

# **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: Initial**

**Funding Opportunity Number: W81XWH-21-VRP-FTTSA**

**Catalog of Federal Domestic Assistance Number: 12.420 Military Medical  
Research and Development**

## **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), July 21, 2021
- **Invitation to Submit an Application:** September, 2021
- **Application Submission Deadline:** 11:59 p.m. ET, November 16, 2021
- **End of Application Verification Period:** 5:00 p.m. ET, November 19, 2021
- **Peer Review:** January 2022
- **Programmatic Review:** March 2022

*This program announcement must be read in conjunction with the General Application Instructions, version 604. 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

|                    |  |           |
|--------------------|--|-----------|
| <b>I.</b>          | <b>OVERVIEW OF THE FUNDING OPPORTUNITY.....</b>  | <b>1</b>  |
| <b>II.</b>         | <b>DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY.....</b>   | <b>3</b>  |
| II.A.              | Program Description.....   | 3         |
| II.A.1.            | FY21 VRP Focus Areas .....   | 3         |
| II.A.2.            | Award History .....  | 4         |
| II.B.              | Award Information .....  | 4         |
| II.C.              | Eligibility Information.....   | 8         |
| II.C.1.            | Eligible Applicants .....  | 8         |
| II.C.2.            | Cost Sharing.....  | 9         |
| II.C.3.            | Other .....  | 9         |
| II.D.              | Application and Submission Information.....  | 9         |
| II.D.1.            | Address to Request Application Package.....  | 10        |
| II.D.2.            | Content and Form of the Application Submission .....   | 10        |
| II.D.3.            | Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM) ..... | 33        |
| II.D.4.            | Submission Dates and Times.....  | 34        |
| II.D.5.            | Funding Restrictions.....  | 35        |
| II.D.6.            | Other Submission Requirements .....  | 36        |
| II.E.              | Application Review Information .....   | 36        |
| II.E.1.            | Criteria .....   | 36        |
| II.E.2.            | Application Review and Selection Process.....  | 41        |
| II.E.3.            | Integrity and Performance Information.....   | 41        |
| II.E.4.            | Anticipated Announcement and Federal Award Dates.....  | 42        |
| II.F.              | Federal Award Administration Information .....   | 42        |
| II.F.1.            | Federal Award Notices.....   | 42        |
| II.F.2.            | Administrative and National Policy Requirements.....   | 43        |
| II.F.3.            | Reporting.....   | 43        |
| II.G.              | Federal Awarding Agency Contacts.....  | 44        |
| II.G.1.            | CDMRP Help Desk .....  | 44        |
| II.G.2.            | Grants.gov Contact Center .....  | 44        |
| II.H.              | Other Information.....   | 45        |
| II.H.1.            | Program Announcement and General Application Instructions Versions.....                                      | 45        |
| II.H.2.            | Administrative Actions.....  | 45        |
| II.H.3.            | Application Submission Checklist .....   | 48        |
| <b>APPENDIX 1:</b> | <b>ACRONYM LIST .....</b>  | <b>50</b> |

## **II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY**

### **II.A. Program Description**

Applications to the Fiscal Year 2021 (FY21) Vision Research Program (VRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC). The VRP was initiated in 2009 to fund impactful military-relevant vision research that has the potential to significantly improve the healthcare and well-being of military Service Members, Veterans, their family members and caregivers, and the American public. Appropriations for the VRP from FY09 through FY20 totaled \$124.95 million (M). The FY21 appropriation is \$20M.

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

The goal of the VRP is to transform visual system trauma care for our Armed Forces and the Nation. Eye injury and visual dysfunction resulting from battlefield trauma affect a large number of Service Members and Veterans. Surveillance data from the Department of Defense (DOD) showed more than 275,000 eye injuries in the U.S. armed services between 2000 and 2017. More than 6,000 of the injuries were categorized as high risk of blindness. In addition, statistics from the Defense and Veterans Brain Injury Center show that through the third quarter of 2020, more than 430,000 Service Members have been diagnosed with traumatic brain injury (TBI), which can have significant impact on vision even when there is no injury to the eye. In a study sponsored by the Department of Veterans Affairs (VA), as many as 75% of Service Members who suffered a TBI self-reported visual dysfunction, with some patients suffering vision loss and functional blindness<sup>1</sup>.

The FY21 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-relevant trauma. Research outcomes are expected to ultimately improve the care of Service Members and Veterans as well as the American public.

