

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Congressionally Directed Medical Research Programs

Defense Medical Research and Development Program (DMRDP)

**Joint Program Committee-6/Combat Casualty Care Research
Program**

Trauma Immunology Research Award

Announcement Type: Initial

Funding Opportunity Number: HT9425-23-DMRDP-TIRA

**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), August 15, 2023
- **Invitation to Submit an Application:** September 21, 2023
- **Application Submission Deadline:** 11:59 p.m. ET, November 9, 2023
- **End of Application Verification Period:** 5:00 p.m. ET, November 14, 2023
- **Peer Review:** January 2024
- **Programmatic Review:** March 2024

This program announcement must be read in conjunction with the General Application Instructions, version 803. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”

TABLE OF CONTENTS

I. OVERVIEW OF THE FUNDING OPPORTUNITY.....	1
II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY.....	3
II.A. Program Description.....	3
II.A.1. FY23 DMRDP TIRA Focus Areas.....	4
II.B. Award Information	4
II.C. Eligibility Information.....	7
II.C.1. Eligible Applicants	7
II.C.2. Cost Sharing.....	7
II.C.3. Other	7
II.D. Application and Submission Information.....	8
II.D.1. eBRAP and Grants.gov	8
II.D.2. Content and Form of the Application Submission	9
II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)	24
II.D.4. Submission Dates and Times.....	24
II.D.5. Funding Restrictions.....	25
II.D.6. Other Submission Requirements	26
II.E. Application Review Information	27
II.E.1. Criteria	27
II.E.2. Application Review and Selection Process.....	29
II.E.3. Integrity and Performance Information.....	30
II.E.4. Anticipated Announcement and Federal Award Dates.....	30
II.F. Federal Award Administration Information	31
II.F.1. Federal Award Notices.....	31
II.F.2. Administrative and National Policy Requirements.....	31
II.F.3. Reporting.....	32
II.G. Federal Awarding Agency Contacts.....	33
II.G.1. eBRAP Help Desk.....	33
II.G.2. Grants.gov Contact Center	33
II.H. Other Information.....	33
II.H.1. Program Announcement and General Application Instructions Versions.....	33
II.H.2. Administrative Actions.....	33
II.H.3. Application Submission Checklist	36
APPENDIX 1: ACRONYM/TERM LIST	38

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2023 (FY23) Joint Program Committee 6/Combat Casualty Care Research Program (JPC-6/CCCRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Development Command (USAMRDC) Congressionally Directed Medical Research Programs (CDMRP) provides DMRDP execution management support for DHP core research program areas, including the JPC-6/CCCRP. This funding opportunity announcement and subsequent awards will be managed and executed by CDMRP on behalf of the JPC-6/CCCRP. The FY23 Consolidated Appropriations Act identified Trauma Immunology as an important research gap and included \$10M in funding for research to address this gap. This Congressional Special Interest program area is administered by JPC-6/CCCRP with support from CDMRP.

The JPC-6/CCCRP is a committee of Department of Defense (DOD) and non-DOD medical and military technical experts in combat casualty care-related program areas. The Combat Casualty Care Research Program (CCCRP) seeks to drive medical innovation through development of knowledge and materiel solutions for the acute and early management of combat-related trauma, including point-of-injury, en route, and facility-based care in order to optimize survival and recovery from combat-related injury in current and future operational scenarios. A primary emphasis of the CCCRP is to identify and develop medical techniques, knowledge products, and materiel (medical devices, drugs, and biologics) for early intervention in life-threatening battle injuries and prolonged care. Development and validation of in vitro and in vivo assessment models that represent military-relevant conditions in wounded Service Members, as well as those that incorporate a systems biology approach, are of interest to the CCCRP when they can be used to identify and describe the safety and efficacy of novel technologies in patients in a predictable manner.

The immunological response to traumatic injuries has been studied over the years, but much remains unknown. Traumatic injuries initiate a chain of reactions with immune cells and modulators that, depending on various factors, could be advantageous or deleterious. Traumatic injuries can affect multiple organ systems and cell types, trigger the release of damage-associated molecular patterns (DAMPs) and other sterile inflammatory responses to hemorrhage and tissue damage, and subsequent responses involving pathogen-associated molecular patterns (PAMPs) from infectious agents. Traumatic injuries lead to barrier dysfunction and other complex pathologies locally and systematically. This Trauma Immunology program area seeks to advance military trauma research to address unsolved traumatic injury-associated immunology questions to include mechanisms and early-stage development of potential therapeutics.

