I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Joint Warfighter Medical Research Program

Military Medical Research and Development Award

Intramural Funding Opportunity

Announcement Type: Initial

Funding Opportunity Number: HT9425-23-JWMRP-MMRDA

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), June 15, 2023
- **Invitation to Submit an Application:** July 20, 2023
- **Application Submission Deadline:** 11:59 p.m. ET, September 7, 2023
- **End of Application Verification Period:** 5:00 p.m. ET, September 12, 2023
- **Peer Review:** November 2023
- **Programmatic Review:** January 2024

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

NOTE: 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. This program announcement is intended for intramural applicants only. ***Intramural Submission: 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 academia, biotechnology companies, foundations, government, and research institutes (e.g., intramural investigators submitting through a research foundation). Submissions from extramural investigators to this program announcement will be withdrawn. ***Extramural Submission: Application submitted by a non-DOD organization to Grants.gov.***

Extramural applicants applying through extramural organizations should use the separate program announcement that is available through the electronic Biomedical Research Application Portal (eBRAP) at https://eBRAP.org/ under funding opportunity number HT9425-23-S-JWMRP.

II.A. Program Description

Applications to the Fiscal Year 2023 (FY23) Joint Warfighter Military Research Program (JWMRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC).

The JWMRP was initiated by Congress in 2012 to augment and accelerate high-priority DOD and Service medical requirements and to continue prior year initiatives that are close to achieving their objectives and yielding a benefit to military medicine. The ultimate goal of the program is to expedite the delivery of highly impactful medical solutions to Service Members and Military Health System (MHS) beneficiaries, thus, the Service advanced product development communities are critical partners in executing the JWMRP. Appropriations for the JWMRP from FY12 through FY22 totaled $570 million (M). The FY23 appropriation is $25M.

Congressional direction stipulates that the funds from the JWMRP shall not be used for new projects or for basic research. To be eligible for JWMRP funding, applicants must have already received DOD core or DOD Congressional Special Interest prior year funding (including DOD Small Business Innovation Research [SBIR]/Small Business Technology Transfer [STTR]

awards) for the same project proposed for continuation under this MMRDA program announcement. The funding shall be awarded at DOD discretion following a review of medical research and development gaps as well as unfinanced medical requirements of the Services. The projects funded through this appropriation are expected to benefit both civilian and military communities, with particular focus on initiatives that impact our forward deployed Forces and rehabilitation efforts for injured military.

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

II.A.1. FY23 JWMRP Focus Areas

The JWMRP Programmatic Panel identified the following Focus Areas as the highest priorities for FY23 JWMRP funding to meet critical research and development gaps and Service medical requirements. **To be considered for funding, applications to the FY23 JWMRP must address at least one of the Focus Areas listed under the categories below**.

Endemic and Emerging Disease Threats

Note: **Malaria and COVID proposals are excluded from this solicitation;** ***for this funding opportunity, the JWMRP is soliciting proposals in the late preclinical or early clinical stage of development, preferentially with initial preclinical efficacy and toxicity data.***

- Preventative and therapeutic measures for endemic and emerging infectious diseases
- Preventative and therapeutic measures for combat-associated wound infections in austere, prolonged field care, and large-scale combat environments
- Capabilities to support conducting real-time research during the response to an emerging infectious disease outbreak with a focus on (1) identification and characterization of emerging biothreats, and (2) development of pan-pathogen response tools to improve response and recovery times

Operational Medicine and Readiness

- Research aimed toward injury prevention, rapid return-to-duty capabilities, and rehabilitation solutions to maintain Service Member readiness (musculoskeletal and neurosensory)
- Portable neuromodulation devices that effectively treat behavioral health conditions, including sleep disorders, and alleviate their common comorbidities (e.g., insomnia, pain)
- Criteria and injury prediction models for ballistic/blast and/or accelerative events from loading regimes seen with current and likely future weapons systems, with the goal of informing the development of more effective personal protective equipment
- Innovative strategies and technologies that may include medical devices, pharmaceuticals, rehabilitation strategies, and regenerative medicine-based approaches, to prevent, assess,

diagnose, treat, restore, maintain, and/or rehabilitate sensory system (vision, hearing, and balance) function due to combat-related sensory injuries

Environmental Medicine

- Countermeasures to prevent injury/illness and enhance Service Member performance in extreme cold (Arctic) conditions

- Solutions to enhance the provision of combat casualty care (including tactical combat casualty care, en route care, and damage control surgery) in extreme cold weather environments

Combat Casualty Care

- Modernized combat casualty care capabilities that can deliver lifesaving care at the point of injury, enable prolonged casualty care, provide advanced resuscitative and damage control surgical care, and long-distance en route care consistent with the demands of an all-domain battlespace against a near-peer competitor:

    - Novel solutions for hemorrhage control and resuscitation, including devices for non-compressible torso hemorrhage, drugs that extend the physiologic resuscitation window during hemorrhagic shock, and next-generation blood products and blood substitutes

    - Novel wound solutions for combat wounds, including severe burn and complex wound management

    - Intelligent imaging technologies that provide increased diagnostic capability in the forward operating environment, particularly those that can identify life-threatening hemorrhage or traumatic brain injury, or facilitate early return to duty for less severe injuries

    - Tools that enhance medical decision-making capabilities and reduce cognitive burden on medical providers and Warfighters (e.g., artificial intelligence-based clinical decision support, augmented reality systems, procedural telementoring capabilities)

    - Autonomous care and evacuation capabilities that augment the individual medic/ Warfighter or system to increase the capability and capacity for casualty response

    - Solutions that improve the combat casualty care system's ability to manage large numbers of casualties including improved triage, medical regulating, medical documentation, and evacuation capabilities

    - Prophylactic medical countermeasures for ionizing radiation/nuclear injury

    - Validated training platforms for the acquisition and retention of knowledge, skills, and abilities aligned to wartime medical specialties of the operational force

II.A.2. Award History

JWMRP awards were first offered in FY12. Since the inception of the JWMRP, a total of 179 individual projects have received funding.

II.B. Award Information

The MMRDA mechanism is **intended to fund the logical continuation of previously funded, prior year research or development efforts relevant to the above FY23 JWMRP Focus Areas** with the highest potential to augment and accelerate medical product development and health care solutions for military Service Members, Veterans, their families, other MHS beneficiaries, and/or the American public. The USAMRDC will implement this research program through the awarding of assistance agreements (grants and cooperative agreements), research contracts, or Other Transaction Agreements (OTAs). All invited applicants must submit full applications in accordance with the procedures outlined in this program announcement. Collaboration with DOD organizations is encouraged when this alliance would contribute to the success of the research effort, and any funds designated for DOD laboratories or activities should be identified in the application through submission of a "Suggested Collaborating DOD Military Facility Budget Format" (see Appendix VI, Budget Instructions).

The MMRDA mechanism supports a wide range of research projects, spanning late-stage preclinical studies, late-state technology development efforts, technology demonstration, and translational research.

A **Clinical Research/Trial Option** is available to specifically support clinical research/ observational studies, all phases of clinical trials/interventional studies, and correlative studies in support of the development of promising pharmaceutical or biologic candidates, medical devices, and technologies. ***Note:*** Applications proposing research that constitutes clinical research or a clinical trial will be required to submit additional application materials under the application category designated for this type of research.

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

As of January 20, 2020, U.S. institutions engaged in non-exempt cooperative research ***must*** rely on a single IRB to review and approve the portion of the research conducted at domestic sites in accordance with Code of Federal Regulations, Title 45, Part 46.114(b) (45 CFR 46.114[b]). If

the proposed, non-exempt research involves more than one U.S.-based institution, a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

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

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

Submission Options: Applications must be submitted under one of the two following options. It is important to choose the option that is most appropriate for the proposed research and to submit all of the documents required for the option selected. Please contact the CDMRP Help Desk (at help@eBRAP.org or 301-682-5507) if there is any question as to which option should be selected.

- **Military Medical Research and Development Award (MMRDA)**, for applications proposing research that does *not* constitute clinical research or a clinical trial.

- **Military Medical Research and Development Award – Clinical Research/Trial Option (MMRDA–CRTO)**, for applications proposing research that constitute clinical research or a clinical trial.

The anticipated total costs budgeted for the entire period of performance for an FY23 JWMRP MMRDA should not exceed **$2,300,000, or $3,500,000** for the MMRDA–CRTO. Refer to Section II.D.4, Funding Restrictions, for detailed funding information.

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

The CDMRP expects to allot approximately $11.6M to fund approximately two Military Medical Research and Development Award and two Military Medical Research and Development Award – Clinical Research/Trial Option Award applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY23 funding opportunity will be funded with FY23 funds, which will expire for use on September 30, 2029.