#### **II.A.1. FY21 VRP Focus Areas**

To meet the intent of the award mechanism, applications to the FY21 VRP Focused Translational Team Science Award (FTTSA) must address research in one or more of the following Focus Areas:

- Eye injury or visual dysfunction as related to a military-relevant traumatic event. Examples of military-relevant trauma may include, but are not limited to:
  - Blast, penetrating, blunt, thermal, or chemical trauma
  - Trauma caused by directed energy weapons such as laser, high-power microwaves, and particle beams
- Diagnosis, stabilization, and treatment of eye injuries in austere environments and prolonged field care settings
- Restoration of visual function after trauma-related vision loss or severe visual impairment

## II.A.2. Award History

The VRP FTTSA mechanism was first offered in FY18. Since then, 17 FTTSA applications have been received, and 2 have been recommended for funding.

## II.B. Award Information

The FY21 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 a military-relevant traumatic event (e.g., blast, blunt, thermal, chemical, directed energy trauma).

**New for FY21:** Applicants are encouraged to leverage resources and expertise at the National Center for Advancing Translational Sciences (NCATS) to improve efficiency and accelerate the translational process. A list of NCATS programs and resources supporting preclinical innovation can be found at <https://ncats.nih.gov/preclinical>.

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 a military-relevant trauma 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 near 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

[FY21 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 a military-relevant trauma
  - Identification of significant changes in pathophysiology over time after trauma 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 a military-relevant trauma
  - Development or improvement of clinically relevant trauma models
  - Design of protection to mitigate the impact of military-relevant trauma 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 FY21 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 FY21 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.
- ***A clinical trial is defined*** as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. For more information on how to distinguish clinical trials from observational studies, see the [Human Subject Resource Document](#).
  - Funded PCTs are required to post a copy of the Institutional Review Board (IRB)-approved informed consent form used to enroll subjects on a publicly available

federal website in accordance with federal requirements described in Code of Federal Regulations, Title 32, Part 219 (32 CFR 219).

- **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:** The overall effort will be led by a Principal Investigator (PI) with demonstrated success in leading large collaborative research project(s). In addition to leading the overall effort, the overall lead PI may serve as the project leader for one project. Each project leader, including the overall lead PI, may lead no more than one project. 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.

Applicants may consult the following resource documents as applicable:

- [Blast Term Dictionary and Guidance Documents for Blast Injury Research](#)
- [A Primer for Conducting 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 anticipated direct costs budgeted for the entire period of performance for an FY21 VRP Focused Translational Team Science Award will not exceed **\$4,000,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2022. For additional information refer to [Section II.F.1, Federal Award Notices](#).

***The CDMRP expects to allot approximately \$6.0M to fund approximately one VRP FT TSA application. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY21 funding opportunity will be funded with FY21 funds, which will expire for use on September 30, 2027.***

The types of awards made under the program announcement will be assistance agreements. An assistance agreement is appropriate when the federal government transfers a “thing of value” to a

“state, local government,” or “other recipient” to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the DOD during project performance is the key factor in determining whether to award a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

**Rigor of Experimental Design:** All projects should adhere to accepted standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. Core standards are described in Landis, S.C., et al., A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 (<https://www.nature.com/nature/journal/v490/n7419/full/nature11556.html>). While these standards were written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in research and should be applied consistently across basic and translational studies.

**Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers:** All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 1, and the Human Research Protections Office Resources and Overview document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

If the proposed research is cooperative (i.e., involving more than one institution), plans for the multi-institutional structure governing the research protocol(s) should be outlined.

A written plan for single IRB review arrangements must be provided for cooperative clinical research conducted in the United States. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements. The master protocol and consent form must be reviewed by the HRPO prior to distribution to the additional sites for IRB/EC review. Communication and data transfer between or among the collaborating institutions, as well as how specimens and/or imaging products obtained during the study will be handled, should be included in the appropriate sections of the application.

**Use of DOD or VA Resources:** If the proposed research involves access to active-duty military or Veteran patient populations and/or DOD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

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

## **II.C. Eligibility Information**

### **II.C.1. Eligible Applicants**

**II.C.1.a. Organization:** All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.

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

As applications for this program announcement may be submitted by extramural and intramural organizations, these terms are defined below.

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

**Intramural DOD Organization:** A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission: Application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.***

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

### **II.C.1.b. Principal Investigator**

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.***



Each investigator may be named on only one FT TSA application as the overall lead PI.