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

II.A.1. FY23 DMRDP TIRA Focus Areas

In order to meet the intent of the award mechanism, applications ***must address*** at least one of the following FY23 Trauma Immunology Research Award (TIRA) Focus Areas:

- Studies seeking to understand the initial inflammation and immune response profile to severe polytrauma that involves multiple organs at the molecular, cellular, tissue, and organ level.
- Studies seeking to understand the post traumatic local and systemic immune responses and pathophysiological mechanisms. Of particular interest are studies that seek to understand how the immune response leads to secondary organ damage.
- Early-stage development of potential novel products and knowledge for treating severe polytrauma and associated deleterious immune responses.
- Development and optimization of animal models that mimic the human trauma immunologic response, to improve the understanding of the human immune response and functions during and post severe polytrauma.

II.B. Award Information

The Trauma Immunology Research Award (TIRA) will support basic and applied research and early-stage development of materiel and knowledge products to address critical gaps in the understanding of immune system, immune response, immune function, and other associated host responses in combat injuries, in particular, severe polytrauma as encountered in the operational environment. Polytrauma is defined as two or more injuries to physical regions or organ systems, one of which may be life-threatening, resulting in physical, cognitive, psychological, or psychosocial impairments and functional disability (<https://www.polytrauma.va.gov/understanding-tbi/definition-and-background.asp>). Specifically, the research that supports the understanding of inflammation, immune responses, and other host reactions at and post trauma as well as associated potential treatments represents key priorities for the CCCRP¹.

The types of awards made under the program announcement will be assistance agreements. An assistance agreement is appropriate when the federal government transfers a “thing of value” to a “state, local government,” or “other recipient” to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the DOD during project performance is the key factor in determining whether to award a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a

¹ U.S. General Accounting Office. 2018. New trauma care system: DOD should fully incorporate leading practices into its planning for effective implementation. *GAO-18-300 Report*.

grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The anticipated total costs budgeted for the entire period of performance for an FY23 DMRDP Trauma Immunology Research Award should not exceed **\$2.0M**. Refer to [Section II.D.5, 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 CCCRP expects to allot approximately \$10.0M to fund approximately five FY23 DMRDP TIRA 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.

Research Involving Human Data, Human Anatomical Substances, or Human Cadavers:

All DOD-funded research involving new and ongoing research with human data, human anatomical substances, 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://mrhc.health.mil/index.cfm/collaborate/research_protections/hrpo for additional information.

Research involving animals, human anatomical substances, and human data is permitted; however, this award may not be used to conduct prospectively enrolled human subject clinical trials or clinical research.

Clinical trials are not allowed under this mechanism. A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Clinical research conducted with prospectively enrolled human subjects is not allowed under this mechanism. 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.

Use of DOD or VA Resources: If the proposed research involves access to VA or DOD resources, or databases, the proposal/application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information. ***Note, the CDMRP will not serve as the government sponsor or signatory on any access applications or agreements for DOD or VA patient populations, resources, or databases.***

Access to certain DOD or VA patient samples, 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 the application is recommended for funding, the government reserves the right to withdraw or revoke funding until the Principal Investigator (PI) has demonstrated support for and access to the relevant population(s) and/or resource(s).

Research Involving Animals: All research funded by the FY23 DMRDP TIRA 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: All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.

Government Agencies Within the United States: Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this program announcement may be submitted by extramural and intramural organizations, 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

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

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to [Section II.H.2, 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 propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

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 and Grants.gov

The electronic Biomedical Research Application Portal (eBRAP) (<https://ebrap.org>) is a secure web-based system that allows PIs to submit their pre-applications, view and verify extramural full applications submitted to Grants.gov (<https://grants.gov>), receive communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission.

Grants.gov is a federal system required to be utilized by agencies to receive and process extramural grant applications. Full applications may only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Contact information for the eBRAP Help Desk and the Grants.gov Contact Center can be found in [Section II.G, Federal Awarding Agency Contacts](#).

