamental Research

Any awards to universities or industry and funded by Basic Research funds (6.1), or to universities for on-campus research and funded by Applied Research funds (6.2), meet the DOD definition of "Contracted Fundamental Research." The results of this research are to be unrestricted to the maximum extent possible. The research shall not be considered fundamental in those rare and exceptional circumstances where the effort presents a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense, and where agreement on restrictions have been recorded in the award.

## J. Property/Equipment

Unless otherwise specified in the award, the title to equipment or other tangible property acquired with government funds will vest in institutions of higher education, nonprofit, and for-

profit organizations whose primary purpose is conducting scientific research. Normally, the title will vest in the recipient if vesting will facilitate scientific research performed by the organization for the government. However, if the award is subsequently transferred to a new organization, the DOD reserves the right to require the transfer of equipment acquired with the award funds to the federal government or to an eligible third party.

**K. Title to Inventions and Patents**

In accordance with the Bayh-Dole Act (35 USC 200 et seq.), the recipient and collaborators may elect to retain title to their subject inventions, subject to meeting the reporting and patent filing requirements and retained rights to the U.S. government. The U.S. government shall, at a minimum, retain nonexclusive rights for the use of such inventions. Instructions in the assistance agreement concerning subject inventions must be followed.

## APPENDIX XIV: NATIONAL POLICY REQUIREMENTS

### A. Certification

**Accuracy of Current and Pending Support Documentation:** The applicant, by checking "I Agree" on the SF424 (R&R) Block 17, agrees to abide by the following statement: By signing this application, I certify the proposing entity is in compliance with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 which requires that: (a) the PI and other key personnel certify that the current and pending support provided on the proposal is current, accurate, and complete; (b) the PI and other key personnel agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and (c) the PI and other key personnel have been made aware of the requirements under Section 223(a)(1) of this Act.

**Disclosure of Lobbying Activities:** Certification of compliance with the national policy requirement regarding lobbying activities is required from all recipients of awards over $100,000. Submission of this certification is required by 31 USC 1352 and is a prerequisite for making or entering into an award over $100,000. Complete Standard Form LLL (Disclosure of Lobbying Activities), if applicable, and attach to Block 18 of the SF424 (R&R) (Application for Federal Assistance) Form.

### B. Representations

**Required Representations:** Corporations must disclosure any Unpaid Federal Tax Liabilities and/or Conviction of Felony Criminal Violations Under Any Federal Law. The form for completion and submission is posted in eBRAP (https://ebrap.org/eBRAP/public/Program.htm).

**Representation Regarding the Prohibition on Using Funds Under Grants and Cooperative Agreements with Entities That Require Certain Internal Confidentiality Agreements:** In accordance with DOD appropriations, the following representation is required. The applicant, by its signature on the SF424 (R&R), represents:

By submission of its application, the applicant represents that it does not require any of its employees, contractors, or subrecipients seeking to report fraud, waste, or abuse to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting those employees, contractors, or subrecipients from lawfully reporting that waste, fraud, or abuse to a designated investigative or law enforcement representative of a federal department or agency authorized to receive such information. Note that: (1) the basis for this representation is a prohibition in Section 743 of the Financial Services and General Government Appropriations Act, 2015 (Division E of the Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113-235) and any successor provision of law on making funds available through grants and cooperative agreements to entities with certain internal confidentiality agreements or statements; and (2) Section 743 states that it does not contravene requirements applicable to FM 312, Form 4414, or any other form issued by a federal department or agency governing the nondisclosure of classified information.

## C. National Policy Requirements

The recipient must comply with the following requirements, as applicable. The full text of National Policy Requirements is available at https://www.nre.navy.mil/work-with-us/manage-your-award/manage-grant-award/grants-terms-conditions. Awards will incorporate the most recent set of National Policy Requirements available at the time of award.

- Nondiscrimination
- Environmental Standards
- Live Organisms (Human Subjects and Animals)
- Debarment and Suspension
- Drug-Free Workplace
- Lobbying
- Officials Not to Benefit
- Hatch Act
- Native American Graves Protection and Repatriation Act
- Fly America Act
- Use of United States Flag Vessels
- Research Misconduct
- Requirements for an Institution of Higher Education Concerning Military Recruiters and Reserve Officer Training Corps
- Historic Preservation
- Relocation and Real Property Acquisition
- Confidentiality of Patient Records
- Pro-Children Act
- Constitution Day
- Trafficking in Persons
- Whistleblower Protections
- Certain Internal Confidentiality Agreements
- FY21 National Defense Authorization Act, Section 223(a), (a1) 18 USC 1001
- FY24 National Defense Authorization Act, Sections 1223 and 1224

## APPENDIX XV: REPORTING REQUIREMENTS

If an application is recommended for funding, there are several types of reporting requirements that may be required per the terms and conditions of the specific award. The award document will specify the nature and frequency of reports, i.e., financial, technical, annual, quarterly, etc. All awards will require, at a minimum, annual and final technical reports. Detailed descriptions of the reporting requirements can be found on the USAMRDC Technical Reporting Requirements website at https://mrdc.health.mil/index.cfm/resources/researcher_resources/reporting/technical.

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

Details regarding Financial Reporting requirements are incorporated by reference into assistance agreements, with the Division III - USAMRAA Addendum to the DOD R&D General Terms and Conditions, available at https://usamraa.health.mil/Pages/Resources.aspx. More general financial information is also incorporated by reference into assistance agreements and can be found in the DOD Research and Development General Terms and Conditions at https://www.nre.navy.mil/work-with-us/manage-your-award/manage-grant-award/grants-terms-conditions. Organizational representatives and PIs should be sure to refer to the terms and conditions that are specific to the fiscal year in which their assistance agreement is issued.