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

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

### **II.C.1.c. Project Leader**

The leader of each project must be an independent investigator at or above the level of Assistant Professor (or equivalent).

### **II.C.2. Cost Sharing**

Cost sharing/matching is not an eligibility requirement.

### **II.C.3. Other**

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

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

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

## **II.D. Application and Submission Information**

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

*Exception: Applicants to the FY21 VRP FT TSA are permitted to simultaneously submit individual projects as applications to the FY21 VRP Translational Research Award (TRA) (Funding Opportunity Number: W81XWH-21-VRP-TRA) or Funding Level 2 of the FY21 VRP Investigator-Initiated Research Award (IIRA) (Funding Opportunity Number: W81XWH-21-VRP-IIRA). The scope and budget of the FT TSA 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.*

### ***Extramural Submission:***

- Pre-application content and forms must be accessed and submitted at [eBRAP.org](http://eBRAP.org).
- Full application packages must be accessed and submitted at Grants.gov.

### ***Intramural DOD Submission:***

- Pre-application content and forms must be accessed and submitted at [eBRAP.org](http://eBRAP.org).
- Full application packages must be accessed and submitted at [eBRAP.org](http://eBRAP.org).

***Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.***

## **II.D.1. Address to Request Application Package**

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

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

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

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

***The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process.*** Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507 prior to the application submission deadline.

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

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

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

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

All pre-application components must be submitted by the overall PI through eBRAP (<https://eBRAP.org>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

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

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

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

- **Tab 1 – Application Information**

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

- **Tab 2 – Application Contacts**

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

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

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

- **Tab 3 – Collaborators and Key Personnel**

Enter the name, organization, and role of all collaborators and key personnel associated with the application.

[FY21 VRP Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

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

- **Tab 5 – Pre-Application Files**

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

- **Preproposal Narrative (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 forbidden and may result in administrative withdrawal of the application.*

The Preproposal Narrative should include the following:

- **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-relevant trauma. Identify what is achievable in the long term (10 to 15 years) and what should and can be achieved in the near term. Articulate how the overarching challenge or question relates to the barrier(s)/gap(s), the long-term expectation and the near-term goals, and how it aligns with one or more of the [FY21 VRP Focus Areas](#).
- **Overall Strategy**
  - Clearly state the title and hypothesis or objective of each research project.

- Articulate how each project relates to the overarching challenge or question.
  - Concisely state the rationale, specific aims, and experimental approach of each research project. As applicable, identify the animal models to be studied, the data to be analyzed, and/or the human subject population to be engaged during the study.
  - If applicable, clearly identify which projects involve preclinical or clinical studies and which project involves a PCT. Describe how the outcome of the PCT will inform the feasibility, rationale, and design of subsequent clinical trials.
  - 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, the contribution of the overall lead PI as the leader, and how the collaboration leverages expertise and strengths of investigators specializing in different fields. Outline the overall lead PI’s past experience in leading large collaborative projects. Outline the collective expertise, experience, and resources of the participating research groups that are the most relevant to the proposed team initiative. 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.
- **Tab 6 – Submit Pre-Application**

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

## Pre-Application Screening

- **Pre-Application Screening Criteria**

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

- **Overarching Challenge:** How well the overarching challenge or question addresses a barrier(s) and/or gap(s) in the understanding, prevention, diagnosis, mitigation, and/or treatment of eye injury or visual dysfunction associated with a military-relevant trauma. How well the overarching challenge or question is related to well-defined long-term vision and near-term goals. How well the overarching challenge or question aligns with [FY21 VRP Focus Areas](#).
- **Research Strategy:** How well the individual projects relate to the overarching challenge or question. How well the projects are supported by rationale. To what extent the specific aims and approaches form a coherent research plan to address clearly defined objective(s)/hypothesis(es). 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. To what extent the overall lead PI is well-prepared and committed to lead the research team and proposed projects. To what extent the collective expertise, experience, and resources of the participating research groups are appropriate to successfully complete the projects. 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.

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

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

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

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

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

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

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

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

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

**Table 1. Full Application Submission Guidelines**

| Extramural Submissions  | Intramural DOD Submissions   |
|---|--|
| <b>Application Package Location</b>   |  |
| Download application package components for W81XWH-21-VRP-FTTSA from Grants.gov ( <a href="https://www.grants.gov/">https://www.grants.gov/</a> ) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission. | Download application package components for W81XWH-21-VRP-FTTSA from eBRAP ( <a href="https://ebrap.org/">https://ebrap.org/</a> ).  |
| <b>Full Application Package Components</b>  |  |
| <b>SF424 Research &amp; Related Application for Federal Assistance Form:</b> Refer to the General Application Instructions, Section III.A.1, for detailed information.  | <b>Tab 1 – Summary:</b> Provide a summary of the application information.<br><b>Tab 2 – Application Contacts:</b> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative. |
| Descriptions of each required file can be found under Full Application Submission Components:   | <b>Tab 3 – Full Application Files:</b> Upload files under each Application Component in eBRAP.   |



| Extramural Submissions   | Intramural DOD Submissions   |
|--|--|
| <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">Research &amp; Related Subaward Budget Attachment(s) Form</a></li> </ul>  | <p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Key Personnel</a></li> <li>• <a href="#">Budget</a></li> <li>• <a href="#">Performance Sites</a></li> </ul> <p><b>Tab 4 – Application and Budget Data:</b> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>  |
| <b>Application Package Submission</b>  |  |
| <p><b>Create a Grants.gov Workspace.</b><br/>Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p><b>Submit a Grants.gov Workspace Package.</b><br/>An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package <b>at least 24-48 hours prior to the close date</b> to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p><i>Note:</i> If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <b>prior to</b> the application submission deadline. <b>Do not password protect any files of the application package, including the Project Narrative.</b></p> | <p><b>Submit package components to eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</b></p> <p><b>Tab 5 – Submit/Request Approval Full Application:</b> After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. <b>Do not password protect any files of the application package, including the Project Narrative.</b></p> |
| <b><u>Application Verification Period</u></b>  |  |
| <p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <b>with the</b></p>   | <p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the</p>  |



| Extramural Submissions  | Intramural DOD Submissions  |
|---|---|
| <i>exception of the Project Narrative and Research &amp; Related Budget Form.</i>   | application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research &amp; Related Budget Form</i> . Your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline. |
| Further Information   |   |
| <p><b>Tracking a Grants.gov Workspace Package.</b><br/>After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p> | Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.  |

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

**Attachments:**

*Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.*

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

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

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

Describe the proposed project in detail using the outline below.

**1. 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.

**1.1. 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 a military-relevant trauma. 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 near term. Support the long-term expectation and near-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 near-term goals.
- Explain how the overarching challenge or question aligns with one or more of the [FY21 VRP Focus Areas](#).

**1.2. 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 clinical studies that will also 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.

### 1.3. 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 leaders, including the levels of effort.
- Clearly demonstrate that there is sufficient expertise for all aspects of the proposed work.

### 1.4. 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.

## 2. 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.*

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

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

- 2.3. 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.
- 2.4. 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.
- 2.5. 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.
- 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 9, Animal Research Plan](#), as applicable.
  - If human subjects or human biological samples will be used, describe the study population and include a detailed plan for the recruitment of subjects or the acquisition of samples. Further details of research involving human subjects or human biological substances will be required in [Attachment 10, Human Subjects/Samples Acquisition and Safety Procedures](#), as applicable. Additionally, research containing a PCT should include a pilot clinical trial plan, as outlined below in 2.6.
  - Describe the statistical plan and the rationale for the statistical methodology. Provide a sample size estimate and the method by which it was derived, including power analysis calculation, if applicable. **Note:** The statistical plan under [2.5, Research Strategy](#) is for the preclinical and/or non-PCT clinical studies that will also be performed through this award. If proposing a PCT, the statistical plan for the PCT should be included in [2.6, Pilot Clinical Trial Plan](#).
  - Describe measures to be taken to reduce bias and achieve reproducible and rigorous results, including controls, blinding, randomization, and data handling, as applicable.

- Describes measures to be taken to ensure data quality and integrity.
- Address potential problems that may arise and present alternative methods and approaches.
- Explain how the research can be completed within the proposed period of performance.

**2.6. Pilot Clinical Trial Plan (if applicable):** 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. Briefly identify the intervention to be tested, projected outcomes, study variables, controls, and endpoints. Demonstrate the availability of, and access to, the intervention to be tested.
- As appropriate for the proposed PCT, describe the statistical model and data analysis plan. If applicable, include power analysis calculations.
- Describe potential challenges and alternative strategies, where appropriate.

**2.7. 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. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e.,

author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not 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 or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.
- **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 availability of the product for the duration of the study, support for the proposed phase of research, and support for the indication to be tested.
- **Intellectual Property:** Information can be found in 2 CFR 200.315, "Intangible Property."
  - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.

- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
  - All TBI clinical research projects are required to report data to the Federal Interagency TBI Research (FITBIR) informatics system (<https://fitbir.nih.gov/>) on a quarterly basis.
- **Quad Chart:** Provide a Quad Chart for the proposed project. The format for the quad chart is available on the eBRAP “Funding Opportunities & Forms” web page at <https://ebrap.org/eBRAP/public/Program.htm>.
- **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.
- **Use of VA Resources (if applicable):** Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **Attachment 3: 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. **Do not include proprietary or confidential information.** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

*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 be written using the outline below:

- **Overarching Challenge:** Describe the overarching challenge or question of the proposed collaborative effort. 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-relevant trauma. State the long-term expectation and near-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 near-term goals. Describe how the overarching challenge aligns with one or more of the [FY21 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 [FY21 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. Abstracts of all funded research projects will be posted publicly. **Do not include proprietary or confidential information. Do not duplicate the technical abstract.** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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) (12-page limit): Upload as “SOW.pdf”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>. For the FTTSA mechanism, use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

Refer to the “Suggested SOW Strategy Generic Research” document for guidance on preparing the overarching section of the SOW. The overarching SOW should include a list of major tasks that support the coordination and collaboration between projects.



For project-specific sections of the SOW, refer to either the “Suggested SOW Strategy Generic Research” or “Suggested SOW Strategy Clinical Research”, whichever format is most appropriate for the project. Each project-specific section should include a list of major tasks that support the proposed specific aims of the project, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

- Include the name(s) of the key personnel and contact information for each study site/subaward site.
- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
- Identify cell line(s) and commercial or organizational source(s) to be used.
- If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug [IND] and Investigational Device Exemption [IDE] applications) by DOD HRPO, the U.S. Food and Drug Administration (FDA), or other government agency.
- **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 [FY21 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, 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.
  - 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 healthcare 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).
  - Whether and 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.
    - 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 the FDA regulatory approval requirements, and how the investigative team will include expertise in the FDA regulatory approval process.
  - As applicable, clearly state specific regulatory milestones, such as when an IND/IDE application will be submitted.
  - As applicable, describe how the proposed research facilitates or accommodates the reciprocal transfer of ideas between preclinical and clinical science.

- If the proposed research includes a PCT, explain how the preclinical research, clinical research, and PCT components are connected and synergistic to advance the anticipated research outcomes toward clinical implementation.
- **Attachment 9: Animal Research Plan (required if the proposed research involves the use of animals; no page limit): Upload as “AnimalPlan.pdf”.** Describe the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. Consult the ARRIVE (Animal Research: Reporting In Vivo Experiments) guidelines (<https://journals.plos.org/plosone/article/file?type=supplementary&id=info:doi/10.1371/journal.pone.0146533.s001>) to ensure that animal research is adequately planned for and will be adequately reported. The Animal Research Plan should address the following points for each proposed animal study:
  - Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study’s relevance to human biology. If dogs or cats are proposed, provide the source of the animals.
  - Summarize the procedures to be conducted. Describe the interventions to minimize discomfort, distress, pain, and injury. These include analgesia, anesthesia, sedation, palliative care, and humane endpoints. Identify methods of euthanasia. If the method is not consistent with the American Veterinary Medical Association Guidelines for the Euthanasia of Animals, provide justification.
  - 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, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
  - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
  - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s)/outcome measures.
  - Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- **Attachment 10: Human Subjects/Samples Acquisition and Safety Procedures (required if the proposed research involves human subjects or human biological samples; no page limit): Upload as “HumProc.pdf”.** The Human Subjects/Samples

Acquisition and Safety Procedures attachment should include the components listed below, as applicable.

- **Study Population and Recruitment Process:** Describe the study population (i.e., Service Members/Veterans/civilians, approximate number, age ranges, sex/gender, ethnic groups, and other pertinent demographic characteristics), criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual/retention of human subjects.
  - Demonstrate that the research team has access to the proposed study population. If applicable, discuss past efforts in recruiting human subjects from the target population for previous clinical studies.
  - Address any potential barriers to accrual and plans for addressing unanticipated delays.
  - Describe how the subject-to-group assignments process will be conducted (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable.
  - **Women and Minorities in the Study:** Consistent with the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects,” and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment Report format is a one-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.
  - Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
  - ***For clinical studies proposing to recruit military personnel, refer to the General Application Instructions, Appendix 1, for more information on recruitment process and considerations, payment, and confidentiality. If a non-military population will be used for the proposed study, explain how results obtained will be applicable to military personnel.***

- **Informed Consent Process:** Describe the plan for obtaining informed consent from human subjects. Include relevant draft process documents. **Provide a draft, in English, of the Informed Consent Form.**
- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry.
- **Risks/Benefits Assessment:** Identify all foreseeable study risks (physical, psychological, social, legal, and other). Discuss the importance of the knowledge to be gained in relation to the risks to subjects. Clearly describe measures of risk management and plans for emergency response. Describe known and potential benefits, which may or may not be direct to subjects, in relation to risks.

***Note: Payment and/or other compensation for participation are not considered benefits and must be addressed in Study Population and Recruitment Process.***

- **Human Samples:** Describe the types and source(s) of specimens, records, or data to be collected and evaluated. Include information about specimen storage (i.e., location, duration, special handling conditions). Describe the identifiers that will be associated with the human specimens and data and provide a list of who has access to subjects' identities. Describe how individually identifiable private information will be protected.
- **Attachment 11: 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 the FDA or an international regulatory agency:**

- Explain why the product/intervention is exempt from FDA oversight. Provide confirmation that the PCT does not require regulation by the FDA in writing from the IRB of record or the FDA. If the PCT will be conducted at international sites, provide equivalent information relevant to the host country(ies) regulatory requirements. No further information for this attachment is required.

**For products/interventions that require regulation by the FDA or an international 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 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 is necessary but has not been submitted to the FDA prior to the award date, or if documented status of the IND or IDE has not been obtained within 6 months of the award date.***
- The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed PCT.
- If a technical or a protocol amendment to an IND/IDE is necessary to conduct the PCT, provide a copy of the FDA acknowledgment letter and meeting minutes (pre-IND/pre-IDE 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 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, Good Manufacturing Practice [GMP]-compliant lots available, status of stability testing), non-clinical development (e.g., test facility name, status of pivotal Good Laboratory Practice [GLP] toxicology studies to support Phase I 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 Good Clinical Practice (GCP) guidelines.
- **Attachment 12: Post-Award Transition Plan (three-page limit): Upload as “Transition.pdf”.** The FT TSA mechanism is intended to move promising discoveries into 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. PIs are encouraged to explore developing relationships with industry, DOD advanced developers, 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 as applicable.
  - The next phase of development (e.g., clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by the FDA) after the successful completion of the proposed study.
  - 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.
  - The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication (e.g., Target Product Profile). Describe in detail the FDA regulatory strategy, including the number and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings to be held, the submission filing strategy, and considerations for compliance with GMP, GLP, and GCP guidelines, if appropriate.
  - 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 for knowledge products, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications.
  - Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the Government’s ability to access such products or technologies in the future.

- If applicable, a risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 13: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- **Attachment 14: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility will be a collaborator in performance of the project, complete a separate budget using “Suggested Collaborating DOD Military Facility Budget Format”, available for download on the eBRAP “Funding Opportunities & Forms” page (<https://ebrap.org/eBRAP/public/Program.htm>). A military facility may be a Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center. Include a budget justification for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

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

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

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

- **PI Biographical Sketch (six-page limit):** Upload as “Biosketch\_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health (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”.

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

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

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

- **Extramural Applications Only**

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

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- **Intramural DOD Collaborator(s):** Complete the “Suggested Collaborating DOD Military Facility Budget Format” and upload to Grants.gov attachment form as [Attachment 14](#). (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

### **II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)**

Applicant organizations and all sub-recipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Verify the status of the applicant organization’s Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the federal awarding agency is ready to make a federal award, the federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that

determination as a basis for making a federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

***Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI):*** Through April 2022, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

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

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

#### **Applicant Verification of Full Application Submission in eBRAP**

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

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

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

Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

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

#### **II.D.5. Funding Restrictions**

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

The anticipated direct costs budgeted for the entire period of performance will not exceed **\$4,000,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the government exceeding **\$4,000,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

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

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

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

- Travel costs for the overall lead PI and project leaders to present project information or disseminate project results at a 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:

- Support for multidisciplinary collaborations, including travel.
- Travel costs for the overall lead PI and project leaders to travel to one scientific/technical meeting per year in addition to the required meeting described above to present project information or disseminate project results from the FY21 VRP FTTSA.
- Costs associated with FITBIR data submission, if applicable. A project estimation tool (<https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp>) is available to help estimate FITBIR submission costs.

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

their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

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

## **II.D.6. Other Submission Requirements**

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

## **II.E. Application Review Information**

### **II.E.1. Criteria**

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

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

- **Overarching Challenge**
  - To what degree the barrier(s)/gap(s) is clearly described and its analysis is supported by rationale and literature.
  - To what degree the long-term expectation and near-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 near-term goals.
  - How well the overarching challenge or question aligns with one or more of the [FY21 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 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.
- **Team and Personnel**
  - 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 responsibilities of project leaders are clearly defined and appropriate.
  - To what degree the levels of effort for the overall lead PI and for project leaders are appropriate.
  - To what degree there is evidence of sufficient expertise for 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.
- **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 research idea or solution is innovative or novel or an advancement over existing ideas or solutions, as applicable.

- 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.
- If applicable, how well the chosen cell line(s) or animal model(s) is appropriate for addressing the study aims and is relevant to human visual biology or injury.
- 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.
- To what extent the statistical plan, including sample size estimate, is appropriate.
- How well the proposed research is designed to reduce bias and achieve reproducible and rigorous results.
- To what extent the measures to ensure data quality and integrity are appropriate.
- How well the application acknowledges potential problems and addresses alternative approaches.
- 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, including intervention to be tested, projected outcomes, study variables, controls, and endpoints.
  - To what extent the statistical plan of the PCT, including sample size estimate, is appropriate.
  - To what extent the application demonstrates availability of, and access to, the intervention to be tested.
- Whether the research can be completed within the proposed period of performance.

- **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 the FDA regulatory approval requirement and process.
  - For research involving a PCT: To what extent the Regulatory Strategy provides sufficient evidence for IND/IDE exemption or, if IND/IDE is required, an appropriate plan/timeline for applying for and obtaining IND/IDE status (or other FDA approvals), to ensure a timely start of the PCT.
- As applicable, whether the proposed research has clear and feasible regulatory milestones.
- As applicable, how well the proposed research facilitates or accommodates the reciprocal transfer of ideas between preclinical and clinical science.
- As applicable, how well the preclinical research, clinical research, and PCT components are connected and synergistic to advance the anticipated research outcomes toward clinical implementation.

- **Post-Award Transition Plan**

- Whether the identified next phase of development and/or commercialization is rational.
- 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 an FDA-regulated product (e.g., drug, biologics, or device), to what degree the regulatory strategy and product development plan are appropriate to support a regulatory filing with the FDA.
- 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.

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 accessibility 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 **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 data and resources generated during the performance of the project will be shared with the research community.

- **Application Presentation**

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

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

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY21 VRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Relative impact
  - Relevance to military health
  - Program portfolio composition



## 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.army.mil/about/2tierRevProcess>. An information paper describing the funding recommendations and review process for the award mechanisms for the VRP will be provided to the PI and posted on the CDMRP website.

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

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

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

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

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

## **II.E.4. Anticipated Announcement and Federal Award Dates**

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

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

## **II.F. Federal Award Administration Information**

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

Awards supported with FY21 funds are anticipated to be made no later than September 30, 2022. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

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

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

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

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

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

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

The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

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

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

### **II.F.2. Administrative and National Policy Requirements**

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

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

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

Refer to full text of the latest [DoD R&D General Terms and Conditions](#); the [USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions](#); and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

### **II.F.3. Reporting**

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

Annual progress reports as well as a final progress report will be required.

The Award Terms and Conditions will specify if more frequent reporting is required.

Annual and final quad charts will be required.

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

Inclusion Enrollment Reporting Requirement (***only required for clinical research studies***): Enrollment on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final technical report. The suggested Inclusion Enrollment Report format is available on the

“Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP.

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

## **II.G. Federal Awarding Agency Contacts**

### **II.G.1. CDMRP Help Desk**

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

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

### **II.G.2. Grants.gov Contact Center**

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

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

Email: [support@grants.gov](mailto:support@grants.gov)

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

## **II.H. Other Information**

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

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 604a. The program announcement numeric version code will match the General Application Instructions version code 604.

### **II.H.2. Administrative Actions**

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

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

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

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

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- *For applications containing a PCT:* Human Subjects/Samples Acquisition and Safety Procedures ([Attachment 10](#)) is missing.
- *For applications containing a PCT:* Regulatory Strategy ([Attachment 11](#)) is missing.

#### **II.H.2.b. Modification**

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

#### **II.H.2.c. Withdrawal**

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

- An FY21 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. *A list of the FY21 VRP Programmatic Panel members can be found at <https://cdmrp.army.mil/vrp/panels/panels21>.*

- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY21, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- The pre-application includes fewer than three or more than five research 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 invited application proposes a different research project overall or different individual research projects than that described in the pre-application.
- The invited application differs from the pre-application in title or research objectives of either the overall application or the individual projects.
- Submission of the same research project to different funding opportunities within the same program and fiscal year, while recognizing the specific [exception](#) to this withdrawal criteria stated on page 9.
- The PI does not meet the eligibility criteria.
- Project lead does not meet the eligibility criteria.

#### **II.H.2.d. Withhold**

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

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

| Application Components   | Action   | Completed |
|--|--|-----------|
| SF424 Research & Related Application for Federal Assistance ( <b>extramural submissions only</b> )                               | Complete form as instructed  |           |
| Summary (Tab 1) and Application Contacts (Tab 2) ( <b>intramural submissions only</b> )  | Complete tabs as instructed  |           |
| Attachments  | Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"  |           |
|  | Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"  |           |
|  | Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"  |           |
|  | Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"   |           |
|  | Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"   |           |
|  | Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"   |           |
|  | Relevance to Military Health Statement: Upload as Attachment 7 with file name "Military.pdf"                                 |           |
|  | Translation Statement: Upload as Attachment 8 with file name "Translation.pdf"   |           |
|  | Animal Research Plan: Upload as Attachment 9 with file name "AnimalPlan.pdf" if applicable                                   |           |
|  | Human Subjects/Samples Acquisition and Safety Procedures: Upload as Attachment 10 with file name "HumProc.pdf" if applicable |           |
|  | Regulatory Strategy: Upload as Attachment 11 with file name "Regulatory.pdf" if applicable                                   |           |
|  | Post-Award Transition Plan: Upload as Attachment 12 with file name "Transition.pdf"  |           |
|  | Representations (extramural submissions only): Upload as Attachment 13 with file name "RequiredReps.pdf" if applicable       |           |
| Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 14 with file name "MFBudget.pdf" if applicable |  |           |



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

## APPENDIX 1: ACRONYM 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        |
| DUNS     | Data Universal Numbering System                              |
| eBRAP    | Electronic Biomedical Research Application Portal            |
| EC       | Ethics Committee   |
| ET       | Eastern Time   |
| FAD      | Funding Authorization Document                               |
| FAPIIS   | Federal Awardee Performance and Integrity Information System |
| FDA      | U.S. Food and Drug Administration                            |
| FITBIR   | Federal Interagency TBI Research                             |
| FY       | Fiscal Year  |
| GCP      | Good Clinical Practices                                      |
| GLP      | Good Laboratory Practices                                    |
| GMP      | Good Manufacturing Practices                                 |
| HRPO     | Human Research Protection Office                             |
| IACUC    | Institutional Animal Care and Use Committee                  |
| IDE      | Investigational Device Exemption                             |
| IIRA     | Investigator-Initiated Research Award                        |
| IND      | Investigational New Drug                                     |
| IRB      | Institutional Review Board                                   |
| M        | Million  |
| MIPR     | Military Interdepartmental Purchase Request                  |
| NCATS    | National Center for Advancing Translational Sciences         |
| NIH      | National Institutes of Health                                |
| ORCID    | Open Researcher and Contributor ID, Inc.                     |
| ORP      | Office of Research Protections                               |
| PCT      | Pilot Clinical Trial   |
| PI       | Principal Investigator                                       |
| SAM      | System for Award Management                                  |
| SOW      | Statement of Work  |
| STEM     | Science, Technology, Engineering, and/or Mathematics         |

|         |  |
|---------|--|
| TBI     | Traumatic Brain Injury                             |
| TRA     | Translational Research Award                       |
| UEI     | Unique Entity Identifier                           |
| URL     | Uniform Resource Locator                           |
| USAMRAA | U.S. Army Medical Research Acquisition Activity    |
| USAMRDC | U.S. Army Medical Research and Development Command |
| USC     | United States Code                                 |
| VA      | Department of Veterans Affairs                     |
| VRP     | Vision Research Program                            |