I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Vision Research Program

Focused Translational Team Science Award

Announcement Type: Modified

Funding Opportunity Number: HT942524VRPFTTSA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern time (ET), July 11, 2024

- **Invitation to Submit an Application:** September 2024

- **Application Submission Deadline:** 11:59 p.m. ET, November 12, 2024

- **End of Application Verification Period:** 5:00 p.m. ET, November 14, 2024

- **Peer Review:** January 2025

- **Programmatic Review:** March 2025

This program announcement must be read in conjunction with the General Application Instructions, version 901. 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

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Vision Research Program (VRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the VRP in 2009 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the VRP from FY09 through FY23 totaled $184.95 million (M). The FY24 appropriation is $20M.

The goal of the VRP is to transform visual system trauma care for our Armed Forces and the nation. Eye injury accounted for approximately 15% of all injuries from battlefield trauma sustained during the wars in Afghanistan and Iraq.[1] An epidemiology study of 652 Soldiers admitted to Walter Reed Army Medical Center from 2001 to 2011 showed that 30% of patients became legally blind in their injured eyes.[2] There were more than 270,000 ambulatory eye injuries and 5,237 hospitalizations between 2000 and the first quarter of 2017, with 6,087 injuries at high risk of blindness.[3] In addition, traumatic brain injury (TBI), which affected more than 485,000 Service Members through the second quarter of 2023,[4] can have significant impact on vision even when there is no injury to the eye.[5]

The FY24 VRP challenges the scientific community to design innovative research that will significantly advance the understanding, prevention, diagnosis, mitigation, and/or treatment of eye injury or visual dysfunction associated with military exposure. Research outcomes are expected to ultimately improve the care of Service Members and Veterans as well as the American public.

II.A.1. FY24 VRP Focus Areas

To meet the intent of the funding opportunity, applications to the FY24 VRP Focused Translational Team Science Award (FTTSA) must address research in one of more of the following Focus Areas:

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[1] Ari AB. 2006. Eye injuries on the battlefields of Iraq and Afghanistan: Public health implications. *Optometry* 77(7):329-339.

[2] Harvey MM, Justin GA, Brooks DI, et al. 2021. Ocular trauma in Operation Iraqi Freedom and Operation Enduring Freedom from 2001 to 2011: A Bayesian network analysis. *Ophthalmic Epidemiology* 28(4):312-321.

[3] Frick KD and Singman EL. 2019. Cost of military eye injury and vision impairment related to traumatic brain injury: 2001-2017. *Military Medicine* 184(5-6):e338-e343.

[4] https://health.mil/Military-Health-Topics/Centers-of-Excellence/Traumatic-Brain-Injury-Center-of-Excellence/DOD-TBI-Worldwide-Numbers

[5] Reynolds ME, Barker FM 2nd, Merezhinskaya N, et al. 2019. Incidence and temporal presentation of visual dysfunction following diagnosis of traumatic brain injury, active component, U.S. Armed Forces, 2006-2017. *Medical Surveillance Monthly Report* 26(9):13-24.

- Understand and treat eye injury or visual dysfunction as related to military exposure

- Diagnose, stabilize, and treat eye injuries in austere environments and prolonged care settings

- Restore visual function after military exposure-related vision loss or severe visual impairment

II.A.2. Award History

The VRP FTTSA mechanism was first offered in FY18. Since then, 23 FTTSA applications have been received, and 4 have been recommended for funding.

II.B. Award Information

The FY24 VRP FTTSA is intended to support a highly collaborative and translational team initiative that will fundamentally advance the understanding and treatment of eye injury and/or visual dysfunction that result from military exposure (e.g., blast, blunt, thermal, chemical, directed energy trauma).

Key aspects of the FTTSA include:

- **Overarching Challenge:** Team science is a collaborative effort that leverages the strengths of investigators specializing in different fields to address an overarching scientific challenge or question. To identify an overarching challenge or question that meets the intent of the FTTSA, investigators are strongly encouraged to consider barrier(s) to and/or gap(s) in the understanding, prevention, diagnosis, mitigation, and/or treatment of eye injury or visual dysfunction associated with military exposure and envision what may be achievable in 10 to 15 years. Based on the long-term expectation, investigators will identify what should and can be achieved in the short term and will design projects and research teams around these goals.

- **Research Projects**

  ○ Applications shall include *at least three but no more than five distinct research projects that together form a concerted and synergistic effort* to address the overarching challenge. Each project, as well as the overall effort, must align with one or more of the FY24 VRP Focus Areas. The potential topics of individual projects are wide-ranging. The examples provided below are illustrative and *not exhaustive*:

    – Elucidation of molecular, cellular, and biophysical mechanisms of eye injury or visual dysfunction associated with military exposure

    – Identification of significant changes in pathophysiology over time after military exposure to inform targeted treatments

    – Identification of biomarkers and potential therapeutic targets

    – Development and validation of therapeutic agents and/or devices

- Development and validation of drug delivery platforms appropriate for eye injury or visual dysfunction associated with military exposure

- Development or improvement of clinically relevant trauma models

- Design of protection to mitigate the impact of military exposure on eye and vision

- Development of lightweight portable assessment or diagnostic capability

○ ***Individual projects must be capable of standing on their own scientific merits.*** The FY24 VRP FTTSA is not intended to support a series of research projects dependent on the success of any other project. Each project should propose a unique approach to address the overarching challenge and be capable of producing research findings with potential to impact the visual system trauma research field and/or patient care. ***Preliminary data to support the feasibility of each proposed research project are required***.