Applications received in response to both the FY23 JWMRP BAA and intramural program announcement will be evaluated and considered for funding together. No advantage is conferred by submitting an application via one funding opportunity versus the other. The government reserves the right to fund any combination of extramural and/or intramural applications.

Use of DOD or Department of Veterans Affairs (VA) Resources: If the proposed research involves access to active-duty military and/or VA patient populations and/or DOD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to Section II.D.2.b.ii, Full Application Submission Components, for detailed information. Refer to Appendix III for additional information.

Research Involving Animals: All DOD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHARO Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is ***not*** required. ***Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

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 extramural organizations

should apply through eBRAP under funding opportunity number HT9425-23-S-JWMRP. These terms are defined below.

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

Intramural DOD Organization: A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission:*** **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.***

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

II.C.1.b. Principal Investigator (PI)

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

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

It is expected that the work funded through this program announcement will be performed by an intramural DOD organization. It is permissible, however, for an extramural investigator to be named as a collaborator in a submission from an intramural investigator. In such cases, the intramural organization will receive all funds and is responsible for executing all necessary awards to collaborating partners through their agency's procedures. Regardless of location, any work that is to be performed by associated non-DOD organizations must be limited to work performed under existing contracts, and resource sharing should be accomplished through Cooperative Research and Development Agreements or Material Transfer Agreements. The government reserves the right to administratively withdraw any application that does not meet these eligibility criteria. ***Applications that require research to be performed by a non-DOD organization under a new service contract will not be considered for funding.***

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

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

II.D. Application and Submission Information

Submission of applications that are essentially identical or that propose research that is not a logical continuation of a previously funded research or development effort will result in administrative withdrawal of the application(s).

Inclusion of classified research data within the application and/or proposing research of which the anticipated outcomes may be classified or deemed sensitive to national security concerns may result in application withdrawal. Refer to the General Application Instructions Appendix 2, Section E.

II.D.1. eBRAP

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs to submit their pre-applications and invited full applications, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

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

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.

Note: Applications from an intramural DOD organization may be submitted to Grants.gov through a research foundation under funding opportunity number HT9425-23-S-JWMRP.

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

Submission is a two-step process requiring both ***pre-application*** and ***full application*** through eBRAP (eBRAP.org) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-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 CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

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

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

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.** ***Note: Applications for this program announcement may only be submitted by intramural organizations. Submissions from extramural DOD organizations to this funding opportunity will be withdrawn.***

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

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.org/). Because the invitation to submit an 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.

The applicant organization and associated PI identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507) and at the discretion of the CDMRP Program Manager.

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

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

- **Tab 1 – Application Information**

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

- **Tab 2 – Application Contacts**

  Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration. The Business Official must be either selected from the eBRAP list or invited in order for 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.**

  Select the organization submitting on behalf of the PI and click on "Add Organizations to this Pre-application." The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

  It is recommended that PIs 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.

  FY23 JWMRP Programmatic Panel members should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to Section II.H.1.c, Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

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

- **Tab 5 – Pre-Application Files**

  Note: Upload documents as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

  Note: No figures, charts, graphs, or other additional material will be accepted during the pre-application process.

  Provide responses to the questions in the **FY23 JWMRP Pre-Application Template**. The template and the Clinical Trial and Technology/Knowledge Readiness Level Definitions are posted in eBRAP for your use.

  The submitted, completed FY23 JWMRP Pre-Application Template should not exceed five pages. The maximum period of performance for applications submitted to the FY23 JWMRP is 3 years with a budget not to exceed $2,300,000 total costs for the MMRDA or $3,500,000 total costs for the MMRDA–CRTO.

Pre-applications should be submitted under one of the following submission options in eBRAP:

- ***MMRDA – Military Medical Research and Development Award; or***
- ***MMRDA–CRTO – Military Medical Research and Development Award – Clinical Research/Trial Option***

Note: Upload the completed FY23 JWMRP Pre-Application Template as an individual PDF file. eBRAP will not allow the file to be uploaded if the number of pages exceeds the limit specified above.

- **Tab 6 – Submit Pre-Application**

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

Pre-Application Screening

- **Pre-Application Screening Criteria**

  To determine the technical merits of the pre-application and the relevance to the mission of the Defense Health Program (DHP) and the JWMRP, pre-applications will be screened based on the following criteria:

  - Whether the pre-application describes the continuation of a prior year effort that is ongoing/active at the time of pre-application submission or that completed no more than 2 years prior to the pre-application submission deadline.
  - Whether the pre-application describes the continuation of a prior year effort that has already achieved a Technology Readiness Level (TRL)/Knowledge Readiness Level (KRL) of 5 or greater.
  - Whether the PI for the proposed follow-on effort is the same as the PI of the prior year effort described in the pre-application.
  - How well the pre-application describes a follow-on effort that is a logical continuation of a previously funded, prior year research or product development effort, while avoiding interdependency of aims.
  - How well the proposed research or development effort addresses one or more of the FY23 JWMRP Focus Areas.
  - Relative potential of the proposed effort to augment and/or accelerate clinical, technical, or materiel/knowledge product development with a clear benefit to military medicine.
  - How well the pre-application adequately describes the products or deliverables expected from the proposed follow-on effort and any associated challenges.
  - How well the regulatory strategy, commercialization strategy, and the estimated

TRL/KRL demonstrates transition potential of the anticipated product/outcome.

- **Notification of Pre-Application Screening Results**

  Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated in Section I, Overview of the Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

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

Applications will not be accepted unless notification of invitation has been received.

Full application components, which are listed in Table 1 below, must be submitted by the PI through eBRAP.

II.D.2.b.i. Full Application Guidelines

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

Table 1. Full Application Submission Guidelines

Download application package components for HT9425-23-JWMRP-MMRDA from eBRAP (https://ebrap.org).
Full Application Package Components
Tab 1 – Summary: Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Tab 3 – Full Application Files: Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel • Budget • Performance Sites **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.
Application Package Submission
Submit package components to eBRAP (https://ebrap.org). **Tab 5 – Submit/Request Approval Full Application:** After all components are 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

notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. ***Do not password protect any files of the application package, including the Project Narrative.***
Application Verification Period
After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.
Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

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

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

For the intramural FY23 JWMRP MMRDA, the eBRAP 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. Page limits are validated as a document is uploaded. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specific below.

- **Tab 1 – Summary:** Provides a summary of the application information.
- **Tab 2 – Application Contacts:** This tab will be populated by eBRAP. Edit contact information as applicable.
- **Tab 3 – Full Application Files:** Under each Application Component in eBRAP, upload each as an individual PDF file.

  Application Component - 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 V.

  For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 megabytes (MB), and the file size for the entire full application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (20-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

  Describe the proposed project in detail using the outline below.

  Background/Rationale:

  - Describe the previously funded research or product development effort identified in the notification of invitation, including a description of the accomplishments and outcomes from that award. Explain how this proposed effort is a logical continuation of the previous research or product development effort.

  - Explain how the research has the potential to augment and/or accelerate medical product development in at least one of the FY23 JWMRP Focus Areas.

  - Present the scientific rationale behind the proposed research or product development effort, including relevant literature citations, preliminary data, and/or preclinical data that led to the development of the proposed research, to support feasibility. Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team.

  - Describe previous experience among members of the project team most pertinent to the proposed research.

  - Clearly demonstrate that there is sufficient scientific evidence to support moving into the proposed stage of research.

  - As applicable to the proposed research, provide a summary of relevant studies, clinical studies or clinical trials, and distinguish how the proposed study differs from other relevant or recently completed research or clinical trials. If applicable, include a discussion of any current clinical use of the intervention under investigation and/or details of its study in clinical trials for other indications.

  - **Hypotheses/Objectives:** State the hypotheses to be tested and/or the objective(s) 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 this application is part of a larger study, present only tasks that this award would fund. Avoid interdependency of specific aims when possible (i.e., dependency on successful outcomes of other ongoing related research efforts).

– **Research Strategy and Feasibility:**

  - Describe the experimental design, methods, and analyses, including appropriate controls, choice of animal model (if applicable), and the endpoints/outcome measures to be used, in sufficient detail for evaluation of feasibility and effectiveness in supporting completion of the project aims.

  - Applications that include research on animal models are also required to submit Attachment 7, Animal Research Plan.

  - Applications that include human subjects, human biological samples, or correlated data are also required to submit Attachment 9, Human Subjects/Sample Acquisition and Safety Procedures.

  - Describe potential problem areas and discuss alternative methods/approaches that may be employed to overcome them, including interdependency of aims (i.e., dependency on successful outcomes of other ongoing related research efforts).

  For applications submitted under the Clinical Research/Trials Option:

  - Provide detailed plans for initiating and conducting the clinical trial during the course of this award. Describe the type of clinical trial to be performed (e.g., treatment, prevention, diagnostic), the phase of trial and/or class of device (as appropriate), and the study model (e.g., single group, parallel, crossover).