Extramural Submission:

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

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 or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.

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

Submission is a two-step process requiring both *pre-application* (eBRAP.org) and *full application* (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to [Table 1, Full Application Guidelines](#)).

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 eBRAP 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.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the eBRAP Help Desk at help@eBRAP.org 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 eBRAP 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 eBRAP Help Desk at help@eBRAP.org or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

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

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B, for additional information on pre-application submission):

- **Tab 1 – Application Information**

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

- **Tab 2 – Application Contacts**

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

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

It is recommended that 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 DMRDP TIRA Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the eBRAP Help Desk at help@eBRAP.org 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.*

- **Preproposal Narrative (three-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that

provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should include the following:

- **Focus Area:** Describe how the project addresses at least one of the [FY23 DMRDP TIRA Focus Areas](#).
- **Rationale:** State the hypothesis and scientific rationale on which the proposed research project is based. Concisely describe how preliminary data and/or referenced literature support the research hypothesis and scientific rationale.
- **Specific Aims and Study Design:** Concisely describe the project’s objectives, specific aims, and ultimate endpoints, and how they support the proposed research. If applicable, describe the animal models to be used and their relevance to human disease.
- **Research Team:** Provide a description of the PI and key personnel that clearly demonstrates the appropriate background and experience to accomplish the proposed work.
- **Impact and Military Benefit:** Describe the potential near-term and long-term impact of the proposed research. Explain how the effort will advance military trauma research.
- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* and are limited to the following:
 - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
 - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
 - **Key Personnel Biographical Sketches (six-page limit per individual):** *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.
- **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 FY23 DMRDP, pre-applications will be screened based on the following criteria:

- **Focus Area:** How well the proposed study addresses at least one [FY23 DMRDP TIRA Focus Areas](#).
- **Rationale:** How well the hypothesis and scientific rationale are supported through preliminary data and/or referenced literature.
- **Specific Aims and Study Design:** To what degree the project's objectives, specific aims, and ultimate endpoints support the proposed research. If applicable, how relevant the chosen animal model is to human disease.
- **Research Team:** Whether the background and experience of the PI and key personnel are appropriate to perform the proposed research.
- **Impact and Military Benefit:** To what extent the proposed research will have potential near-term and long-term impact and advance military trauma research.

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

Following the pre-application screening, Initiating PIs will be notified as to whether 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.

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

Each application submission must include the completed full application package for this program announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines.

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

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the *same version* of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user’s computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

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

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DOD Submissions
Application Package Location	
Download application package components for HT9425-23-DMRDP-TIRA from Grants.gov (https://grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for HT9425-23-DMRDP-TIRA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	<p>Tab 1 – Summary: Provide a summary of the application information.</p> <p>Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget 	<p>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:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget

Extramural Submissions	Intramural DOD Submissions
<ul style="list-style-type: none"> • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form 	<ul style="list-style-type: none"> • Performance Sites <p>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.</p>
Application Package Submission	
<p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>Submit a Grants.gov Workspace Package. An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package at least 24-48 hours prior to the close date to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p><i>Note:</i> If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>	<p>Submit package components to eBRAP (https://ebrap.org).</p> <p>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. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>
<u>Application Verification Period</u>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i></p>	<p>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 <i>with the exception of the Project Narrative and Research & Related Budget Form.</i> Your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review</p>

Extramural Submissions	Intramural DOD Submissions
	and to approve prior to the application verification deadline.
Further Information	
<p>Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

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 the General Application Instructions, Appendix 4.