○ Individual research projects may focus on any phase of research (e.g., basic, translational, applied, clinical, observational). **The FY24 VRP FTTSA allows one of the projects to include a pilot clinical trial (PCT), but not a full-scale clinical trial**. In contrast to full-scale clinical trials that are designed to determine safety or efficacy, the purpose of the PCT is **to inform the feasibility, rationale, and design of subsequent clinical trials** through limited clinical testing of a novel intervention. Applications that do include a PCT as part of the proposed research will have additional submission requirements and review criteria and should demonstrate sufficient understanding of regulatory approval requirements and the regulatory approval process.

- **Implementation:** The research strategy to address the overarching challenge should include a detailed implementation plan for participating research groups to coordinate efforts, facilitate collaboration, and create synergy through open and frequent communication, interaction, sharing of results/data/resources, and other means as applicable and necessary. The coordination, collaboration, and synergy are intended to advance a solution beyond what would be possible through individual efforts.

- **Research Team:** *(New in FY24)* The FY24 FTTSA is structured to have an ***Overall Lead Principal Investigator (PI)*** and multiple ***Project PIs***. The Overall Lead PI will lead the overall effort as well as the execution of one project. The Overall Lead PI must have demonstrated success in leading large collaborative research project(s). Leaders of the other projects will be designated as Project PIs. Each PI may lead no more than one project.

  o The Overall Lead PI will be responsible for the majority of the administrative tasks associated with application submission. Project PIs will have their own submission requirements. If recommended for funding, all PIs will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Overall Lead PI and Project PIs, refer to [Section II.D.2, Content and Form of the Application Submission](#).

o   All key personnel should be committed to regular and open discussions of research plans, exchange of ideas, sharing of expertise and results, and other collaborative efforts. The CDMRP Science Officer assigned to a resulting award must be invited to participate in periodic research team meetings. The plan for such meetings should be noted in the application.

A clinical trial is defined in 45 CFR 46.102 as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Studies that *retrospectively* analyze data generated from *previously conducted* clinical trial(s) are not 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 encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

(1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does not seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.

(2) Epidemiologic and behavioral studies that do not seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.

(3) Outcomes research and health services research that do not fit under the definition of clinical trial.

Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

Applicants may consult the following resource documents as applicable:

•   Blast Term Dictionary and Guidance Documents for Blast Injury Research

•   A Primer for Conducting Department of Defense (DOD) Funded Human Research with Military Populations

•   A Beginner's Guide to Army Healthcare System

A description of health services across the range of military operations can be found in the Joint Health Services Joint Publication 4-02.

The funding instrument for awards made under the program announcement will be cooperative agreements (31 USC 6305). Substantial CDMRP programmatic involvement with recipients is anticipated during the performance of award activities. Substantial involvement means that, after award, CDMRP staff will assist, guide, coordinate, or participate in project activities including but not limited to participation in periodic research team meetings and interaction with PIs on a regular basis to monitor study progress.

The anticipated direct costs budgeted for the entire period of performance for an FY24 VRP FTTSA should not exceed **$4M**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

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

The CDMRP expects to allot approximately $6.4M to fund approximately one FTTSA application. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

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

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

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

II.C.1.b. Principal Investigators

The Overall Lead PI must be an independent investigator at or above the level of Associate Professor (or equivalent). ***The Overall Lead PI is required to devote a minimum of 20% effort to this award.***

Project PIs must be independent investigators at or above the level of Assistant Professors (or equivalent).

An investigator may be named on only one FTTSA application as the Overall Lead PI.

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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

II.D. Application and Submission Information

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).

Exception: Applicants to the FY24 VRP FTTSA are permitted to simultaneously submit individual projects as applications to the FY24 VRP Translational Research Award (TRA) (Funding Opportunity Number: HT942524VRPTRA) or Funding Level 2 of the FY24 VRP Investigator-Initiated Research Award (IIRA) (Funding Opportunity Number: HT942524VRPIIRA). The scope and budget of the FTTSA and the TRA or IIRA projects must be appropriate for the respective award mechanism. Accepting multiple awards to support the same project will not be allowed.

II.D.1. Location of Application Package

Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

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

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

DOD applicants to submit and verify full applications following their pre-application submission.

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

Application Submission Workflow

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│        Step1: Submit Pre-Application          │
│   (Extramural and Intramural Submissions)     │
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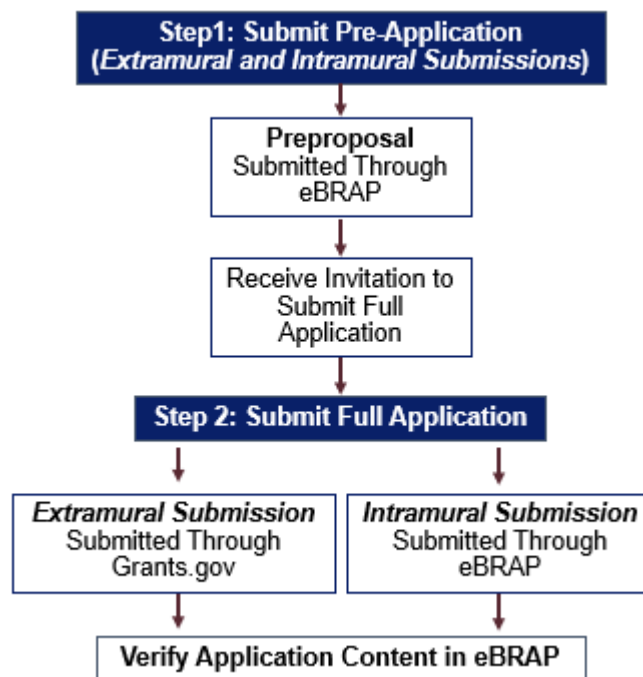
Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524VRPFTTSA from Grants.gov (https://grants.gov). Full applications from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations <u>may</u> submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524VRPFTTSA from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

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

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

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

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

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

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

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

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

(New in FY24) All pre-application components must be submitted by the Overall Lead PI through eBRAP (https://eBRAP.org/), *including the submission of contact information for the Project PIs*.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for each PI, the Business Official(s), performing organization(s), and contracting organization(s) 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.

After the Overall Lead PI confirms submission of the pre-application, Project PIs will be notified of the pre-application submission via an email from eBRAP. *Project PIs should not initiate a new pre-application based on the same research project submitted by the Overall Lead PI. Instead, Project PIs must follow the link in the notification email to ASSOCIATE the partnering pre-application with their eBRAP account.* If not previously registered, a Project PI must register in eBRAP.

After associating the pre-application with their eBRAP account, the Project PI should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated with their pre-application. The email should include the pre-application log number, the name of the

Business Official, the name(s) of the Performing/Contracting Organization(s), and the submission-type for the pre-application (extramural or intramural).

Project PIs are urged to complete these steps as soon as possible. If they are not completed:

- Project PIs will not be able to view and modify their full application during the verification period in eBRAP.

- Any intramural Project PI will not be able to submit their full application package components to eBRAP.

When starting the pre-application, applicants will be asked to select a "Mechanism Option". Please be sure to select the correct option appropriate to your pre-application:

	Select Option:
Without PCT component	**FTTSA**
With a PCT component	**FTTSA - PCT**

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

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

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

- **Preproposal Narrative (four-, five-, or six-page limit, for preproposals containing three, four, or five projects, respectively):** 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.

  Note: Changing the title or research objectives of either the overall application or the individual projects between the pre-application and the application is prohibited and may result in administrative withdrawal of the application.

  The Preproposal Narrative should include the following:

  o **Overarching Challenge:** Describe the overarching challenge or question of the proposed collaborative effort. Identify the barrier(s) to and/or gap(s) in the understanding, prevention, diagnosis, mitigation, and/or treatment of eye injury or visual dysfunction associated with a military exposure. Identify what is achievable in the long term (10 to 15 years) and what should and can be achieved in the short term. Articulate how the overarching challenge or question relates to the barrier(s)/gap(s), the long-term expectation, and the short-term goals. Explain how the overarching challenge or question aligns with one or more of the FY24 VRP Focus Areas.

- **Overall Strategy:**

    – Clearly state the title and hypothesis or objective of each research project.

    – Articulate the rationale for each project, including key preliminary data and how each project relates to the overarching challenge or question.

    – Concisely state the specific aims of each research project. ***Do not go into details of experimental design.***

    – If applicable, clearly identify which projects involve preclinical or clinical studies and which project involves a PCT.

    – Clearly and concisely describe when, where, and how each research project will interact with other research projects and how the interaction will accelerate progress toward the overarching goal and/or maximize the chance of success.

- **Research Team:** Describe the nature and scale of the collaboration and how the collaboration leverages expertise and strengths of investigators specializing in different fields. Describe when, where, and how the research groups will interact and collaborate.

- **Impact:** Describe the anticipated short- and long-term impact of these collaborative studies on the field of visual system trauma research and/or care.

- **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.

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

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

- **Overarching Challenge:** How well the overarching challenge or question meets the intent of the award mechanism.

- **Research Strategy:** How well the individual projects relate to the overarching challenge or question. How well the projects are supported by rationale. How well the interaction between projects will accelerate progress toward the overarching goal and/or maximize the chance of success.

- **Research Team:** To what extent the projects leverage the strengths of investigators specializing in different fields. Whether the proposed interaction and collaboration between research groups are appropriate.

- **Impact:** To what extent the short- and long-term outcomes of the proposed collaborative studies will impact the field of visual system trauma research and/or care.

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

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

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

Applicants must receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

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

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

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

II.D.2.b.ii. Full Application Submission Components for the Overall Lead PI

Applicants must receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

The CDMRP requires *separate full application package submissions* from the Overall Lead PI and each Project PI, even if the PIs are located within the same organization. Project PIs should follow instructions in Section II.D.2.b.iii., Full Application Submission Components for Project PIs, to assemble the full application package. Each full application package must be submitted using the unique eBRAP log number received by the Overall Lead and Project PIs during pre-application submission.

All associated applications (the Overall Lead PI's and the Project PIs') must be submitted by the full application submission deadline.

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

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

(b) 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 2.

○ **Attachment 1: Project Narrative (48-, 60-, or 72-page limit total, depending on the number of projects; page limit per project is specified below): 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 that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Note: Changing the title or research objectives of either the overall application or the individual projects between the pre-application and the application is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

– **Overall Program (12-page limit):** Provide a description of the comprehensive effort using the following outline. *Applications must include a minimum of three but no more than five research projects.* Clearly identify areas of synergy throughout the narrative.

- **Overarching Challenge:** Describe the overarching challenge or question of the proposed collaborative effort.

  - ❖ Describe the barrier(s) to and/or gap(s) in the understanding, prevention, diagnosis, mitigation, and/or treatment of eye injury or visual dysfunction associated with military exposure. Support the gap analysis with relevant literature and clear rationale.

  - ❖ Identify what is achievable in the long term (10 to 15 years) and what should and can be achieved in the short term. Support the long-term expectation and short-term goals with rationale and relevant data.

  - ❖ Describe how the overarching challenge or question of the proposed collaborative effort relates to the barriers/gaps, the long-term expectation, and the short-term goals.

  - ❖ Explain how the overarching challenge or question aligns with one or more of the FY24 VRP Focus Areas.

- **Overall Strategy:** Provide an overview of the strategy to address the overarching challenge or question through a collaborative team effort.

  - ❖ Explain how the choice of projects leverages the strengths of investigators specializing in different fields and forms a coherent plan to address the overarching challenge or question.

  - ❖ If applicable, clearly identify which projects involve preclinical or clinical studies and which project involves a PCT. Describe how the PCT is linked to the preclinical and/or non-PCT clinical studies that will be performed through this award.

  - ❖ Identify the key points of interaction between the projects and how such interaction will create synergy to address the overarching challenge more effectively than if the projects were conducted independently.

- **Team**

  - ❖ Outline the Overall Lead PI's responsibilities, including the level of effort. Describe the Overall Lead PI's past success in leading a large collaborative research effort.

  - ❖ Outline the responsibilities of Project PIs, including the levels of effort.

  - ❖ Clearly demonstrate that there is sufficient expertise for all aspects of the proposed work.

- **Implementation Plan:** Present a management plan to coordinate efforts, facilitate collaboration, and create synergy. Include the following elements:

  - When, where, and how the participating research groups will interact, share results and newly acquired knowledge, and synergistically advance the goals of the project.

  - Plans for communication and data transfer among the participating research groups, as well as how data, specimens, and/or imaging products obtained during the study will be handled.

  - If applicable, plans to share resources and access to facilities.

  - Plans for assessing overall and individual project's performance and progress, including progression toward defined milestones, during the course of the award.

- **Project-Specific Narratives (12-page limit for each individual project):** Applications shall include *at least three but no more than five distinct research projects* that together form a concerted and synergistic effort to address the overarching challenge. Describe each individual project using the outline below. ***Start each project on a separate page.***

  - **Title:** Provide a title for the project.

  - **Personnel:** Identify the PI and any key personnel, as appropriate. Concisely describe each person's qualifications and role(s) in the project.

  - **Background/Rationale:** Provide a sound scientific rationale for the proposed research, including the objective(s) to be reached and/or the hypothesis(es) to be tested.

    - Provide a critical summary of relevant completed and ongoing studies in the field. Present sufficient evidence, including preliminary data and relevant literature, to support the readiness of the objective(s), the soundness of the hypothesis(es), and the feasibility of the approach(es).

    - Describe element(s) of the project that are innovative or novel or offer significant refinements, improvements, or new applications of existing ideas or solutions.

  - **Specific Aims:** Concisely explain the project's specific aims. Explain how the aims address the objective(s) and/or hypothesis(es) of the proposed research.

  - **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate randomization, blinding/masking, and controls. Provide sufficient detail so that the appropriateness and feasibility of the research strategy can be fully evaluated. Describe the statistical plan as appropriate for the

proposed research. Outline whether researchers, subjects, clinicians, data analysts, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias. Address potential problem areas and present alternative methods and approaches.

❖ If cell lines or animals are to be used, justify the selection of the proposed cell line(s) or animal model(s). Be specific as to why the cell line or animal model was chosen over other cell lines or models, how it is appropriate for addressing the study aims, and how it is relevant to human visual biology and/or injury. Further details of research involving animals will be required in Attachment 10: Animal Research Plan, as applicable.

❖ If human subjects, human anatomical samples or data will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples or data, including evidence that the research team has access to subjects, samples, and/or data. 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 Institutional Review Board [IRB] review) are exempt from this requirement. Anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity should be provided as part of the application's Supporting Documentation (Attachment 2) Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the Food and Drug Administration (FDA), if applicable.

▪ **Outcome:** Describe the anticipated outcome(s) (knowledge and/or materiel product) that will be directly attributed to the results of the proposed research. Compare the outcome(s) to existing knowledge and/or materiel product(s). Explain how the outcome(s) will be used to address the overarching challenge.

○ **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

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

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

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

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

- **Letters of Organizational Support (two-page limit per letter *is recommended*):** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the 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 *is recommended*):** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

- **Letter of Commitment** *(if applicable)* **(two-page limit per letter is recommended):** If the proposed study involves use of a commercially produced investigational drug, device, or biologic, provide a letter of commitment from the commercial entity indicating the availability of the product for the duration of the study, support for the proposed phase of research, and support for the indication to be tested.

- **Inclusion Enrollment Plan** *(if the proposed research involves recruitment of human subjects)*: Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

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

- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about CDMRP's expectations for making data and research resources publicly available.

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

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

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

- ○ **Attachment 3: Technical Abstract (two-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Programmatic Reviewers rely on the technical abstract for appropriate description of the project's key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

Technical abstracts should include the following elements:

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

– **Overarching Challenge:** Describe the overarching challenge or question of the proposed collaborative effort. Clearly state the injury or condition (e.g., retinal detachment, optic nerve injury) to which the proposed research is applicable. Concisely state the barrier(s) to and/or gap(s) in the understanding, prevention, diagnosis, mitigation, and/or treatment of eye injury or visual dysfunction associated with a military exposure. State the long-term expectation and short-term goals to address the barrier(s) and/or gap(s). Articulate how the overarching challenge or question relates to the barrier(s) and/or gap(s), the long-term expectation, and short-term goals. Describe how the overarching challenge aligns with one or more of the FY24 VRP Focus Areas.

– **Research Plan:** Clearly articulate the overall research strategy and the role of individual projects within the overall strategy. Present the ideas and scientific rationale behind both the overall strategy and individual projects. Briefly describe the hypothesis/objective and study design of each project, the relationship between projects, and the strategy to coordinate efforts and create synergy. Describe how each project aligns with one or more of the FY24 VRP Focus Areas. If applicable, clearly identify which project involves a PCT.

– **Impact:** Concisely explain the significance of addressing the overarching challenge or question. Briefly describe the anticipated short-term and long-term outcomes and the potential impact on the field of visual system trauma research and/or care.

○ **Attachment 4: Lay Abstract (two-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers, and addresses issues of particular interest to the affected community. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community. Lay abstracts should be written using the outline below in a manner readily understood by readers without a background in science or medicine. Minimize use of acronyms and abbreviations, where appropriate.

– Clearly describe the overarching challenge or question that the proposed collaborative effort will address.

– Clearly describe the rationale, objectives, and aims of each project.

- Explain how each project relates to the overarching challenge and how the projects will interact with each other to create synergy.

- Describe the anticipated short-term and long-term outcomes of the proposed research. Explain how the outcomes will impact the field of visual system trauma research and/or care.

○ **Attachment 5: Statement of Work (SOW) (twelve-page limit): Upload as "SOW.pdf".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested SOW format and recommended strategies for assembling the SOW.

Each PI must submit *an identical copy* of a jointly created SOW, which must contain *an Overarching section* and *Project-specific sections.* The Overarching section should list tasks that support the coordination and collaboration between projects. Project-specific sections should list tasks that support project-specific activities.

Overarching section: Refer to the "Example: Assembling a Generic Statement of Work" document for guidance on preparing the overarching section. *The specific contributions of the Overall Lead PI and Partnering PIs should be clearly noted for each task.*

Project-specific sections: Refer to either the "Example: Assembling a Generic Statement of Work" or "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work" document, depending on which one is most appropriate for the project.

○ **Attachment 6: Impact Statement (two-page limit): Upload as "Impact.pdf".** This should be written with a broad audience in mind, including readers without a background in science or medicine.

- Clearly identify the overarching challenge or question to be addressed in the context of the FY24 VRP Focus Areas.

- Describe the anticipated short-term and long-term outcomes of the proposed research. Explain how the outcomes will collectively overcome the overarching challenge or answer the overarching question.

- Describe the significance of overcoming the overarching challenge. Explain how it will advance the field of visual system trauma research, advance patient care, improve quality of life, contribute to the development or validation of evidence-based policy or guidelines, or otherwise impact the visual health of Service Members, Veterans, and the American public.

- In addition to articulating the impact of the overall program, describe the impact(s) of each individual project. If applicable, identify broader impact(s) beyond the scope/ objective of the collaboration.

○ **Attachment 7: Relevance to Military Health Statement (one-page limit): Upload as "Military.pdf".** Explain how the proposed research is responsive to the health care needs and quality of life of Service Members and Veterans with eye injury and/or visual impairment and/or to their Family Members and caregivers.

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 active-duty military, Veteran, or military Family Member population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed research, and the feasibility of using the population.

– 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 8: Translation Statement (one-page limit): Upload as "Translation.pdf".** Describe the translational aspects of the proposed research and the translational potential of the anticipated outcome(s).

– Explain how the proposed research will move promising discovery(ies) toward definitive clinical testing. As applicable, clearly address the following points:

▪ Briefly describe the promising discovery(ies).

▪ Explain what steps need to be taken and what barriers need to be overcome in order to translate the promising discovery into clinical application.

▪ Describe how the proposed research takes the necessary steps and removes barriers toward clinical translation.

– Describe how the research is designed with sufficient understanding and consideration of regulatory approval requirements, and how the investigative team will include expertise in the regulatory approval process.

– As applicable, clearly state specific regulatory milestones, such as when an IND/IDE application will be submitted.

○ **Attachment 9: Post-Award Transition Plan (three-page limit): Upload as "Transition.pdf".** The FTTSA mechanism is intended to move promising discoveries toward clinical applications. Assuming the projects will be successful, investigators

should plan in advance the methods and strategies to transition the anticipated outcomes of the proposed research to the next phases of development and to eventual clinical use. Applicants are strongly encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the Post-Award Transition Plan. However, ***regardless of the availability of support from a Technology Transfer Office, the Post-Award Transition Plan must provide sufficient details for each required components to allow appropriate peer review***. PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the anticipated research outcomes into the next phase of development.

The Post-Award Transition Plan should include the components listed below:

– The project's anticipated research outcomes.

– The next phase of development after the successful completion of the proposed study, including the scientific, technical and/or regulatory steps that will take place during this phase of development.

– The methods and strategies to move the anticipated research outcomes to the next phase of development and/or commercialization.

– A brief schedule and feasible milestones for transitioning the anticipated research outcomes to the next phase of development.

– As applicable, the FDA regulatory strategy for the next phase of development, including the number and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings to be held, the submission filing strategy, and considerations for compliance with Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), and Good Clinical Practice (GCP) guidelines, if appropriate.

– As applicable, the planned indication for the product label and an outline of the development plan required to support that indication (e.g., Target Product Profile).

– Details of the funding strategy to transition to the next level of development and/or commercialization (e.g., specific potential industry partners, internal/external funding opportunities to be applied for). Include a description of collaborations and other resources that will be used to provide continuity of development.

– If applicable, a description of collaborations and other resources that will be used to provide continuity of development.

– A discussion of ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award including a plan for resolving intellectual and material property issues among participating organizations. If the intellectual property rights are not owned by the performer(s), describe the planned next steps necessary to make the product available to the patient community.

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

○ **Attachment 10: Animal Research Plan (no page limit): Upload as "AnimalResPlan.pdf".** *(Attachment 10 is only applicable and required for applications proposing animal studies.)*

Provide a summary describing the animal research that will be conducted. Consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines 2.0 (https://arriveguidelines.org/arrive-guidelines) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the Institutional Animal Care and Use Committee (IACUC). The Animal Research Plan should address the following points to achieve reproducible and rigorous results for each proposed animal study:

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

– Summarize the procedures to be conducted. Describe how the study will be controlled. Identify the ages, sex, and total number of animals by species to be used.

– Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.

– Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.

– Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).

– Describe how data will be reported and how it will be assured that the documentation will support potential regulatory filing, if applicable.

○ **Attachment 11: Pilot Clinical Trial Plan (required only if proposing a PCT; five-page limit): Upload as "PCT.pdf".** Describe the plans for initiating and conducting the PCT during the course of this award.

– Describe how the PCT is linked to the preclinical and/or clinical studies that will also be performed through this award.

– Describe the objective(s) of the PCT; explain how it will inform the feasibility, rationale, and design of subsequent clinical trials.

- – Describe the design of the PCT and outline the proposed methodology in sufficient detail to show a clear course of action. Identify the intervention to be tested. Describe the procedures to be conducted, projected outcomes, study variables, controls, length of the follow-up period, examinations and/or procedures to be performed during the follow-up period, and endpoints.

- – Describe whether subjects, clinicians, data analysts, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias.

- – Identify the study population and describe the methods that will be used to recruit a sample of human subjects from the accessible population. *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.* List the inclusion and exclusion criteria for the proposed PCT.

- – As appropriate for the proposed PCT, describe the statistical model and data analysis plan with respect to the study objectives. If applicable, include power analysis calculations.

- – 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.

- – Describe potential challenges and alternative strategies, where appropriate.

- ○ **Attachment 12: Regulatory Strategy (required only if proposing a PCT; no page limit): Submit this attachment *only if required*. 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 name of the product/intervention to be tested.

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

    - – For the purposes of this funding opportunity, Regulatory Agency refers to the U.S. Food and Drug Administration (FDA) or any relevant international regulatory agency.

    - – For investigator-sponsored regulatory exemptions (e.g., IND, IDE, or international equivalent) provide evidence of institutional support. Provide evidence that the PCT does not require regulation by a Regulatory Agency. 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 described in 21 CFR 312, Subpart D, and commitment to oversee execution of the study.

- If an IND or IDE application is required, provide documentation of submission (e.g., a copy of the FDA acknowledgment letter to include submission date and receipt date, status of the application) or a timeline for planned submission. *Submission must be made prior to the award date.*

  The government reserves the right to withdraw funding if an IND or IDE application is necessary but has not been submitted to the FDA prior to the award date or if the documented status of the IND or IDE application has not been obtained within 6 months of the award date.

- The IND or IDE application 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 PCT.

- If a technical or a protocol amendment to an IND/IDE application is necessary to conduct the PCT, provide a copy of the FDA acknowledgment letter and meeting minutes (pre-IND/pre-IDE application and/or Type C) that confirm the FDA's concurrence with the proposed regulatory approach. Documents must demonstrate clear evidence that the proposed investigational drug or device will not require new IND/IDE application submission pertaining to the indication and formulation to be used in the PCT.

- If the PCT 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 a 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).

- – Describe the overall regulatory statement and product development plan that will support the planned product indication. Include considerations for compliance with current GMP, GLP, and GCP guidelines.

- ○ **Attachment 13: Representations** *(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 8, Section B, Representations.

- ○ **Attachment 14: Suggested Intragovernmental/Intramural Budget Form** *(if applicable)***: Upload as "IGBudget.pdf".** If an [intramural DOD organization](https://ebrap.org/eBRAP/public/Program.htm) will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The *total* costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- ○ **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 NIH Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

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

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

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

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.

- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.

- Overall Lead and Project PIs must *each* submit, as part of their respective Grants.gov or eBRAP application package, a budget and justification *specific to their distinct portions of the effort*. The Overall Lead PI should not include budget information for Project PIs even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

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

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.

- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 14.

II.D.2.b.iii. Full Application Submission Components for Project PIs

The application submission process for *Project PIs* uses an *abbreviated* full application package. Refer to the equivalent attachment above for details specific to each of the following application components.

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

(b) Attachments:

- **Attachment 5: Statement of Work (twelve-page limit): Upload as "SOW.pdf".** Each Project PI must submit an SOW that is *identical* to that submitted by the Overall Lead PI. The SOW shall be jointly created by all PIs. *The specific contributions of each PI should be clearly noted for each task in the Overarching section of the SOW.*

- ○ **Attachment 13: Representations** *(Extramural submissions only)***: Upload as "RequiredReps.pdf".**

- ○ **Attachment 14: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed information.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed information.

- ○ **PI Biographical Sketch (six-page limit):** Upload as "Biosketch_LastName.pdf".

- ○ **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".

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed information.

- ○ **Budget Justification (no page limit):** Upload as "BudgetJustification.pdf".

- ○ The Overall Lead and Project PIs must **each** submit, as part of their respective Grants.gov or eBRAP application package, a budget and justification *specific to their distinct portions of the effort*. The Research & Related Budget for a Project PI should not include budget information for the Overall Lead PI or other Project PI(s), even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to General Application Instructions, Section V.A.(f), for detailed information.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)***:** Refer to the General Application Instructions, Section IV.B.(g), for detailed information.

- ○ **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov.

- ○ **Intramural DOD Subaward:** Complete the "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled IGBudget.pdf to Grants.gov as Attachment 14.

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

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

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

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

II.D.4. Submission Dates and Times

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

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

II.D.5. Funding Restrictions

The maximum period of performance is **4** years.

The application's direct costs budgeted for the entire period of performance should not exceed **$4M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

- The funding restriction applies to the ***combined*** direct costs for the applications of the Overall Lead PI and Project PIs. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

- A separate award will be made to each PI's organization.

- The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.

For this award mechanism, direct costs:

Must be requested for:

- Travel costs for the Overall Lead PI and Project PIs to present project information or disseminate project results at DOD-sponsored meeting (e.g., Military Health System Research Symposium). For planning purposes, it should be assumed that the meeting will be held in the Central Florida Area. Costs associated with travel to this meeting should be included in Year 2 or 3 of the budget. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for:

- Travel in support of multi-institution collaborations.

- Travel for the Overall Lead PI and Project PIs to attend one scientific/technical meeting per year, in addition to the required meeting described above, to present project information or disseminate project results from the FY24 VRP FTTSA.

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, 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 individually evaluated according to the following **scored criteria**, which are of equal importance:

- **Overarching Challenge**

  - To what degree the barrier(s)/gap(s) is clearly described and its analysis is supported by a rationale and the literature.

  - To what degree the long-term expectation and short-term goals are clearly described and supported by rationale and relevant data.

  - To what degree the overarching challenge or question relates to the barrier(s)/gap(s) identified, long-term expectation, and short-term goals.

  - How well the overarching challenge or question aligns with one or more of the FY24 VRP Focus Areas.

- **Overall Strategy**

  - To what degree the choice of projects demonstrates a coherent plan to address the overarching challenge or question.

  - To what degree the choice of projects leverages the strengths of investigators specializing in different fields.

  - If applicable, to what degree the PCT is linked to the preclinical and/or non-PCT clinical studies that will be performed through this award.

  - To what degree the interaction between projects will create synergy to address the overarching challenge more effectively than if the projects are conducted independently.

- **Impact**

  - To what extent the proposed collaborative effort, as well as individual projects, will advance the field of visual system trauma research, change the standard of care, improve the quality of life, contribute to the development or validation of evidence-based policy or guidelines, or otherwise impact the visual health of Service Members, Veterans, and the American public.

- **Leadership**

  - To what degree the Overall Lead PI's responsibilities in the overall program are clearly defined and appropriate.

  - To what degree the Overall Lead PI has demonstrated success in leading large collaborative research project(s).

  - To what degree the level of effort for the Overall Lead PI is appropriate.

  - To what degree the responsibilities of Project PIs in the overall research plan are clearly defined and appropriate.

○ To what degree the combined expertise of the Overall Lead PI and Project PIs is appropriate to lead all aspects of the proposed work.

- **Implementation Plan**

  ○ To what degree the plans for participating research groups to interact, share results and newly acquired knowledge, and synergistically advance the goals of the project are appropriate and feasible.

  ○ To what degree the plans for communication and data transfer among the participating research groups, as well as how data, specimens, and/or imaging products obtained during the study, are appropriate and feasible.

  ○ If applicable, to what degree the plans to share resources and access to facilities are appropriate and feasible.

  ○ To what degree the plans for assessing progress of both the overall effort and individual projects are appropriate and feasible.

- **Translation**

  ○ How well the proposed research will move a promising discovery (or discoveries) toward definitive clinical testing.

  ○ To what extent the design of the proposed research demonstrates sufficient understanding and consideration of regulatory approval requirements and process.

    – For research involving a PCT: To what extent the Regulatory Strategy provides sufficient evidence for an IND/IDE exemption or, if IND/IDE approval is required, an appropriate plan/timeline for applying for and obtaining IND/IDE approval status (or other regulatory approvals) to ensure a timely start of the PCT.

  ○ As applicable, whether the proposed research has clear and feasible regulatory milestones.

- **Post-Award Transition Plan**

  ○ Whether the identified next phase of development and/or commercialization is realistic.

  ○ Whether the methods and strategies to move the anticipated research outcomes to the next phase of development and/or commercialization are feasible.

  ○ Whether the schedule and milestones for bringing the anticipated research outcomes to the next level of development are achievable.

  ○ If the ultimate goal is to produce a regulated product (e.g., drug, biologics, or device), to what degree the regulatory strategy and product development plan are appropriate to support a filing with a Regulatory Agency.

- ○ Whether the funding strategy to bring the anticipated research outcomes to the next level of development is reasonable and realistic.

- ○ As applicable, whether the proposed collaborations and other resources for providing continuity of development are established and/or achievable.

- ○ As applicable, whether the applicant has identified intellectual property ownership, demonstrated appropriate access to all intellectual property rights necessary for development and/or commercialization, and described an appropriate intellectual and material property plan among participating organizations for products or technologies supported by this award.

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

- **Project-Specific Strategy:** Each individual project shall be evaluated by the criteria below.

- ○ To what extent the idea of the proposed project, including the objective(s) and/or hypothesis(es), is based on sound scientific rationale, critical analysis of literature, and preliminary data.

- ○ To what extent the specific aims are appropriate to address the objective(s) and/or hypothesis(es) of the project.

- ○ To what extent the experimental design, methods, and analyses are appropriate and feasible.

- ○ To what extent the statistical plan is appropriate.

- ○ How well the proposed research is designed to achieve reproducible and rigorous results, including controls, sample size(s), blinding, randomization, data handling, and measures to reduce bias.

- ○ How well the application acknowledges potential problems and addresses alternative approaches.

- ○ If applicable, how well the animal study is designed to achieve the study objectives, including the appropriateness and relevance of animal model(s), experimental procedures, randomization and blinding procedures, and endpoints/outcome measures.

- ○ If applicable, how well the human study is designed to achieve the study objectives, including description of and access to the study population(s) or human biological sample(s), plans for subject recruitment, consent, screening and retention, and plans for addressing ethical and regulatory considerations.

- ○ If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment is appropriate for the proposed study.

- ○ If applicable, whether data will be appropriately reported and documented to support a regulatory filing.

- ○ For research involving a *PCT*, the following *additional* criteria apply:

  - – How well the PCT is linked to the preclinical and/or clinical studies to be performed through this award.

  - – To what extent the objective(s) of the PCT is clear and appropriate.

  - – To what extent the design of the PCT supports its objective and demonstrates a clear course of action.

  - – To what extent the statistical plan and data analysis plan of the PCT, including sample size estimate, is appropriate.

  - – To what extent the PCT is supported by an appropriate regulatory strategy.

  - – To what extent the application demonstrates the availability of and access to the intervention to be tested.

- **Project Team and Personnel**: Each individual project shall be evaluated by the criteria below.

  - ○ To what extent the backgrounds, expertise, and past accomplishments of the PI and key personnel are appropriate to accomplish the proposed research.

  - ○ Whether the levels of effort by the PI and key personnel are appropriate for the successful conduct of the proposed research.

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

- **Environment**

  - ○ To what extent the scientific environment is appropriate for the proposed research projects.

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

  - ○ To what extent the quality and level of institutional support are appropriate for the proposed research projects.

- **Budget**

  - ○ Whether the **combined direct** costs exceed the allowable direct costs as published in the program announcement.

  - ○ Whether the budget is appropriate for the proposed research.

- **Data and Resources Sharing**

  ○ Whether the plan for sharing data and resources with the research community is appropriate and reasonable.

- **Application Presentation**

  ○ To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers

- Relevance to the priorities of the DHP and FY24 VRP, as evidenced by the following:

  ○ Adherence to the intent of the award mechanism, including alignment with at least one of the FY24 VRP Focus Areas

  ○ Relative impact

  ○ Relevance to military health

  ○ Contribution to program portfolio

II.E.2. Application Review and Selection Process

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

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of confidentiality can result in the dissolution of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting

persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

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

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

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

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

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

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

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

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

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

II.F.2. PI Changes and Award Transfers

An organizational transfer of an award supporting the Overall Lead PI or Project PIs is discouraged and will be evaluated on a case-by-case basis.

An organizational transfer of an award supporting the Overall Lead PI or Project PIs 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 7, Section F, for general information on organization or PI changes.

II.F.3. Administrative and National Policy Requirements

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

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

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

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

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD

animal and/or human subjects protection requirements and approved by the USAMRDC OHARO, prior to implementation. This administrative review requirement is in addition to the local IACUC, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

Funded PCTs are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Funded studies are required to register the PCT in the NIH clinical trials registry, www.clinicaltrials.gov, prior to initiation of the PCT. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

The VRP requires that all TBI-related clinical research with at least 50 subjects funded by this program be shared through the jointly supported DOD-National Institutes of Health Federal Interagency TBI Research Information System (FITBIR). Recipients will be required to upload study data annually and in accordance with the FITBIR data submission policies. There is no fee to use FITBIR, and detailed guidance and policies, including a cost estimator tool for budgeting considerations, can be found at https://fitbir.nih.gov.

II.F.4. Reporting

Annual technical progress reports and quad charts as well as a final technical progress report and quad chart will be required. Annual and final technical reports must be prepared in accordance with the Research and Performance Progress Report (RPPR). In addition, quarterly progress reports are required for awards containing a PCT.

The Award Terms and Conditions will specify whether 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.

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

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

specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

> Phone: 301-682-5507

> Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

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

> Email: support@grants.gov

II.H. Other Information

II.H.1. 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 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- Preproposal Narrative exceeds page limit.

- Preproposal Narrative is missing.

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

- Submission of an application for which a letter of invitation was not issued.

- Project Narrative exceeds page limit.

- Project Narrative is missing.

- Budget is missing.

- ***For applications containing a PCT:*** Pilot Clinical Trial Plan ([Attachment 11](#)) is missing.

- ***For applications containing a PCT:*** Regulatory Strategy ([Attachment 12](#)) 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 the Project Narrative.

- Documents not requested will be removed.

II.H.2.c. Withdrawal

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

- Failure to submit all associated (Overall Lead PI and Project PIs) applications by the deadline.

- An FY24 VRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation. ***A list of the FY24 VRP Programmatic Panel members can be found at https://cdmrp.health.mil/vrp/panels/panels24.***

- The application fails to conform to this program announcement description.

- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.

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

- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety

of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.

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

- Submission of the same research project to different funding opportunities within the same program and fiscal year.

- The pre-application includes fewer than three or more than five research projects.

- The invited application differs from the pre-application in title or research objectives of either the overall application or the individual projects.

- An investigator being named as the Overall Lead PI on more than one FTTSA application will result in withdrawal of all FTTSA applications received after the first submission.

- The Overall Lead PI does not meet the eligibility criteria.

- A Project PI does not meet the eligibility criteria.

- Failure to submit all associated (Overall Lead PI and Project PIs) applications by the deadline.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded	
	Overall Lead PI	Project PI
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐	☐
Attachments		
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐	
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐	
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐	
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐	
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐	
Relevance to Military Health Statement – Attachment 7, upload as "Military.pdf"	☐	
Translation Statement – Attachment 8, upload as "Translation.pdf"	☐	
Post-Award Transition Plan – Attachment 9, upload as "Transition.pdf"	☐	
Animal Research Plan – Attachment 10, upload as "AnimalResPlan.pdf", if applicable	☐	
Pilot Clinical Trial Plan – Attachment 11, upload as "PCT.pdf", if applicable	☐	
Regulatory Strategy – Attachment 12, upload as "Regulatory.pdf", if applicable	☐	
Representations *(Extramural submissions only)* – Attachment 13, upload as "RequiredReps.pdf", if applicable	☐	☐
Suggested Intragovernmental Budget Form – Attachment 14, upload as "IGBudget.pdf", if applicable	☐	☐
Research & Related Personal Data	☐	☐
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐	☐
Budget *(Intramural submissions only)* Include budget justification	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐	☐

APPENDIX 1: 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
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FTTSA	Focused Translational Team Science Award
FTTSA - PCT	Focused Translational Team Science Award with Pilot Clinical Trial
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
PCT	Pilot Clinical Trial
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
UEI	Unique Entity Identifier
URL	Uniform Resource Locator

USAMRAA   U.S. Army Medical Research Acquisition Activity
USAMRDC   U.S. Army Medical Research and Development Command
USC   United States Code
VA   U.S. Department of Veterans Affairs
VRP   Vision Research Program