  - Identify and describe the hypothesis/intervention to be studied and the projected outcomes.

  - Define the study variables and how they will be measured. Include a description of appropriate controls and the endpoints to be tested.

  - Provide a brief description of the study population, criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual of human subjects, samples, and/or correlated data.

  - Describe measures that will be taken to reduce bias, such as blinding of subjects, clinicians, data analysts, and/or others during the study.

  - Discuss risk/benefit considerations, including a clear and detailed description of potential ethical issues raised by the proposed study, and a detailed plan for how the ethical issues will be addressed.

  - Document the availability and accessibility of the drug/compound, device, or other materials needed for the duration of the proposed study, and describe how quality control will be addressed.

  - Describe the potential for subject loss to follow-up, and how such loss will be handled/mitigated.

- **Data and Statistical Analysis Plan:**

  - Describe how data will be collected and analyzed in a manner that is consistent with the study objectives. If applicable, include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. Specify the approximate number of human subjects/samples that will be accrued, if applicable. If multiple study sites are involved for human subject recruitment, state the approximate number to be enrolled at each site.

  - 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), if applicable.

- **Study Personnel:** Identify the key members of the study team and describe their roles on the project, including sufficient clinical and/or statistical expertise. For studies involving human subjects, an independent research monitor (external to the study), study coordinator(s), and statistician should be included as applicable.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

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

  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.

  - **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.

- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- **Letters of Organizational Support:** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.

- **Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual or organization demonstrating that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- **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.

  - **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 how data and resources generated during the performance of the project will be shared with the research community. Refer to Appendix IV, Section J, for more information about the CDMRP expectations for making data and research resources publicly available.

- **Traumatic Brain Injury (TBI) Data Reporting (if applicable):** For projects involving TBI, PIs may be required to report data to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system (https://fitbir.nih.gov/). While there is no direct charge to users of the FITBIR informatics system, a project estimation tool (https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp) is available to help estimate costs and manpower needs that may be associated with data submission.

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

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

- **Use of VA Resources (if applicable):** Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation (NPC) is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

- **Attachment 3: Abstracts (one-page limit each): Upload as "Abstracts.pdf".**

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

  Technical abstracts should be written using the outline below. The technical abstract should provide an appropriate description of the project's key aspects; therefore, clarity and completeness within the space limits of the technical abstract are highly important.

  - **Background:** State how the proposed research addresses at least one of the FY23 JWMRP Focus Areas. Present the scientific rationale behind the proposed work. Include the current TRL/KRL of the product or knowledge outcome (must be 5 or greater), and the estimated target TRL/KRL upon completion of the proposed research.

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

  - **Specific Aims:** State the specific aims of the study.

  - **Study Design:** Briefly describe the study design including appropriate controls.

  - **Impact:** Highlight the likely contributions of the initiative to augment and/or accelerate a product development effort. Briefly explain how the proposed project will have an immediate or potential long-term benefit that may lead to a major impact on the health and well-being of Service Members, Veterans, their families, and/or the American public.

  Lay Abstract (one-page limit): The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. Do not include proprietary or confidential information. Do not duplicate the technical abstract. Use only characters

available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the outline below. Minimize use of acronyms and abbreviations, where appropriate.

- Describe the rationale, scientific objective, and aims for the proposed project in a manner that will be readily understood by readers without a background in science or medicine.

- State the FY23 JWMRP Focus Area(s) that the project addresses.

- What are the military benefits of the proposed project and the potential impact on the health and welfare of military Service Members, Veterans, their families, and/or the American public?

- Describe the ultimate applicability of the research.

  - What types of patients will it help, and how will it help them?

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

  - What is the projected time it may take to achieve a patient-related outcome?

  - If the research will not result in immediate clinical applicability, describe the interim outcomes.

- What are the likely contributions of the study to augment and/or accelerate a product development effort?

- **Attachment 4: Statement of Work (six-page limit): Upload as "SOW.pdf".** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). Recommended strategies for assembling the SOW can be found at https://ebrap.org/eBRAP/public/Program.htm.

  Refer to the **"*Suggested SOW Strategy Generic Research*"** document for the MMRDA mechanism or the "***Suggested SOW Strategy Clinical Research***" for the MMRDA–CRTO mechanism. The SOW must be in PDF format prior to attaching.

- **Attachment 5: Impact Statement (two-page limit): Upload as "Impact.pdf".** Explain why the proposed research or product development effort is important and relevant to the role of the JWMRP in addressing high-priority DOD medical requirements and capability gaps and accelerating the development of products that will impact the Warfighter within the context of the FY23 JWMRP Focus Area(s) being addressed.

  - ***Describe the potential impact on civilian and military populations:*** Provide information about the incidence and/or prevalence of the disease or condition in the

general population, as well as in military Service Members, Veterans, and/or their beneficiaries. 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. Describe how the research will result in faster and/or better delivery of health care solutions for the Warfighter.

- ***Describe the short-term impact:*** Detail the anticipated short-term outcome(s)/ product(s) (knowledge and/or materiel) that will be directly attributed to the results of the proposed research or product development effort and describe how they will impact the relevant populations. Describe how the study will augment and/or accelerate product development, as applicable.

- ***Describe the long-term impact:*** Explain the anticipated long-term gains from this research and describe how they may impact the health and readiness of Warfighters. Compare to the information known/products currently available, as applicable.

- **Attachment 6: Transition Plan (three-page limit): Upload as "Transition.pdf".** Describe/discuss the methods and strategies proposed to move the product/knowledge/ intervention to the next phase of development (clinical trials, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Demonstrate how the proposed product or knowledge outcome is currently at a minimum TRL or KRL of 5, and estimate the target TRL/KRL upon completion of the proposed research (Appendix II). Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development. The plan for post-award transition of the anticipated research outcomes should include the components listed below, as appropriate and applicable to the research proposed.

  - Details of the funding strategy to transition to the next level of development and/or commercialization (e.g., specific 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.

  - 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 (CPGs) and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. (A "knowledge product" is a non-materiel product that addresses an identified need, topic area, or capability gap, is based on current evidence and research, aims to transition into medical practice, training, tools, or to support materiel solutions [systems to develop, acquire, provide, and sustain medical solutions and capabilities], and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.)

- A brief schedule and milestones for transitioning the anticipated research outcomes to the next phase of development (i.e., next-phase clinical trials, commercialization/ transition to industry, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by a Regulatory Agency).

- Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government's ability to access such products or technologies in the future.

- If prior federally funded SBIR/STTR data supports the proposed follow-on development effort, describe the connection between the prior SBIR/STTR and the current project and explain all active SBIR/STTR data rights.

- If applicable, state and identify the proprietary information that will be provided to the government and indicate whether the applicant will require a waiver of the federal purpose license.

- If applicable, a risk analysis for cost, schedule, manufacturability, and sustainability.

- **Attachment 7: Animal Research Plan (if applicable; three-page limit): Upload as "AnimalResPlan.pdf".** If the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. ***Proposed studies should not rely on samples, reagents, or tools that are contingent upon completion of other ongoing efforts outside the scope of this proposal.*** Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. In accordance with the ARRIVE 2.0 (*Animal Research: Reporting In Vivo Experiments*) guidelines (https://arriveguidelines.org/arrive-guidelines), the Animal Research Plan should address the following points for each proposed animal study:

  - Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.

  - Summarize the procedures to be conducted. Describe how the study will be controlled.

  - Describe the randomization and blinding procedures for the study and 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 endpoints(s).

- Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

- **Attachment 8: Intervention (if applicable*; required for clinical trial applications submitted under the Clinical Research/Trials Option*) (no page limit): Upload as "Intervention.pdf".** The Intervention attachment should include the components listed below.

  - **Description of the Intervention:** Identify the intervention to be tested and describe the particular outcomes. Describe how the intervention addresses high-priority clinical needs and represents an advancement over currently available interventions and/or standards of care. As applicable, the description of the intervention should include the following components: complete name and composition, storage and handling information, source, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed. Description of devices should include general concept of design, detailed operational instructions, any potential risks to users, and intended benefits. Other types of interventions should be fully described. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights for conduct of the clinical trial.

    Summarize key preclinical pharmacological findings, dosage studies, and other clinical studies (if applicable) that examine the safety and stability (as appropriate) of the intervention. Describe measures to ensure consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).

  - **Study Procedures:** Describe the interaction with the human subject, including the study intervention that he/she will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will experience. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures. Clearly delineate research procedures from routine clinical procedures. Discuss how compliance with current Good Laboratory Practice (GLP) guidelines, Good Manufacturing Practice (GMP), and other regulatory considerations will be established, monitored, and maintained, as applicable.

  - **Clinical Monitoring Plan:** Describe how the study will be conducted by and monitored for current ICH E6 (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) Good Clinical Practice (GCP) compliance, by an independent clinical trial monitor (or clinical research associate). The monitoring plan should describe the types of monitoring visits to be conducted, the intervals (based on level of risk), how corrective actions will be reported to the Sponsor and PI, and how they will be corrected and prevented by the clinical trial site/PI.

- **Attachment 9: Human Subjects/Sample Acquisition and Safety Procedures (if applicable*; required for all applications submitted under the Clinical Research/Trials***

Option* (no page limit): Upload as "HumSubProc.pdf".** If the proposed study involves human subjects, human biological samples, or correlated data the applicant is required to submit a summary describing the human research that will be conducted. ***Proposed studies should not rely on samples, reagents, or tools that are contingent upon completion of other ongoing efforts outside the scope of this proposal.

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

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

- **Women and Minorities in the Study:** Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The Public Health Service (PHS) Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. Include an appropriate justification if women and/or minorities will be excluded from the clinical trial.

- **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care provider identification).

  - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.

  - If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan.

  - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.

- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.

  - ***For the proposed study, provide a draft, in English, of the Informed Consent Form.***

  - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.

  - 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 the potential human subject will be allowed to discuss the study with anyone before making a decision.

  - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.

  - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. ***Note:*** In compliance with 10 USC 980 (https://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf), the application must describe a clear intent to benefit for

human subjects who cannot give their own consent to participate in the proposed clinical trial. If applicable, refer to Appendix III for more information.

- ***Assent:*** If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, 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 trial. Consider psychological, legal, social, and economic risks as well as physical risks. Consider how the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study. 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, 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 10: Regulatory Strategy (if applicable; *relevant for all product development efforts and required for all applications submitted under the Clinical Research/Trials Option)* (no page limit). If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".** Answer the following questions and provide supporting documentation as applicable.

  – State the product/intervention name.

  For products/interventions that do not require regulation by a Regulatory Agency:

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

  For products/interventions that require regulation by a Regulatory Agency:

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

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

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

  – If the proposed research or trial requires an Investigational New Drug (IND) application or an Investigational Device Exemption (IDE) application, the application

must be submitted to the FDA by/before September 30, 2024. 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. The government reserve the right to withdraw funding if an IND or IDE is necessary but has not been submitted to the FDA by/before ***September 30, 2024***.

- If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed. The government reserves the right to withdraw funding if this documentation has not been obtained by ***March 31, 2025***.

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

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

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

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

- **Attachment 11: Data Management (if applicable; *required for all applications submitted under the Clinical Research/Trials Option*) (no page limit): Upload as "Data_Manage.pdf".** The Data Management attachment should include the components listed below.

- **Data Management:** Describe the data to be gathered and all methods used for collection, including the following:

  - **Data:** The types of data, software, or other materials to be produced.

  - **Acquisition and processing:** How the data will be acquired, including the time and location of data acquisition, if scientifically pertinent. If use of existing data resources is proposed, describe the origin of the dataset. Provide an account of the standards to be used for data and metadata format and content. Explain how the data will be processed.

  - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.

  - **Confidentiality:**

    - Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.

    - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of the DOD are eligible to review study records.

    - Address the requirements for reporting sensitive information to state or local authorities.

  - **Data capture, verification, and disposition:** Describe how data will be captured and verified, including the quality assurance and quality control measures taken during collection, analysis, and processing. Describe where data (both electronic and hard copy) will be stored; who will keep the data; how the data will be stored, if applicable; the file formats and the naming conventions that will be used; the process for locking the database at study completion; and the length of time that data will be stored, along with a justification for the time frame of preservation, which may include considerations related to the balance between the relative value of data preservation and other factors such as the associated cost and administrative burden of data storage. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. Describe the database lock process. For studies requiring Regulatory Agency oversite, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) is required.

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

        - **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether the results of screening and/or study participation will be shared with human subjects or their primary care provider, including results from any screening or diagnostic tests performed as part of the study. In cases of national security or controlled unclassified information concerns, include a statement that the data cannot be made available to the public (e.g., "This data cannot be cleared for public release in accordance with the requirements in DoD Directive 5230.09.").

    - **Laboratory Evaluations:**

        - **Specimens to be collected, schedule, and amount:** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.

        - **Evaluations to be made:** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).

        - **Storage:** Describe specimen storage, including location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the plan to store specimens for future use, including considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.

        - **Labs performing evaluations and special precautions:** Identify the laboratory performing each evaluation, the applicable quality standard, and any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.

- **Attachment 12: Study Personnel and Organization (if applicable; *required for all applications submitted under the Clinical Research/Trials Option*) (no page limit): Start each document on a new page. Combine into one document and upload as "Personnel.pdf".** The Study Personnel and Organization attachment should include the components listed below.

    - **Organizational Chart:** Provide an organizational chart that identifies key members of the study team and provides an outline of the governing structure for multi-institutional studies. Identify collaborating organizations, centers, and/or departments and name each person's position on the project. Include any separate laboratory or testing centers. Identify the data and clinical coordinating center(s) and note any involvement from Contract Research Organizations, as appropriate. Identify and provide justification for the inclusion of international sites, as appropriate. If applicable, identify the Regulatory Agency sponsor and any external consultants or other experts who will assist with Regulatory Agency sponsor applications. While

there is no specified format for this information, a table(s) or diagram is recommended. ***Note:*** This item may be made available for programmatic review.

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

- **Study Management Plan:** Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial involves more than one institution, clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. Provide a regulatory submission plan for the master protocol and master consent form by the lead institution. If the research involves more than one institution, a single IRB is required for all institutions located in the United States. If applicable, describe how communication and data transfer between/among the collaborating institutions will occur, as well as how data, specimens, and/or imaging products obtained during the study will be handled and shared.

- **Attachment 13: Questionnaires and Other Research Data Collection Instruments (if applicable; no page limit): Upload as "Data_Collection.pdf".** The Questionnaires and Other Research Data Collection Instruments attachment should include a copy of the most recent version of questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study. Describe how and when the instrument(s) will be administered. Describe how the instrument(s) will be adapted to the subject population, if applicable.

Application Component – Research & Related Personal Data

This form will be used by DOD as the source of demographic information, such as gender, race, ethnicity, and disability information, for the Project Director (PD)/PI and all other persons identified as Co-PD(s)/Co-PI(s).

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 merit reviewers. Applicants who do not wish to provide some or all of the information should check or select the "Do not wish to provide" option.

Upload the Research & Related Personal Data Form as "PersonalData_LastName.pdf" under the Key Personnel Application Components.

Application Component – Research & Related Senior/Key Person Profile

- **Research & Related Senior/Key Person Profile (Expanded):** The Degree Type and Degree Year fields on the Research and Related Senior/Key Person Profile (Expanded) will be used by the DOD as the source for career information. In addition to the required fields on the form, applicants must complete these two fields for all individuals that are identified as having the project role of PD/PI or Co-PD/Co-PI on the form. Additional senior/key persons can be added by selecting the "Next Person" button.

  Upload the Research & Related Senior/Key Person Profile (Expanded) as "KeyPersonnel_LastName.pdf" under the Key Personnel Application Components.

  - PI Biographical Sketch (six-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The National Institutes of Health (NIH) Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.

  - PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

  - Key Personnel Biographical Sketches (six-page limit each): Upload as "Biosketch_LastName.pdf".

  - Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

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

  - Certify that the current and pending support provided on the application is current, accurate, and complete;

  - Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and

  - Have been made aware of the requirements under Section 223(a)(1) of this Act.

  False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (U.S. Code, Title 18, Section 1001).

Application Component – Budget

Use the Suggested DOD Military Facility Budget Format available for download on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/

public/Program.htm). Refer to Appendix VI for detailed information on completing this form.

- Upload the DOD Military Budget Format and Justification form as "MFBudget.pdf."

- Budget Justification (no page limit): Upload as "BudgetJustification.pdf". The budget justification must include a Federal Agency Financial Plan, as described in Appendix VI. The budget justification for the *entire* period of performance must be included.

- Subaward Budget: Include all Subaward budgets. Describe in detail funding arrangements with extramural partners (if applicable). For each subaward (intramural or extramural), complete a separate detailed budget using the DOD Military Budget Format and Justification form including a budget justification for each subaward in accordance with the instructions listed above. Title each individual subaward "Budget" or "Budget Justification," with the name of the subawardee/subrecipient organization. Refer to Appendix VI for detailed information on completing this form.

Application Component – 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.

- **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 of the 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 Resource Manager/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.

II.D.3. Submission Dates and Times

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity. Pre-application and application submissions are required. 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.

Applicant Verification of Full Application Submission in eBRAP

eBRAP allows an organization's representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***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 application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

After eBRAP has processed the full application, the organizational Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official and PI (or PIs, if application involves multiple/Partnering PIs) will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified. The Resource Manager/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.

Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

II.D.4. Funding Restrictions

The maximum period of performance is **3** years.

The application's total costs budgeted for the entire period of performance should not exceed **$2,300,000 for the MMRDA or $3,500,000 for the MMRDA–CRTO**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

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

- Travel between collaborating organizations
- Travel costs for one investigator to disseminate project results at two separate DOD-sponsored meetings (e.g., the MHS Research Symposium)
- Travel costs for one investigator to travel to one scientific/technical meeting per year, after the first year of the period of performance, to present project information or disseminate project results from the FY23 JWMRP MMRDA

Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators. Out-year funds may not be available in the event that subsequent annual congressional appropriations are not authorized. Intramural applicants should have a plan in place for accepting the entire award amount up front and managing those funds throughout the life of the award. If such a plan is not feasible, intramural applicants may consider working with a foundation.

Refer to Appendix VI for budget regulations and instructions. ***For federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in Appendix VI.***

II.D.5. Other Submission Requirements

Refer to Appendix V for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications will be evaluated according to the following **scored criteria**, which are of equal importance:

- **Research Strategy and Feasibility**
    - How well the application presents the scientific rationale behind the proposed research or product development effort, including relevant literature citations, preliminary data, and/or preclinical data, to support feasibility.
    - How well the application states the hypotheses to be tested and/or the objective(s) to be reached.
    - How well the application describes the experimental design, methods, and analyses, including appropriate controls, choice of animal model (if applicable), and the endpoints/

outcome measures to be used, in sufficient detail for evaluation of feasibility and effectiveness in supporting completion of the project aims.

- Whether the SOW indicates a feasible plan and timeline to conduct the research and how well it provides clearly defined milestones to be accomplished.

- How well the application describes potential problem areas and discusses alternative methods/approaches that may be employed to overcome them, including interdependency of aims (i.e., dependency on successful outcomes of other ongoing related research efforts).

***For applications submitted under the Clinical Research/Trials Option*:**

- As applicable, how well the application describes the type of clinical trial to be performed, the phase of trial and/or class of device, and the study model.

- How well the application identifies and describes the hypothesis/intervention to be studied and the projected outcomes.

- To what degree the intervention addresses high-priority clinical needs and represents an advancement over currently available interventions and/or standards of care.

- To what degree the application includes preclinical and/or clinical evidence to support the safety and stability (as appropriate) of the intervention.

- How well the application documents access to the intellectual property rights to the intervention for the duration of the proposed clinical trial (if applicable).

- How well the application provides a brief description of the study population, criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual of human subjects, samples and/or correlated data.

- Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.

- How well the application describes the plan for obtaining informed consent from human subjects.

- Whether the application demonstrates that the research team has access to the proposed study population at each site, and describes the efforts that will be made to achieve accrual goals.

- How well the application addresses any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment and/or subject loss to follow-up.

- How well the application describes measures that will be taken to reduce bias, such as blinding of subjects, clinicians, data analysts, and/or others during the study.

- How well research procedures are delineated from routine clinical procedures.
- How well the application discusses risk/benefit considerations, including a clear and detailed description of potential ethical issues raised by the proposed study, and a detailed plan for how the ethical issues will be addressed.
- How well the application explains measures taken to protect the privacy of human subjects and maintains confidentiality of study data.

- **Data and Statistical Analysis Plan**
  - To what degree the data analysis plan is consistent with study objectives.
  - To what degree the statistical plan, including power analysis for sample size projections, is appropriate to meet the objectives of the study.
  - To what degree the application describes how the data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

- **Impact**
  - The degree to which the proposed effort is relevant to the role of the JWMRP in addressing high-priority DOD medical requirements and capability gaps and accelerating the development of products that will impact the Warfighter within the context of the FY23 JWMRP Focus Area(s) being addressed.
  - To what degree the knowledge, technologies, or products gained from the research could benefit the civilian population and also address the health care needs of military Service Members, Veterans, and/or their beneficiaries.
  - To what degree the research will result in faster and/or better delivery of high-priority health care solutions for the Warfighter.
  - To what degree the anticipated short-term outcomes(s)/products(s) (knowledge and/or materiel) of the proposed effort will impact the relevant populations, and augment and/or accelerate product development as applicable.
  - How significantly the long-term gains from this research may impact the health and readiness of Warfighters.

- **Transition Plan and Regulatory Strategy**
  - Whether the transition plan and regulatory strategy are appropriate and well described.
  - Whether the proposed research meets a current TRL or KRL of 5 or higher, and whether the proposed target TRL or KRL is realistic and appropriate.

- Whether the funding strategy to transition to the next level of development and/or commercialization (e.g., specific industry partners, specific funding opportunities to be applied for) is reasonable and achievable.

- For knowledge products, whether the proposed collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of CPGs and recommendations, provider training materials, patient brochures, clinical support tools, scientific journal publications, models, simulations, and applications are established and/or achievable.

- Whether the schedule and milestones for transitioning the anticipated research outcomes to the next phase of development (i.e., next-phase clinical trials, commercialization/ transition to industry, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by the FDA) are achievable.

- How well the application identifies intellectual property ownership rights and/or demonstrates the appropriate access to the intellectual property necessary for the development and/or commercialization of products or technologies supported by this program announcement, and identifies the government's ability to access such products or technologies in the future.

- How well the application describes any active SBIR/STTR data rights (if applicable).

- How well the application describes an appropriate Intellectual and Material Property Plan for resolving intellectual and material property issues among participating organizations (if applicable).

- If applicable, whether the risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.

- The extent to which the regulatory strategy to support the product label indication or product label change, if applicable, is appropriate and well described.

- Whether the application explains why the product/intervention is exempt from FDA oversight, or, for products that require FDA regulation, whether the plans/timeline for IND or IDE application submission to the FDA are appropriate, or the IND or IDE submission has already taken place.

- If clinical studies will be conducted outside of the United States, whether there is documentation of pre-IND communication between the applicant and the FDA regarding phase 1 studies.

- Whether the identified status for manufacturing development, non-clinical development, and clinical development demonstrates readiness for the next level of development and/or commercialization.

- Whether the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy are appropriate.

- Whether plans to comply with GMP, GLP, and GCP guidelines are appropriate.

- **Personnel**

  - To what degree the study personnel's background and expertise are appropriate with respect to its ability to perform the proposed work, including whether there is evidence of sufficient clinical and/or statistical expertise (as applicable).

  - To what degree the levels of effort by the PI and other key personnel are appropriate for successful conduct of the proposed work.

  - How the PI's record of accomplishment demonstrates their ability to accomplish the proposed work.

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

- **Environment**

  - How the scientific environment is appropriate for the proposed research and/or product development effort.

  - How the research and/or product development requirements are supported by the availability of, and accessibility to, facilities and resources (including collaborative arrangements).

  - How the quality and extent of institutional support are appropriate for the proposed effort.

- **Budget**

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

  - Whether the budget is appropriate for the proposed research.

- **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 mission of the DHP and FY23 JWMRP, as evidenced by the following:
    - Military relevance, including alignment with and balance within and across the identified DOD and Services medical research priorities and portfolios
    - Relative potential of the research to augment and/or accelerate clinical, technical, or materiel/knowledge product development efforts that directly benefit military medicine
    - Relative transition potential of the anticipated product/outcome
    - Relative impact of the research on Service Members, Veterans, and their families

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. An information paper describing the funding recommendations and review process for the MMRDA and the MMRDA–CRTO will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

II.E.3. Anticipated Announcement and Federal Award Dates

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

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY23 funds are anticipated to be made no later than September 30, 2024. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

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

Federal Government Organizations: Funding made to federal government organizations (to include intramural DOD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Funds will be transferred to organizations, not to individual PIs. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

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

Refer to Appendix IV, Section B, for general information on changes to PIs and organizational transfers.

II.F.2. Reporting

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

Annual progress reports with quad charts, as well as a final progress report with quad chart will be required. The Award Terms and Conditions will specify if additional and/or more frequent reporting is required.

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

PHS Inclusion Enrollment Reporting Requirement: Enrollment reporting on the basis of sex/gender, race, and ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

Awards resulting from this program announcement may incorporate additional reporting requirements related to recipient integrity and performance matters.

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to program announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET (closed on most U.S. federal holidays). Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

II.H. Other Information

II.H.1. Administrative Actions

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

II.H.1.a. Rejection

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

- Completed FY23 JWMRP Pre-Application is missing.
- FY23 JWMRP Pre-Application Template exceeds page limit.

The following will result in administrative rejection of the application:

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

For applications involving animal research:

- Attachment 7, Animal Research Plan is missing.

For applications submitted under the Clinical Research/Trials Option:

- Attachment 9, Human Subjects/Sample Acquisition and Safety Procedures is missing.
- Attachment 10, Regulatory Strategy is missing.
- Attachment 11, Data Management is missing.

II.H.1.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the **FY23 JWMRP Pre-Application and Application Project Narrative**.
- Documents not requested will be removed.

II.H.1.c. Withdrawal

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

- An FY23 JWMRP 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. ***A list of the FY23 JWMRP Programmatic Panel members can be found at https://cdmrp.health.mil/jwmrp/panels/panels23.***
- 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.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY23, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Pre-applications or applications from extramural organizations, including non-DOD federal agencies.

- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Application includes research data that are classified and/or proposes research of which the anticipated outcomes are classified or deemed sensitive to national security will be considered for application withdrawal.
- The application does not address at least one of the FY23 JWMRP Focus Areas.
- The invited application proposes a different research project than that described in the pre-application.
- The invited application proposes research that is not a logical continuation of the previously funded research or development effort identified in the notification of invitation.

II.H.1.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.2. Application Submission Checklist

Application Components	Action	Completed
Summary (Tab 1) and Application Contacts (Tab 2)	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Abstracts: Upload as Attachment 3 with file name "Abstracts.pdf"	
	Statement of Work: Upload as Attachment 4 with file name "SOW.pdf"	
	Impact Statement: Upload as Attachment 5 with file name "Impact.pdf"	
	Transition Plan: Upload as Attachment 6 with file name "Transition.pdf"	
	Animal Research Plan: Upload as Attachment 7 with file name "AnimalResPlan.pdf" if applicable	
	Intervention: Upload as Attachment 8 with file name "Intervention.pdf" if applicable	
	Human Subjects/Sample Acquisition and Safety Procedures: Upload as Attachment 9 with file name "HumSubProc.pdf" if applicable	
	Regulatory Strategy: Upload as Attachment 10 with file name "Regulatory.pdf" if applicable	
	Data Management: Upload as Attachment 11 with file name "Data_Manage.pdf" if applicable	
	Study Personnel and Organization: Upload as Attachment 12 with file name "Personnel.pdf" if applicable	
	Questionnaires and Other Research Data Collection Instruments: Upload as Attachment 13 with file name "Data_Collection.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

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

APPENDIX I: ACRONYM LIST

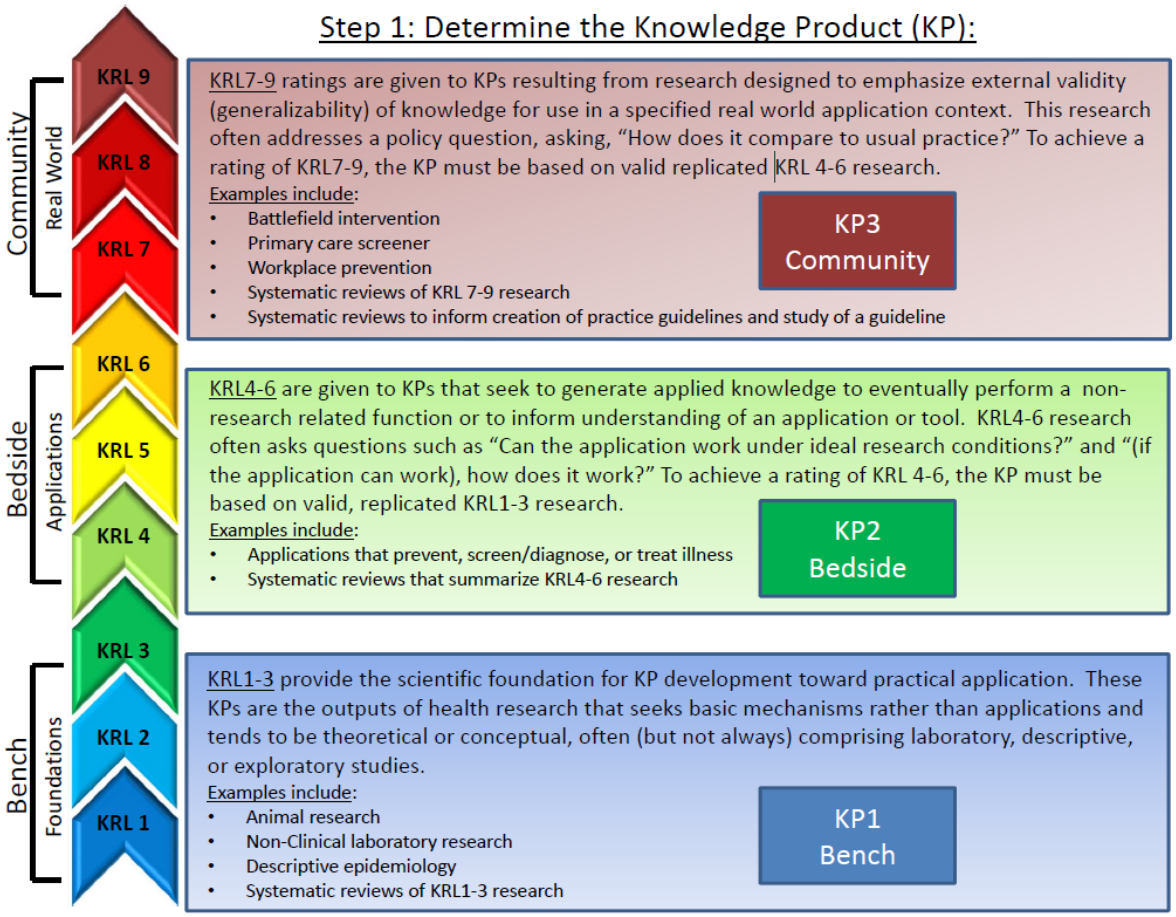
ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
ARRIVE	Animal Research: Reporting In Vivo Experiments
BAA	Broad Agency Announcement
CDC	Centers for Disease Control and Prevention
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CPG	Clinical Practice Guideline
DA PAM	Department of the Army Pamphlet
DHHS	U.S. Department of Health and Human Services
DHP	Defense Health Program
DOD	Department of Defense
DoDI	DoD Instructions
DTIC	Defense Technical Information Center
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FITBIR	Federal Interagency Traumatic Brain Injury Research
FOIA	Freedom of Information Act
FWA	Federalwide Assurance
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HIPAA	Health Insurance Portability and Accountability Act
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
ICH E6	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
IRP	Inquiry Review Process
JWMRP	Joint Warfighter Medical Research Program

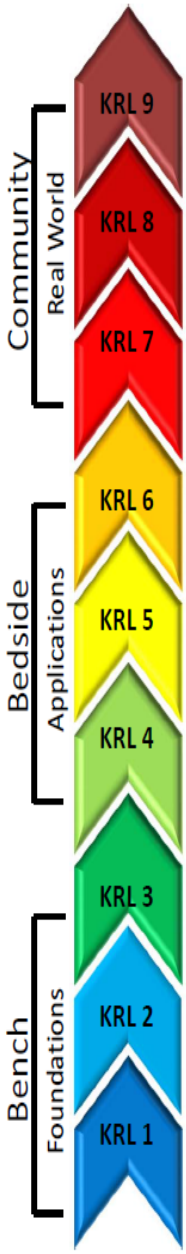
KRL	Knowledge Readiness Level
LAR	Legally Authorized Representative
LSGD	Large-Scale Genomic Data
M	Million
MB	Megabyte
MDO	Multi-Domain Operation
MHS	Military Health System
MIPR	Military Interdepartmental Purchase Request
MMRDA	Military Medical Research and Development Award
MMRDA–CRTO	Military Medical Research and Development Award – Clinical Research/Trials Option
NIH	National Institutes of Health
NPC	Non-Profit Corporation
OHARO	Office of Human and Animal Research Oversight
OHRO	Office of Human Research Oversight
ORCID	Open Researcher and Contributor ID, Inc.
PD	Project Director
PHS	Public Health Service
PI	Principal Investigator
PII	Personally Identifiable Information
RDT&E	Research, Development, Test and Evaluation
SBIR	Small Business Innovation Research
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
STTR	Small Business Technology Transfer
TBI	Traumatic Brain Injury
TRA	Technology Readiness Assessment
TRL	Technology Readiness Level
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs

APPENDIX II: TECHNOLOGY READINESS LEVELS AND KNOWLEDGE READINESS LEVELS

Technology Readiness Levels: TRLs are used to categorize the product maturity of materiel solutions. The DOD's Technology Readiness Assessment (TRA) Deskbook is a reference for systematic assessment of technical maturity of relevant materiel solutions. For biomedical applications, Biomedical TRL definitions and descriptions have been developed that account for regulatory context for technology maturity and *intended context of use*. Information on Biomedical TRLs can be found in Appendix E of the DOD TRA Deskbook (July 2009, https://apps.dtic.mil/docs/citations/ADA524200).

Knowledge Readiness Levels: The scientific maturity of knowledge products resulting from biomedical research is not assessed in the same manner as that of materiel solutions. At the request of the USAMRDC, the Rand Corporation developed and released a framework to assess the relative scientific maturity of knowledge products. This process is described in a 2019 Rand Corporation Report (https://www.rand.org/pubs/research_reports/RR2127.html). The figures below represent a quick reference guide for assessing KRLs for knowledge products.





Step 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 III: REGULATORY REQUIREMENTS

A. Safety and Environmental Requirements

Based on changes to DOD compliance requirements (Department of the Army Pamphlet [DA PAM] 385-69, DA PAM 385-10, 32 CFR 651, September 6, 2012), provisions previously required for Safety and Environmental Compliance have been removed. However, in certain instances, 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, specific chemical agent(s), or pesticides outside of an established laboratory. The USAMRDC Office of Surety and Environment will identify any need for compliance review, and documents must be submitted upon request.

Additional information is available at https://mrdc.health.mil/.

B. Research Protections Review Requirements

The USAMRDC OHARO ensures that research conducted, contracted, sponsored, supported, or managed by the DOD and involving human subjects, human anatomical substances, human data, human cadavers, or animals is conducted in accordance with federal, DOD, Army, USAMRDC, and international regulatory requirements.

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. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects.

All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, human data, or human cadavers must be reviewed and approved by the USAMRDC OHARO, OHRO, prior to research implementation. This administrative review requirement is in addition to the local IRB or EC review.

PIs and applicant organizations **may not commence performance** of research involving the above, **or expend funding** on such efforts, until regulatory documents are submitted and approved by the USAMRDC ORP 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."

Additional information is available at https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo.

1. Research Involving Animal Use

The ACURO must review and approve all animal use funded by the award prior to the start of working with animals, including amendments to ongoing projects. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. PIs must

submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled "Research Involving Animals." For guidance, visit the ACURO website at 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.***

For additional information, send questions via email to ACURO (usarmy.detrick.medcom-usamrdc.other.acuro@health.mil).

2. Research Involving Human Subjects

The OHRO ensures that DOD-supported research complies with specific laws, regulations, and requirements governing human subjects research. 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 OHARO OHRO reviews.

NOTE: The 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.

Effective 20 January 2020, The Revised Common Rule (i.e., the 2018 Requirements) at 45 CFR 46.114(b) requires that all institutions located in the United States that are engaged in cooperative research conducted or supported by a Common Rule department or agency rely upon approval by a single IRB for the portion of the research that is conducted in the United States. These provisions apply to DOD-funded research. Applicants must provide a written plan for single IRB review arrangements at the time of application submission or award negotiation.

Questions regarding applicable human subjects protection regulations, policies, and guidance should be directed to the local IRB or the OHARO OHRO (usarmy.detrick.medcomusamrdc.otherhrpo@health.mil). For in-depth information and to access OHRO protocol submission forms, refer to the OHARO OHRO website (https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo). Key requirements found in the OHARO OHRO guidance document, "Information for Investigators – Human Subjects Research" include:

- **Assurance of Compliance:** Each institution engaged in non-exempt human subjects research must have a current DHHS Office for Human Research Protection Federalwide Assurance (FWA) or DOD Assurance.

- **Training:** Personnel involved in human subjects research must have completed appropriate training in the protection of human subjects per institutional requirements. Documentation confirming completion of appropriate training will be required during the OHARO OHRO review process.

- **Informed Consent Form:** 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 Health Insurance Portability and Accountability Act (HIPAA) authorization is required, the DOD must be listed as one of the parties to whom private health information may be disclosed.
- **Access to DOD-Affiliated Personnel for Research:** See the guidance document, "A Primer for Conducting Department of Defense (DOD) Funded Human Research With Military Populations," at Conducting_Research_Military_Pop_DoD_May_2021.pdf.
- **10 USC 980 Waiver:** If the applicant proposes to conduct a trauma clinical trial or other planned emergency research subject to the requirements for exception from advanced informed consent under 21 CFR 50.24, the applicant should plan for 3-6 months of additional time for the OHARO OHRO to review the submission and request a waiver of 10 USC 980 from the Secretary of the Army or the DOD Office of Human Research Protections.

3. Research Involving the Secondary Use of Data/Specimens

Research involving the use of human data and/or specimens not otherwise subject to institutional review requires 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 PI's human subjects protection office as well as a concurrence from the OHARO OHRO.

All USAMRDC-supported research involving the secondary use of human data, human biospecimens (hereafter referred to as data/specimens) must be reviewed for compliance with federal and DOD human subjects protection requirements and approved by the OHARO OHRO prior to implementation. For additional guidance and instructions on OHARO OHRO review of DOD-funded research activities involving access, use, and analysis of data/specimens, see the guidance document, "Information for Investigators – Research with Data/Specimens," found at https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo.

NOTE: The protocol submitted for OHRO review must include only those activities funded by the DOD, as referenced in the 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.

4. Additional Information/Requirements

Site Visits: The USAMRDC OHARO 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 so as to protect the confidentiality of subject information.

Protocol Submission Format: The OHARO OHRO accepts protocol submissions in the format required by the local IRB. The IRB protocol application, if separate from the protocol itself, should be included with protocol submissions.

Research Involving the Use of FDA-Regulated Products (i.e., drugs, devices, in vitro diagnostics) in which the focus of the study is on the safety or effectiveness of the product requires IRB review in accordance with 21 CFR 50 and 21 CFR 56.

Clinical Trial Registry: PIs are required to register applicable clinical trials individually on https://clinicaltrials.gov/ using a Secondary Protocol ID number designation of "CDMRP-eBRAP Log Number" (e.g., CDMRP-JW23####). 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-JW23####-A). Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the NIH database (see https://prsinfo.clinicaltrials.gov/, click on "Support Materials (including data element definitions)") are required to register. 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.

Research Involving Recombinant DNA: The recipient must assure that all work involving the use of recombinant DNA will be in compliance with guidance provided at Biosafety and Recombinant DNA Policy – Office of Science Policy (nih.gov).

5. Use of Human Cadavers or Human Anatomical Substances Obtained from Human Cadavers

Research, development, test and evaluation (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 activities involving exposure of cadavers to impacts, blasts, ballistics testing, crash testing, and other destructive forces.**

Award recipients must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. Specific requirements for submission and review of RDT&E, education, and training involving cadavers and postmortem specimens can be found at https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo.

Written approvals to begin the activity will be issued under separate notification to the recipient. Questions regarding submission of human cadaver research for USAMRDC OHARO review and approval should be directed to the OHARO at usarmy.detrick.medcom-usamrmc.other.hrpo@health.mil.

6. 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. The study must undergo security review and additional approvals by the USAMRDC Office of Human and Animal Research Oversight, 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/how-to-apply.htm). If selected for funding, performers must take these additional requirements into consideration when developing timelines and milestones.

C. Use of DOD or VA Resources

If the proposed research involves access to active-duty military patient populations and/or DOD 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. Access to the target active-duty military patient population(s) and/or DOD resource(s) or database(s) should be confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs/Co-PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the ACOS/R&D or Clinical Service Chief. If appropriate, the application should identify the VA-affiliated NPC as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the application should 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.

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).

APPENDIX IV: REPORTING REQUIREMENTS AND ADMINISTRATIVE INFORMATION

A. Reporting Requirements for Awards

The government requires periodic reports to be submitted to continue the research and funding through the entire period of performance. Specific reports required by the government will be described in each award and may include:

- Technical/Scientific:
    - In addition to annual progress reports, the Terms and Conditions of the award will indicate any additional reporting required.
    - Final progress report
    - Quad Chart: The Quad Chart template is a one-page Word document or PowerPoint file that must be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm, and completed for submission with the application.
    - USAMRDC research progress reporting requirements and instructions can be found at https://mrdc.health.mil/index.cfm/resources/researcher_resources/reporting/technical.
- Fiscal (SF425 "Federal Financial Report"):
    - Annual reports
    - Final report
- Regulatory:
    - Research Involving Human Subjects: For DOD awards that include funding to support research with human subjects, the USAMRDC's OHRO requires submission of institutional continuing review reports and study event reports. Instructions are found at https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo.
    - The USAMRDC's OHRO will no longer require submission of local IRB annual continuing review materials for studies that no longer require continuing review under the 2018 Revised Common Rule (49 CFR Part 11).
    - Research Involving Animals: For DOD awards that include funding to support animal studies, staff from the USAMRDC's ACURO will contact the PI regarding submission requirements and deadlines. Questions related to ACURO review and approval should be directed to the ACURO central email account at usarmy.detrick.medcom-usamrdc.other.acuro@health.mil.
    - PHS Inclusion Enrollment Report: This is used to report the sex/gender, race, and ethnicity of study participants that will be enrolled in the clinical research (both planned and actual). The PHS Inclusion Enrollment Report is a fillable PDF form that may be

downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm and completed for submission with the application.

B. Post-Award Organization and Principal Investigator Changes

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 by the CDMRP Program Manager. 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 study site/clinical trial at its location. Organization transfers are not allowed in the last year of the performance period.

Change in Principal Investigator: Unless otherwise restricted, changes in PI will be allowed at the discretion of the CDMRP Program Manager, provided that the intent of the award mechanism is met.

C. Disclosure of Proprietary or Confidential Information

Do not include proprietary or confidential information in a pre-application or abstract. Proprietary information should only be included in a full application if necessary for evaluation.

Evaluators must agree that proprietary or confidential information in the application will be used for evaluation purposes only and will not be further disclosed or used. All applications may be subject to public release under the Freedom of Information Act (FOIA).

Applications for funded projects will be subject to public release under the 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.

D. Marking of Proprietary or Confidential Information

Conspicuously and legibly mark any proprietary or confidential information that is included in the application.

E. Classified Research Data or Outcomes

In accordance with 32 CFR, Section 2002.4, inclusion of classified research data or anticipated outcomes that may be classified or deemed sensitive to national security concerns within the application are not allowed. 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).

F. Inquiry Review Process (IRP)

Although not required by law or acquisition regulation, CDMRP offers a courtesy to all applicants in an effort to maintain high integrity in its review processes. If an application is not recommended for funding and a factual or procedural error is believed to have occurred during

the review of the application, the organization or PI may submit an inquiry within 15 business days after the notification email is sent. Inquiries submitted after 15 business days will not be considered.

The inquiry must specifically address a factual or procedural error that is believed to have occurred during review of the application, 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. Review process did not follow the procedures as outlined in the program announcement describing peer and programmatic review (e.g., documents requested in the program announcement and submitted with the original application were left out of the peer or programmatic review package).

Inquiries should be submitted through the CDMRP Help Desk at help@eBRAP.org. An inquiry review panel consisting of CDMRP staff will determine whether an error occurred in either peer or programmatic review and, if so, recommend corrective action where appropriate. The determination of an error in the review process is not a guarantee of funding. The final determination of the IRP and the funding decision are not subject to appeal. Questions related to the IRP prior to or after submitting an inquiry should be directed to the CDMRP Help Desk at help@eBRAP.org.

G. Information Service

Applicants may use the technical reference facilities of the U.S. Department of Commerce National Technical Information Service (https://www.ntis.gov) to obtain information about existing research to avoid duplication of scientific and engineering effort.

H. Freedom of Information Act 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 (www.usdoj.gov/oip/index.html).

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.

I. 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. (HT9425-23-1-XXXX). 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 Centers for Disease Control and Prevention (CDC)-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories." (https://www.cdc.gov/safelabs/resources-tools.html)

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

J. 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, duplication of effort can be avoided, allowing for the support of more investigators with 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).

K. Sharing of Data and Research Resources

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

Data and research resources generated by funded research should be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public. The expectations for sharing of data and research resources apply to all types of research funded by the program announcement. This includes all data and research resources generated during the project's period of performance as annotated in the award:

- **Unique Data** are defined as data that cannot be readily replicated. Examples of unique data include large research data collections that are expensive to replicate; studies of unique populations, such as patients to whom access is not widely available; studies conducted at unique times, such as during military conflict; studies of rare phenomena, such as rare diseases. (Adapted from https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique.)

- **Final Research Data** are defined as recorded factual material commonly accepted in the scientific community as necessary to document and support research findings. These are not the summary statistics or tables; rather, final research data are the data on which summary statistics and tables are based. Final research data do not include laboratory notes or notebooks, partial datasets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens. (Adapted from https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique.)

- **Research Resources** include, but are not limited to, the full range of tools that scientists and technicians use in the laboratory, such as cell lines, antibodies, reagents, animal models, growth factors, combinatorial chemistry, DNA libraries, clones and cloning tools, methods, laboratory equipment and machines. (Adapted from https://grants.nih.gov/grants/intell-property_64FR72090.pdf.)

Data and research resources generated from CDMRP-funded research should be made as widely available as possible while safeguarding the privacy of participants and protecting confidential and proprietary data and third-party intellectual property.

By sharing and leveraging data and research resources, duplication of effort can be avoided, allowing for the support of more investigators with federal funds. The USAMRDC believes that such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health. Depending on the program announcement, the PI may be required to participate in the following:

- Traumatic Brain Injury: If the project includes TBI research, the PI may be required to make TBI data generated via an award available to the research community by depositing de-identified research data into the FITBIR Informatics System (https://fitbir.nih.gov).

- Clinical Trials: If the project includes a clinical trial(s), the PI may be required to register the clinical trial(s) individually on the registry and database ClinicalTrials.gov (https://www.clinicaltrials.gov/).

For additional information on CDMRP's expectations and policies for data sharing, refer to "Policy on Sharing Data & Research Resources," available on eBRAP under Resources and Reference Material at https://ebrap.org/eBRAP/public/Program.htm. For unique data-sharing guidelines and requirements, refer to the instructions in the specific program announcement.

L. 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, non-profit, 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.

M. 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 non-exclusive rights for the use of such inventions. Instructions in the assistance agreement concerning subject inventions must be followed.

APPENDIX V: 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 file(s) 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 files; 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 VI: BUDGET INSTRUCTIONS

An estimate of the total proposed research project cost, with a breakdown of all cost categories for each year, must be submitted on the Suggested DOD Military Budget Format and Justification form. For limits on funding amounts, types of costs, and period of performance, refer to Section II.D.4, Funding Restrictions. No budget will be approved by the government exceeding the cost limit stated in this program announcement. 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. ***Additionally, applications that propose consultant, subaward, consortium, or contractual arrangements with foreign organizations or foreign collaborators will be required to provide additional scientific justification explaining why the foreign organization or foreign individual can carry out the scope of work more effectively than a U.S. organization or U.S individual.***

The PI's name, eBRAP Log number, and period of performance fields should be entered at the top of the Suggested DOD Military Budget Format.

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, as those costs were to have been included in infrastructure costs. If salary support is requested, sufficient justification must be provided in the budget justification section.

- **Name:** Beginning with the PI, list all participants 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.

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

- **Type of Appointment (Months):** List the number of months per year reflected in an individual's contractual appointment with the applicant organization. The government assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time (e.g., 50%), note this with an asterisk (*) and provide a full explanation in the budget justification. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.

- **Annual Base Salary:** Enter the annual organizational base salary (based on a full-time appointment) for each individual listed for the project.

- **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. If you do not wish this to be calculated for you, uncheck the small "Calculate Salary" checkbox in the bottom of the field. Calculate the

salary request by multiplying an individual's organizational base salary by the percentage of effort on the project.

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

- **Totals:** Calculated automatically from the data provided.

- **Major Equipment:** Provide an itemized list of proposed equipment, showing the cost of each item. Equipment is any article of nonexpendable tangible property having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit.

- **Materials, Supplies, and Consumables:** The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies.

- **Travel Costs:** PIs are responsible for budgeting for 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. Travel costs may include:

    - Travel costs for the PI to attend a required In-Progress Review meeting each year.

    - Travel costs for up to one investigator to travel to one scientific/technical meeting per year.

    - Travel costs between collaborating organizations.

- **Research-Related Subject Costs:** Include itemized costs of subject participation in the proposed research. These costs are strictly limited to expenses specifically associated with the proposed research.

- **Other Direct Costs:** Itemize other anticipated direct costs such as publication and report costs, equipment rental (provide hours and rates), communication costs, and organizationally provided services. Unusual or expensive items should be fully explained and justified. 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.

- **Contract Costs (Partnership/Collaboration Costs):** Should an intramural organization propose collaboration with an extramural entity for part of the research effort, the intramural organization will receive all funds and is responsible for executing all necessary contractual or assistance funding awards to collaborating partners through the agency's procedures. **All direct and indirect costs of any partnership/collaboration costs must be included in the total direct costs of the primary award**. The nature of the partnership/collaboration should be described in the Budget Justification section.

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

- **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. All direct and indirect costs of any proposed collaborator must be included in the total direct costs of the primary award. Refer to Section II.D.4, Funding Restrictions for detailed information.

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

- **Fee:** A profit or fixed fee is not allowable on awards or on subawards.

  ***Budget Justification Instructions*:** Provide a clear budget justification for each item in the budget over the entire period of performance in the Justification section of the Suggested DOD Military Budget. Itemize direct costs within each budget category for additional years of support requested beyond year one.

- **Federal Agency Financial Plan (required):** Provide a detailed Federal Agency Financial Plan after the budget justification information in the DOD Military Budget. The plan delineates how all FY23 funding will be obligated by **September 30, 2023**. The plan must include the funding mechanism(s) or contractual arrangements that will be used to carry over funds between fiscal years, if applicable. Any FY23 funding not obligated by September 30, 2023 may be withdrawn by the issuing Comptroller.