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

- **Attachment 1: Project Narrative (15-page limit): Upload as “ProjectNarrative.pdf”.** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (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:** Present the scientific rationale behind the proposed work. Cite relevant literature. Describe previous experience most pertinent to the project. Include relevant preliminary data; these data may be unpublished or from the published literature.
- **Hypothesis:** State the hypothesis to be tested. State which [FY23 DMRDP TIRA Focus Area](#) the proposed research addresses.
- **Specific Aims:** Describe the project’s specific aims and the objective(s) to be reached. Specific aims should be independent and not depend on the successful completion of prior aims. These aims should align with the associated tasks described in the Statement of Work (SOW). If the proposed work is part of a larger study, present only aims that this DOD award would fund. The aims should align with the primary aims and associated tasks described in the SOW ([Attachment 5](#)).
- **Research Strategy and Feasibility:**
 - Identify and describe how the study design, methods, models, and analyses will meet the project’s goals and milestones. Describe how the proposed project is feasible and will be completed within the proposed performance period.
 - Describe the statistical model and data analysis plan with respect to the study objectives. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies.
 - Address potential problem areas and pitfalls and provide alternative methods and approaches.
 - If cell lines or animals are to be used, justify why the proposed cell line(s) or animal model(s) were chosen and discuss the model’s clinical relevance to the human condition; ***full details will be required in the Animal Research Plan ([Attachment 6](#))***.
- **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 (two-page limit per letter):** 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) (two-page limit per letter):** 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 Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), “Intangible Property.”
 - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
 - **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial

analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
- **Data Management Plan (two-page limit):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, [DoD Instruction 3200.12](#).
 - For Extramural Applications: Refer to General Application Instructions, Section III.A.2, Attachments Form, Attachment 2, Supporting Documentation, for more detailed information.
 - For Intramural Applications: Refer to General Application Instructions, Section IV.A.1, Application Component – Attachments, Attachment 2, Supporting Documentation, for more detailed information.
- **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to 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 resources and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **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>).
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. **Do not include proprietary or confidential information.** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Technical abstracts should be written using the outline below. The technical abstract should provide an appropriate description of the project’s key aspects; clarity and

completeness within the space limits of the technical abstract are highly important. Describe the proposed research project, including the following elements:

- **Background/Rationale:** Present the ideas and reasoning behind the proposed research project, including sufficient scientific evidence to support the proposed stage of research.
 - **Objective/Hypothesis:** State the objective(s) to be reached or the hypothesis(es) to be tested.
 - **Specific Aims:** State the specific aims of the proposed research project.
 - **Study Design:** Briefly describe the experimental design, including model system(s) and appropriate controls.
 - **Impact:** Identify the [FY23 DMRDP TIRA Focus Area](#) addressed and, if successful, how the research project will make important contributions to the understanding and treatment of the immunological response to traumatic injuries.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. *Do not include proprietary or confidential information. Do not duplicate the technical abstract.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the outline below. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract should be generally free of technical language/jargon and written so that individuals without a scientific or medical background can easily understand. The lay abstract is an important component of the application review process because it addresses issues of particular interest to lived experience subject matter experts (consumers).

- Describe the objectives and rationale for the proposed project in a manner that can be *readily understood by readers without a background in science or medicine.*
 - Describe the ultimate applicability of the research and how it addresses at least one the [FY23 DMRDP TIRA Focus Areas](#).
 - Describe the types of patients that will be helped by the research and how it will help them.
- **Attachment 5: Statement of Work (five-page limit): Upload as “SOW.pdf”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>.

For the FY23 DMRDP TIRA mechanism, refer to the “***Suggested SOW Strategy Generic Research***” document for guidance on preparing the SOW and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

The SOW should state the specific aims described in the Project Narrative and include a list of major tasks and subtasks that support the completion of the stated aims, including milestones for completing the aims during the period of performance. The SOW should describe only the work for which funding is being requested by this application.

- **Attachment 6: Animal Research Plan (*Attachment 6 is required for applications that propose studies utilizing animals; five-page limit per animal study*): Upload as “AnimRschPln.pdf”.** When the proposed study involves animals, the applicant is required to submit a plan describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. Applicants should consult the ARRIVE guidelines 2.0 to ensure relevant aspects of rigorous animal research are adequately planned for and ultimately reported. The ARRIVE guidelines 2.0 can be found at <https://arriveguidelines.org/arrive-guidelines>. 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.
 - Describe approaches that will be undertaken to validate or corroborate findings from animal studies to relevant human data sources/populations. This could include, but is not limited to, validation of animal transcriptomic data using publicly available human transcriptomic datasets, confirmation of histological findings in a human postmortem case series, and validation against fluid-based or imaging biomarkers.
 - Describe how the proposed validation approaches or corroborative studies “de-risk” the possibility that the findings from the animal study cannot be translated into human populations.
 - Summarize the procedures to be conducted. Describe how the study will be controlled.
 - Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
 - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).

- Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA) (or international equivalent) or next stage of development, if applicable.
- **Attachment 7: Impact Statement (one-page limit): Upload as “Impact.pdf”.** The Impact Statement must demonstrate alignment with at least one of the [FY23 DMRDP TIRA Focus Areas](#) and should be written in a manner that will be *readily understood by readers without a background in science or medicine*.
 - **Describe the near-term impact:** Detail the anticipated outcomes that will be directly attributed to the results of the proposed research and describe anticipated short-term benefits for individuals.
 - **Describe the long-term impact:** Explain the long-range vision for implementation of the research in the clinic or field and describe the anticipated long-term benefits on patient care and/or quality of life for the targeted population.
- **Attachment 8: Relevance to Military Health Statement (one-page limit): Upload as “Military.pdf”.** Explain how the proposed research is responsive to the healthcare needs of Service Members with severe polytrauma in the operational environment.

As applicable, include the element(s) below:

- Identify any element(s) or special consideration(s) related to the applicability of the ultimate outcome of the research in the military operational environment (e.g., battlefield, Battalion Aid Stations, Forward Support Medical Battalions). Applicants may consult [A Beginner’s Guide to Army Healthcare System](#) and the [Joint Health Services Joint Publication 4-02](#) for descriptions of health services across the range of military operations.
- If applicable, provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to both benefit the civilian population and address a military need.
- **Attachment 9: Transition Plan (three-page limit): Upload as “Transition.pdf”.** Describe/discuss the methods and strategies proposed to move the 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. 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 post-award transition plan should include the components listed below.

For the purposes of this funding opportunity Regulatory Agency refers to the FDA or any relevant international regulatory agency unless otherwise noted.

- 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 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, or 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.) For knowledge products, include proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications.
- A brief schedule and milestones for transitioning the intervention (e.g., next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by a Regulatory Agency).
- If applicable, ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government’s ability to access such products or technologies in the future.
- A risk analysis for cost, schedule, manufacturability, and sustainability
- **Attachment 10: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- **Attachment 11: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using “Suggested Collaborating DOD Military Facility Budget Format”, available for download on the eBRAP “Funding Opportunities & Forms” web page <https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under

subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] et seq.), the DOD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

Research & Related Personal Data: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- PI Biographical Sketch (six-page limit): Upload as “Biosketch_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.
- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.
 - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
 - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
- 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”.
 - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
 - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

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

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify 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.
- **Intramural DOD Collaborator(s):** Complete the “Suggested Collaborating DOD Military Facility Budget Format” and upload to Grants.gov attachment form as [Attachment 11](#). (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

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

The applicant organization must be registered as an entity in SAM (<https://www.sam.gov/SAM/>) and receive confirmation of an “Active” status before submitting an application through Grants.gov. *As of April 2022, all federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI generated through SAM.gov.* Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-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

For Both Extramural and Intramural Applicants: 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.

Extramural Submission: The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified.

Intramural DOD Submission: 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 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.

For All Submissions: 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.5. 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 **\$2.0M**. 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:

- **Interim (In-Progress) Review (IPR):** Travel costs should be requested for PI attendance at one 2-day IPR meeting located in the National Capital Region.

May be requested for (not all-inclusive):

- Travel in support of multidisciplinary collaborations.
- Starting in year 2, travel costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meetings described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY23 DMRDP TIRA.

Must not be requested for:

- Clinical research/trial costs

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DOD or other federal agency is not allowed except under very limited circumstances. Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer. Intramural 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.

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

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, 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**, of which, **Research Strategy and Feasibility and Impact** are of most importance and the remaining criteria listed are of equal importance:

- **Research Strategy and Feasibility**

- How well the scientific rationale and literature review, unpublished data, preliminary studies, and/or preclinical data support the development of the proposed project and provide the basis for the study questions and/or hypotheses.
- How relevant and applicable the proposed research and findings are to the intent of the mechanism and at least one of the [FY23 DMRDP TIRA Focus Areas](#).
- How well the project's specific aims and objective(s) are described and aligned with the associated tasks in the SOW.
- How well the study design, methods, models, and analyses are described and will meet the project's goals and milestones.
- How thoroughly the application acknowledges potential problem areas and pitfalls and provides alternative methods and approaches.
- Whether the proposed project is feasible and will be completed within the proposed period of performance.

For research involving animals:

- To what extent the choice of animal model is validated and well-justified in the literature.
 - How well the study explains how and why the animal species, strain, and model(s) being used can address the scientific objectives and the relevance to human biology.
 - How the approaches to validate or corroborate findings from animal studies to human data sources/populations are relevant.
 - If applicable, to what extent the proposed validation approaches or corroborative studies “de-risk” the possibility that the findings from the animal study cannot be translated into human populations
- **Impact**
 - How the anticipated outcomes of the proposed research will provide/improve short-term benefits for individuals.

- How significantly the long-term benefits for implementation of the research may impact patient care and/or quality of life.
- **Statistical Plan and Data Analysis**
 - As applicable, describe how the randomization and blinding procedures for the study are appropriate, and specify any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results.
 - If applicable, describe how the justification for not utilizing randomization and/or blinding is appropriate.
 - How the statistical model and data analysis plan, including sample size projections and power analysis, is appropriate to meet the objectives of the study and all proposed correlative studies.
- **Transition Plan**
 - Whether the identified next level of development and/or commercialization is realistic.
 - Whether the funding strategy described to bring the intervention to the next level of development (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 are achievable to provide continuity of development.
 - Whether the schedule and milestones for bringing the intervention to the next level of development (next-phase clinical trials, transition to industry, delivery to the market, incorporation into clinical practice, and/or approval by a Regulatory Agency) are achievable.
 - Whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
 - How well the application identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent government access to products supported by this program announcement.

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

- **Personnel**
 - How appropriate the levels of effort are for successful conduct of the proposed work.

- **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.
- **Environment**
 - How the scientific environment is appropriate for the proposed research.
 - How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
- **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 FY23 DMRDP and CCCRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Relative impact
 - Relevance to military health
 - Relative impact

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 on behalf of the DHA and the OASD(HA). ***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 award mechanisms for the FY23 DMRDP TIRA 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. Integrity and Performance Information

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

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

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

II.E.4. 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.

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

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

Federal Government Organizations: Funding made to federal government organizations (to include intramural DOD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

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

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

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

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

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this program announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the latest [DoD R&D General Terms and Conditions](#) and the [USAMRAA General Research Terms and Conditions: Addendum to the DoD R&D General Terms and Conditions](#) for further information.

Certification Regarding Disclosure of Funding Sources. The proposing entity must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI, 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 (18 USC 1001).

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Annual progress reports and quad charts as well as a final progress report 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 whether and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to

disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP 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 eBRAP 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.G.2. Grants.gov Contact Center

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. federal holidays). Note that the eBRAP Help Desk is unable to provide technical assistance with Grants.gov submission.

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

Email: support@grants.gov

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

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 803a. The program announcement numeric version code will match the General Application Instructions version code 803.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

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

The following will result in administrative rejection of the 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 6](#), Animal Research Plan, is missing.

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

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

- An FY23 DMRDP TIRA 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 DMRDP TIRA Programmatic Panel members can be found at https://cdmrp.health.mil/dmrtp/panels/23jpc_6_tira.***
- 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.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.
- 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 may be classified or deemed sensitive to national security.
- The invited application proposes a different research project than that described in the pre-application.
- Application includes prospectively enrolled human subject clinical trials or clinical research.

II.H.2.d. Withhold

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

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance (extramural submissions only)	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) (intramural submissions only)	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"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Animal Research Plan: Upload as Attachment 6 with file name "AnimalPlan.pdf" if applicable	
	Impact Statement: Upload as Attachment 7 with file name "Impact.pdf"	
	Relevance to Military Health Statement: Upload as Attachment 8 with file name "Military.pdf"	
	Transition Plan: Upload as Attachment 9 with file name "Transition.pdf"	
	Representations (extramural submissions only): Upload as Attachment 10 with file name "RequiredReps.pdf"	
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 11 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	

Application Components	Action	Completed
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field	
Research & Related Budget (extramural submissions only)	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field	
Budget (intramural submissions only)	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 1: ACRONYM/TERM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
CCCRP	Combat Causality Care Research Program
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DHP	Defense Health Program
DMRDP	Defense Medical Research and Development Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IPR	In-Progress Review
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management

SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs