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-18-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), September 4, 2018
- **Invitation to Submit an Application:** October 2018
- **Application Submission Deadline:** 11:59 p.m. ET, December 4, 2018
- **End of Application Verification Period:** 5:00 p.m. ET, December 7, 2018
- **Peer Review:** February 2019
- **Programmatic Review:** March 2019

This Program Announcement must be read in conjunction with the General Application Instructions, version 20180329. The General Applications 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."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

***New for 2018*: Application submission by extramural organizations through Grants.gov requires use of the Workspace interface, which separates the application package into individual forms. Applicants must create a Workspace in Grants.gov, complete the required forms, and submit their application Workspace package.**

II.A. Program Description

Applications to the Fiscal Year 2018 (FY18) Vision Research Program (VRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement is the Congressionally Directed Medical Research Programs (CDMRP). The VRP was initiated in 2009 to fund impactful military-relevant vision research that has the potential to significantly improve the health care and well-being of military Service members, Veterans, their family members and caregivers, and the American public. Appropriations for the VRP from FY09 through FY17 totaled $70.2 million (M). The FY18 appropriation is $15M.

The vision of the FY18 VRP is to transform vision 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) indicate that eye injury accounts for approximately 15% of all injuries from battlefield trauma sustained during the wars in Afghanistan and Iraq, resulting in more than 182,000 ambulatory patients and 4,000 hospitalizations between 2000 and 2011. In addition, traumatic brain injury (TBI) affects approximately 380,000 Service members, according to statistics from the Defense and Veterans Brain Injury Center, and can have significant impact on vision even when there is no injury to the eye. Research sponsored by the Department of Veterans Affairs (VA) showed that as many as 75% of Service members who had suffered a TBI had visual dysfunction. The FY18 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. FY18 VRP Focused Translational Team Science Award (FTTSA) Focus Area

To meet the intent of the award mechanism, all applications to the FY18 VRP FTTSA must address research in the following Focus Area:

- 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, blunt, thermal, or chemical trauma
- Trauma caused by directed energy weapons such as laser, microwaves, and particle beams
- Ionizing radiation

II.A.2. Award History

The VRP FTTSA mechanism is being offered for the first time in FY18.

II.B. Award Information

The FY18 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, biological, directed energy, ionizing radiation).

The anticipated ***direct*** costs budgeted for the entire period of performance for an FY18 VRP FTTSA will not exceed **$5M**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Key aspects of this award 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 meet the intent of the FTTSA, the overarching challenge or question must be defined in the context of the FY18 VRP FTTSA Focus Area. 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 vision, identify what should and can be achieved in the near term, and 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. 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
    - 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 said trauma

- Development or improvement of clinically relevant models for said trauma
- Design of protection to mitigate the impact of said trauma on eye and vision

- While individual projects must be capable of standing on their own scientific merits, they must also be interrelated and synergistic with the other proposed projects and together advance a solution beyond what would be possible through individual efforts. The 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 addressing the overarching challenge and be capable of producing research findings with potential to impact the 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 FY18 VRP FTTSA allows funding for one pilot clinical trial where limited clinical testing of a novel intervention is conducted to inform the feasibility, rationale, and design of subsequent clinical trials. The pilot clinical trial should be limited in scale and scope and should represent only a portion of the proposed research. A clinical trial is defined as a prospective accrual of patients in whom an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention. For more information on how to distinguish clinical research from clinical trials, see the Human Subject Resource Document at https://ebrap.org/eBRAP/public/Program.htm.

- **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.

- **Research Team:** The overall effort will be led by a Principal Investigator (PI) with demonstrated success in leading large collaborative research project(s). ***The overall lead PI is required to devote a minimum of 20% effort to this award.*** The project leader of each of the complementary and synergistic research projects must be an independent investigator with strong qualifications. 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.

The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). 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.

Extramural Organizations: An assistance agreement (grant or cooperative 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. 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 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 (http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards were written for preclinical studies, the basic principles of randomization, blinding/masking, sample-size estimation, and data handling derive from well-established best practices in research and should be applied consistently across basic and translational studies. Projects that include research on animal models are required to submit Attachment 9, Animal Research Plan, as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE (Animal Research: Reporting In Vivo Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at http://www.nc3rs.org.uk/page.asp?id=1357.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (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. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled, "Research Involving Animals." ***Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

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 USAMRMC ORP, Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of

submission is ***not*** required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application as a stand-alone study. Submission to HRPO of protocols involving more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource 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.

DoD/VA Collaboration and Alignment Encouraged: Relevance to the healthcare needs of the Armed Forces, their family members, and/or Veterans is a key feature of this award. Therefore, PIs are strongly encouraged to collaborate, integrate, and/or align their research projects with military and/or VA research laboratories and programs. Although not a comprehensive list, the following websites may be useful in identifying information about ongoing DoD and VA areas of research interest, ongoing research, or potential opportunities for collaboration:

Armed Forces Radiobiology Research Institute
https://www.usuhs.edu/afrri/

Clinical and Rehabilitative Medicine Research Program
https://crmrp.amedd.army.mil/

Combat Casualty Care Research Program
https://ccc.amedd.army.mil

Congressionally Directed Medical Research Programs
http://cdmrp.army.mil

Defense Advanced Research Projects Agency
https://www.darpa.mil/

Defense Technical Information Center
http://www.dtic.mil

Defense Threat Reduction Agency
http://www.dtra.mil/

Military Operational Medicine Research Program
https://momrp.amedd.army.mil

Naval Medical Research Center
http://www.med.navy.mil/sites/nmrc

Uniformed Services University of the Health Sciences
http://www.usuhs.edu/research

U.S. Army Institute of Surgical Research
http://www.usaisr.amedd.army.mil/

U.S. Army Research Laboratory
http://www.arl.army.mil

U.S. Department of Veterans Affairs
Office of Research and Development
www.research.va.gov

Vision Center of Excellence
http://vce.health.mil/

Use of DoD or VA Resources: If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the application must describe the access at the time of submission and a plan for maintaining access as needed throughout the proposed research. Access to target active duty military patient population(s) and/or DoD resource(s) or database(s) should be confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief. If appropriate, the application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the application should include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

Access to certain DoD or VA patient populations, resources, or databases may only be obtained by collaboration with a DoD or VA investigator who has a substantial role in the research and may not be available to a non-DoD or non-VA investigator if the resource is restricted to DoD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DoD or non-VA investigator collaborating with the DoD and/or VA. If access cannot be confirmed at the time of application submission, the Government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s). Refer to Section II.D.2.b.ii, Full Application Submission Components, for detailed information.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 2, Section K.

Awards will be made no later than September 30, 2019. For additional information refer to Section II.F.1, Federal Award Notices.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including 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, Government, and research institutes.

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

Note: Applications from an intramural DoD organization or from an extramural Federal organization may be submitted through a research foundation.

The 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.***

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 http://orcid.org/.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

An investigator may be designated the overall lead PI on only one FY18 VRP FTTSA application.

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

Applicants to the FY18 VRP FTTSA are permitted to simultaneously submit individual projects as applications to the FY18 VRP Investigator-Initiated Research Award (IIRA) (Funding Opportunity Number: W81XWH-18-VRP-IIRA). The scope and budget of the FTTSA and the IIRA projects must be appropriate for the respective award mechanism. Accepting multiple awards to support the same project will not be allowed.

Extramural Submission is defined as an application submitted by an organization to Grants.gov.

Intramural DoD Submission is defined as an application submitted by a DoD organization to eBRAP.

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.

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

Intramural DoD Submissions: Pre-application content and forms and full application packages must be accessed and submitted at eBRAP.org.

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*** and ***full application*** as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-Application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (https://eBRAP.org/).

Full Application Submission: Full applications must be submitted through the online portals as described below.

Submitting Extramural Organizations: Full applications from extramural organizations must be submitted through a Grants.gov Workspace. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in Section II.C.1, Eligible Applicants.

Submitting Intramural DoD Organizations: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP.

For Both Extramural and Intramural Applicants: A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. 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. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement.

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

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

During the pre-application process, each submission is assigned a unique log number by eBRAP. 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 or 301-682-5507 to request a change in designation.

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

The applicant organization and associated PIs 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 PI must contact the CDMRP Help Desk at 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. Note that the codes have recently been revised. 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 (R&R) 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 (R&R) 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.

  FY18 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 or 301-682-5507.

  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 pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY18, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Pre-applications or applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- **Tab 4 – Conflicts of Interest**

  List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). Refer to the General Application Instructions, Appendix 3, Section C, for further information regarding COIs.

- **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-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

    The Preproposal Narrative should include the following sections:

    - **Overarching Challenge:** State which type of trauma is being addressed and how it impacts eyesight. Describe what is achievable in 10 to 15 years. Explain what barrier(s) or gap(s) must be overcome in order to preserve eyesight in the event of the trauma. Articulate the overarching challenge or question that the proposed collaborative research will address and how it relates to the barrier(s)/gap(s) and to the long-term vision. Present rationale and relevant data to support the feasibility of addressing the overarching challenge or question.

    - **Research Strategy**

      - Concisely state the rationale, hypothesis or objective, specific aims, and experimental approach of each research project.

      - 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.

      - If applicable, clearly identify which projects involve preclinical or clinical studies and which involves a pilot clinical trial. Describe how the outcome of the pilot clinical trial will inform the feasibility, rationale, and design of subsequent clinical trials.

    - **Research Team:** Outline the overall lead PI's past experience in leading large collaborative projects. Briefly describe the nature and scale of the collaboration and the contribution of the PI as the leader. 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 this study on the understanding, prevention, diagnosis, mitigation, and/or treatment of eye injury or visual dysfunction associated with the trauma to be addressed.

- **Military Relevance:** Describe how the proposed research is applicable to military Service members, Veterans, and/or their family members and caregivers.

- **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.

  - PI and Project Leaders 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 DHP and the VRP, pre-applications will be screened based on the following criteria:

  - **Overarching Challenge:** To what extent the selection of the overarching challenge or question is based on sound analysis of barriers and/or gaps that must be overcome to preserve eyesight in the event of trauma. How well the PI establishes the feasibility to address the overarching challenge or question.

  - **Research Strategy:** How well the individual projects form a concerted effort to address the overarching challenge. To what extent the projects will synergistically advance a solution beyond what would be possible through individual efforts.

- **Research Team:** To what degree the background and expertise of the overall lead PI and project leaders are appropriate to successfully complete the projects. To what extent the overall lead PI is well prepared and committed to lead the research team and proposed projects.

- **Impact:** To what extent the potential short-term and long-term outcome(s) of the proposed research, as a whole, will make important contributions toward the goal of preserving eyesight in the events of trauma.

- **Military Relevance:** Whether the proposed research is applicable to military Service members, Veterans, and/or their family members and caregivers.

- **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 the PI has received notification of invitation.

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 (http://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 the 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.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-18-VRP-FTTSA from Grants.gov (http://www.grants.gov) and create a Grants.gov Workspace. The 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-18-VRP-FTTSA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • R&R Subaward Budget Attachment(s) Form (if applicable)	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel • Budget • Performance Sites **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to the Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application"

Extramural Submissions	Intramural DoD Submissions
the "Forms" tab. Grants.gov recommends submission of the application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission. Note: 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 prior to the application submission deadline.	button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email.
Application Verification Period	
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.	After eBRAP has processed the full application, the organizational Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified. 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	
Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full

application package may be submitted. 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.

Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.

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 (R&R) 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 (30-page limit):** Upload as "ProjectNarrative.pdf". The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

    Describe the proposed team science research in detail using the outline below.

    1. **Overall Program:** 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.*** Emphasize areas of synergy throughout the narrative.

1.1. Overarching Challenge: State the overarching challenge or question that unifies the individual research projects. Identify the type of trauma that is being addressed and its impact on eyesight. Describe the barriers to and/or gaps in the understanding, prevention, diagnosis, mitigation, and/or treatment of eye injury or visual dysfunction associated with the trauma. Support the gap analysis with relevant literature and clear rationale. Describe how the overarching challenge or question relates to the barriers/gaps.

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

- Explain the short-term and long-term goals and the rationale for choosing each research project, including the anticipated contribution of each project, how the projects relate to each other, and evidence for the feasibility and readiness of the project.

- If applicable, clearly identify which projects involve preclinical or clinical studies and which involves a pilot clinical trial. Describe how the pilot clinical trial 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 in the proposed team science research. ***The overall lead PI is required to devote a minimum of 20% effort to this award.*** Describe the PI's past success in leading a large collaborative research effort, including details on the nature of the collaboration, the scale of the project, and the PI's contribution as the project leader.

- Discuss the qualifications of the research groups being brought together by the collaboration. Outline the responsibilities of group leaders and key members. If applicable, describe group leaders' and key members' past experience in team science research, including details on the nature of the collaboration, the scale of the project, and the role of the investigator.

2. Project-Specific Narratives: 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 (four-page limit per project is recommended). ***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. Describe each person's qualifications and role(s) in the project.

2.3. Research Idea

- Present the ideas and reasoning behind the proposed work. Cite relevant literature. Include relevant preliminary data; these data may be unpublished or from the published literature. Describe previous experience most pertinent to the project.

- If applicable, describe any element of the idea or solution that is innovative or novel or offers refinements, improvements, or new applications of existing ideas or solutions.

2.4. Hypothesis or Objective: State the hypothesis to be tested or the objective to be reached.

2.5. Specific Aims: Concisely explain the project's specific aims.

2.6. Research Strategy: Describe the experimental design, methods, and analyses, including appropriate randomization, blinding/masking, and controls in sufficient detail for critical evaluation.

- Address potential problem areas and present alternative methods and approaches.

- Describe any consideration given or measures taken to maximize the immediate or long-term translational potential of the anticipated research outcome(s), if applicable. Describe any reciprocal flow of ideas and/or information between basic and clinical science, if applicable.

- Describe the statistical plan and sample size estimate, if applicable. Provide the rationale for the statistical methodology as well as an appropriate power analysis.

- 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 animal injury model was chosen over other models and how it is optimal for addressing the study aims and is relevant to human visual system injury. Describe how animal research will be conducted in accordance with the ARRIVE guidelines (http://www.nc3rs.org.uk/page.asp?id=1357). Further details of research involving animals will be required in Attachment 9, 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 human subjects or the acquisition of samples. Further details of research involving human subjects or human biological samples will be required in Attachment 10, as applicable.

- If applicable, describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA).

2.7. Pilot Clinical Trial Plan (if applicable): If the proposed research includes a pilot clinical trial, describe the plans for initiating and conducting the pilot clinical trial during the course of this award.

- Describe the design of the pilot clinical trial 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. Describe potential challenges and alternative strategies, where appropriate.

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

- Describe how the pilot clinical trial is limited in scale and scope, and how it will be utilized to inform the feasibility, rationale, and design of subsequent clinical trials.

2.8. Outcome: Describe the anticipated outcome(s) (knowledge and/or product) that will be directly attributed to the results of the proposed research. Compare the outcome(s) to existing knowledge/product(s), if applicable. Explain how the outcome(s) will be used to advance the goal of preserving eyesight after trauma.

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

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

- 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.

- **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 publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

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

- Letters of Collaboration: 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.

- Letters of Commitment (if applicable): 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 Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), "Intangible Property."

  - Intellectual and Material Property Plan: 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 from the proposed study will be shared with the wider 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.

  FITBIR Data Sharing: For proposed clinical studies that will enroll TBI subjects, the DoD requires that awardees make TBI data generated via this award mechanism available to the research community by depositing de-identified research data into the Federal Interagency TBI Research (FITBIR) Informatics System on a quarterly basis. FITBIR guidance and policies, as well as the considerable advantages of FITBIR use to the researcher, are detailed at FITBIR: Federal Interagency Traumatic Brain Injury Research Informatics System (http://fitbir.nih.gov/).

  Data elements must be reported using the National Institute of Neurological Disorders and Stroke (NINDS) TBI Common Data Elements (CDEs) or entered into the FITBIR data dictionary as new, unique data elements. For the most current version of the NINDS TBI CDEs, go to http://www.commondataelements.ninds.nih.gov. Assistance will be available to help researchers map their study variables to specific CDEs and ensure the formats of the CDEs collected are compatible with the FITBIR informatics system. If the proposed research data cannot be entered in CDE format, the investigators must supply a proposal for an alternative data submission or data sharing vehicle and justification for use. Use of the TBI CDEs is required wherever possible in an effort to create standardized definitions and guidelines about the kinds of data to collect and the data collection methods that should be used in clinical studies of TBI.

- Quad Chart: Complete and upload the Quad Chart template available from the eBRAP "Funding Opportunities and Forms" web page (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 patient 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 ACOS/R&D or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA NPC is not identified as the applicant institution for administering the funds, include a letter from the VA

ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

- **Attachment 3: 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.

  Applicants should note that the members of the Programmatic Panel may 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:

  - **Background:** Present the ideas and reasoning behind the proposed work. Describe the trauma of interest and how it impacts eyesight. Summarize the current knowledge and/or clinical practice related to the trauma, and identify the barrier(s) and/or gap(s) that must be overcome to preserve eyesight in the event of the trauma.

  - **Overarching Challenge:** Describe the overarching challenge or question that unifies the individual research projects.

  - **Research Plan:** Clearly articulate the overall research strategy and the role of individual projects within the overall strategy. Briefly describe the hypothesis/objective and study design of each project, the relationship between projects, and the strategy to coordinate efforts and create synergy. If applicable, clearly identify which project involves a pilot clinical trial.

  - **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 vision research and/or on patient care.

  - **Military Relevance:** Describe how the proposed research is relevant to military Service members, Veterans, and/or their family members and caregivers.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as "LayAbs.pdf". The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information***. 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. Do not duplicate the technical abstract.

- Describe the trauma that the proposed research will address and explain how the trauma leads to eye injury and/or visual impairment.
- Clearly describe the rationale, objectives, and aims of the proposed research.
- Describe the ultimate applicability and potential impact of the research:
  - What types of trauma patients will it help, and how will it help them? Include the current available statistics to the related trauma.
  - What are the potential clinical applications, benefits, and risks? If the research is not expected to have immediate clinical applicability, describe the interim outcomes.
  - If the proposed research includes a pilot clinical trial, describe how it will inform the feasibility, rationale, and design of subsequent clinical trials.
  - What is the projected time it may take to achieve the expected patient-related outcome?
  - What are the likely contributions of the proposed research to advancing the field of vision research?
  - How will the proposed research benefit military Service members, Veterans, their family members and caregivers, as well as the American public?

- **Attachment 5: Statement of Work (SOW) (12-page limit):** Upload as "SOW.pdf". The SOW should include an overarching section followed by project-specific sections (two-page limit per section is recommended). 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). For the FTTSA mechanism, complete each section using the SOW format example titled, "SOW (Statement of Work) Generic Format". The SOW must be in PDF format prior to attaching.

  The overarching section of the SOW should include a list of major tasks that support the coordination and collaboration between projects. The section for each project 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 the FDA or other Government agency.

- **Attachment 6: Impact and Military Relevance Statement (two-page limit):** Upload as "Impact.pdf".

  - **Impact**

    - 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 understanding, prevention, diagnosis, mitigation, and/or treatment of eye injury or visual dysfunction associated with trauma.

    - Describe the likelihood, and the anticipated timeline, that the above advancement will lead to a practical application to preserve eyesight in events of trauma. Compare the anticipated application to existing knowledge and/or practice.

    - 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.

  - **Military Relevance**

    - Explain how the proposed research is responsive to the healthcare needs and quality of life of military Service members and Veterans with eye injury and/or visual impairment.

    - 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).

    - 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 a non-military population will be used for the proposed research project, explain how the population simulates the targeted 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 7: 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).

  - How well the proposed research will move promising ideas, observations, and/or laboratory findings toward clinical applications. Clearly address the following points:

    - Where the field is now.

    - Where the field will be after the successful completion of the proposed research.

    - To translate the outcome(s) of the proposed research into clinical applications, what steps need to be taken, what barriers need to be overcome.

  - How well the proposed research is designed to generate translatable outcome(s). Identify specific considerations that are intended to ensure or promote translational potential.

  - How well the proposed research facilitates or accommodates the reciprocal transfer of ideas between pre-clinical and clinical science, as applicable.

  - If the proposed research includes a pilot clinical trial, explain how the preclinical research, clinical research, and pilot clinical trial components are connected and synergistic to advance the anticipated research outcomes toward clinical implementation.

- **Attachment 8: Post-Award Transition Plan (three-page limit):** Upload as "Transition.pdf". The FTTSA mechanism is intended to advance the pursuit of clinical solutions to critical issues in trauma-related vision research. Assuming the project 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 encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. Articulate the transition plan for the overall effort as well as the individual projects. The transition plan should include the components listed below, as appropriate:

  - A description of the outcomes expected upon completion of the proposed research efforts. Outcomes should be specific and measurable. Clearly indicate the intended end user (e.g., ophthalmologists, optometrists, non-specialist clinicians, combat medics/corpsmen, Service members).

- 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.

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

- If the ultimate goal is to produce an FDA-regulated product (e.g., drug, biologic, or device), state the planned indication for the product label and provide an outline of the development plan required to support that indication (e.g., Target Product Profile). Describe 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 Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), and Good Clinical Practice (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, specific funding opportunities to be applied for). Include a description of collaborations and other resources that will be used to provide continuity of development.

- For knowledge outcomes, a description of how the knowledge will be further developed, disseminated, and incorporated into clinical/patient care, 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.

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

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

- **Attachment 9: Animal Research Plan (required for each project involving animals; no page limit):** Combine all Animal Research Plans into one document and upload as "AnimalPlan.pdf". Start each Plan on a new page. The Animal Research Plan should not be a verbatim replica of the protocol(s) to be submitted to the IACUC. Each Animal Research Plan should address the following points:

  - Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used are appropriate to 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/masking procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding/masking 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).

- **Attachment 10: Human Subjects/Sample Acquisition and Safety Procedures (required for each project involving human subjects or human biological samples; no page limit):** Combine all Procedures into one document and upload as "HumProc.pdf". Start each Procedures on a new page. Each Procedures 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, gender, ethnic groups and other pertinent demographic characteristics), criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual 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 and/or clinical trials.

    - Address any potential barriers to accrual and plans for addressing unanticipated delays.

    - Describe how the subject-to-group assignment process will be conducted (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable.

    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 USAMRMC. This policy is intended to promote equity both in assuming the burdens

and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded from the study.

For clinical studies or trials proposing to recruit military personnel, refer to the General Application Instructions, Appendix 1, for more information.

- **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 Sample:** 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 Statement (required only if proposing a pilot clinical trial; no page limit):** If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf". Answer the following questions and provide supporting documentation as applicable.

  - State the 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 pilot clinical trial does not require regulation by the FDA in writing from the IRB of record or the FDA. If the pilot clinical trial will be conducted at international sites, provide equivalent information relevant to the host country(ies) regulatory requirements. No further information for this Attachment is required.

For products/interventions that require regulation by the FDA and/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 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 pilot clinical trial.

- If a technical or a protocol amendment to an IND/IDE is necessary to conduct the pilot clinical trial, 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 to 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 pilot clinical trial.

- Provide a current status for manufacturing development (e.g., manufacturer's name, GMP-compliant lots available, status of stability testing), non-clinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support Phase I testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).

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

- **Attachment 12: Representations, if applicable (extramural submissions only):** Upload as "MandatoryReps.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 13: DoD Military Budget Form(s), if applicable:** Upload as "MFBudget.pdf". If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the DoD Military Budget Form, available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural and Intramural Applications**

  To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 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, 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.2, for detailed information.

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

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

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

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

Research & Related Budget: 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.

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.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only**

  R&R Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.6, for detailed information.

  - **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, 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 DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 13. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and 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 subrecipient 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.

New Requirement: In March 2018, the General Services Administration (GSA) implemented fraud prevention security measures in the SAM that require every ***new*** contractor registrant to provide a written (hard copy), notarized letter confirming the entity's Administrator authorized

to register the entity in the SAM database or to make changes to its registration. Effective April 29, 2018, the notarized letter process is now mandatory on all ***current*** registrants at SAM who have a requirement to update data on their SAM record. The notarized letter is mandatory and is required before the GSA Federal Service Desk (FSD) will activate the entity's registration. The Office of the Secretary of Defense and GSA realize the length of time needed to transmit, receive, process, and approve the notarized letters presents a significant impact on the ability of the contracting activity to make timely awards, but these steps must be taken to mitigate fraud concern. ***Notarized letters are required for all new and existing SAM-registered entities.*** The notarized letters must be postal service mailed (not emailed or faxed) to the "Federal Service Desk" and must contain the information outlined in the SAM-posted Frequently Asked Questions (FAQs) at https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/sam-update. Instructions for domestic entities and instructions for international entities with embedded templates for use are also provided within the SAM Update notice with frequently asked questions at https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/sam-update.

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

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 retrieved files against the specific Program Announcement requirements and discrepancies will be noted in both the email and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement. ***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 Budget Form cannot be changed after the application submission deadline.

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(s) 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 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 **$5.0M**. 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 **$5.0M** 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 PI and project leaders to present project information or disseminate 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 (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Research-related subject costs
- Clinical research costs
- Support for multidisciplinary collaborations, including travel

- Travel costs for the PI and up to four co-investigators to travel to one scientific/technical meeting per year in addition to the required meetings described above to present project information or disseminate project results from the FY18 VRP FTTSA

- Costs associated with FITBIR data submission. A project estimation tool (https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp) is available to help estimate FITBIR submission costs.

Awards made to extramural organizations will consist solely of assistance agreements (grants and cooperative agreements). 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 fund 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.4, 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.4***.

The CDMRP expects to allot approximately $7.5M of the $15M FY18 VRP appropriation to fund approximately one FTTSA application, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program.

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. The time is considered when establishing the award's period of performance. It is anticipated that awards made from this funding opportunity will be funded with FY18 funds, which will expire for use on September 30, 2024.

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:

- **Impact**
    - The significance of overcoming the overarching challenge. To what extent the overarching challenge impacts a critical problem or question in vision preservation after military-relevant trauma.
    - To what degree the proposed collaborative effort could, if successful, advance the field of vision research, change the standard of care, contribute to the development or validation of evidence-based policy or guidelines for patient evaluation and care, or otherwise impact the visual health of Service members, Veterans and the American public.
- **Overall Strategy**
    - To what degree the choice of projects demonstrates a coherent plan to address the overarching challenge. Whether the short-term and long-term goals are clearly articulated.
    - To what degree the choice of projects leverages the strengths of investigators specializing in different fields.
    - To what degree the interaction between projects will create synergy to address the overarching challenge more effectively than if the projects are conducted independently.
    - Whether the research can be completed within the proposed period of performance.
- **Team and Personnel**
    - To what degree the PI has demonstrated success in leading large collaborative research project(s).
    - To what degree the PI's responsibilities in the proposed research are clearly defined and appropriate.
    - Whether the PI will devote a minimum of 20% effort to this award.
    - To what degree qualifications of the research groups, including the group leaders' and key members' past experience in team science research, support the individual projects as well as the collaborative effort.
    - To what degree there is evidence of sufficient expertise for all aspects of the collaborative effort.
    - To what degree there is evidence of strong commitment by all participating groups to the projects.
    - To what degree the levels of effort are appropriate for successful conduct of the proposed work.

- **Implementation Plan**
    - To what degree the plans for assessing progress of both the overall effort and individual projects are appropriate and feasible.
    - To what degree the plans for participating research groups to interact and share results and newly acquired knowledge are appropriate and feasible.
    - To what degree the plans for communication and data transfer among the participating research groups are appropriate and feasible.
    - To what degree the plans to share resources and access to facilities are appropriate, if applicable.
- **Project-Specific Strategy:** Each individual project shall be evaluated by the criteria below.
    - How well the preliminary data and scientific rationale support the research idea of the project.
    - 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 hypothesis and/or objective of the project.
    - To what extent the experimental design is feasible, as described.
    - How well the application acknowledges potential problems and addresses alternative approaches.
    - How well the proposed research is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding/masking, randomization, statistical analysis, and data handling.
    - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
    - To what extent the statistical plan and power analysis are appropriate for the proposed project.
    - For research involving cell line(s) or animals:
        - To what extent the choice of cell line(s) or animal model(s) is justified. Whether the number of animals is appropriate.
        - To what extent the endpoints/outcome measures are appropriate.

- As applicable, whether the design of animal studies demonstrates adequate planning in accordance with the ARRIVE guidelines (http://www.nc3rs.org.uk/page.asp?id=1357) and supports adequate reporting of animal research.

- As applicable, whether the method of euthanasia and the interventions to minimize discomfort, distress, pain, and injury are appropriate.

  - For research involving clinical research ***except pilot clinical trial (criteria for evaluating the pilot clinical trial plan are described separately)***:

    - As applicable, how well the population(s) or sample(s) of interest is (are) described, access to the population(s) or sample(s) is demonstrated, and viable plans for subject recruitment or sample acquisition, consent, screening, and retention are outlined.

    - How well plans for addressing ethical and regulatory considerations have been developed, including consideration of risks and benefits, protection against risks, justification for limited inclusion, privacy issues, and the process for obtaining informed consent.

  - For research involving ***a pilot clinical trial***:

    - Whether the pilot clinical trial is limited in scale and scope, and how well it will inform the feasibility, rationale, and design of subsequent clinical trials.

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

    - To what extent the pilot clinical trial has a clear and sound design, including appropriate controls, study variables, endpoints, etc.

    - How well the population(s) of interest is (are) described, access to the population(s) or sample(s) is demonstrated, and viable plans for subject recruitment, consent, screening and retention are outlined.

    - How well the application demonstrates sufficient and appropriate consideration of risks and benefits, protection against risks, justification for limited inclusion, privacy issues, and the process for obtaining informed consent.

    - To what extent the Regulatory Statement 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).

- **Translation**

  - How well the proposed research will move promising ideas, observations, and/or laboratory findings toward clinical applications.

- To what extent the design of the proposed research promotes the generation of translatable outcome(s).

- How well the proposed research facilitates or accommodates the reciprocal transfer of ideas between basic and clinical science, as applicable.

- How well the preclinical research, clinical research, and pilot clinical trial components are connected and synergistic to advance the anticipated research outcomes toward clinical implementation, if applicable.

- **Post-Award Transition Plan**

  - To what degree the identified next phase of development and/or commercialization is realistic.

  - To what degree the methods and strategies to move the anticipated research outcomes to the next phase of development and/or commercialization are feasible.

  - To what degree 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.

  - If applicable, to what degree the proposed collaborations and other resources for providing continuity of development are established and/or achievable.

  - If applicable, to what degree the intellectual and material property plan is appropriate.

  - If applicable, to what degree 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 project.

  - 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 project.

- **Budget**
    - Whether the ***direct*** costs are equal to or less than the allowable maximum direct costs as published in the Program Announcement.
    - Whether the budget is appropriate for the proposed research.
- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY18 VRP, as evidenced by the following:
    - Adherence to the intent of the award mechanism
    - Relative impact
    - Military relevance
    - Program portfolio balance

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 of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and VRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***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 http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement 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 will be made no later than September 30, 2019. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

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

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 Organizations: Awards 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.

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

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

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.

Unless otherwise restricted, changes in PI will be allowed at the discretion of the Grants Officer, provided that the intent of the award mechanism is met. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

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

II.F.2. Administrative and National Policy Requirements

PI is required to present project information or disseminate results of this FY18 VRP IIRA at one DoD-sponsored meeting (e.g., Military Health System Research Symposium).

Applicable requirements in the DoDGARs found in 32 CFR, Chapter 1, 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 USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D 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.***

Quarterly, annual, and final technical progress reports will be required.

Quarterly, annual, and final quad charts will be required.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template titled, "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.

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 $10,000,000 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 Terms and Conditions (see General Application Instructions, Section III.A.4).

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

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

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 20180329h. The Program Announcement numeric version code will match the General Applications Instructions version code 20180329.

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 pilot clinical trial:*** Human Subjects/Sample Acquisition and Safety Procedures (Attachment 10) is missing.
- ***For applications containing a pilot clinical trial***: Regulatory Statement (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 FY18 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 FY18 VRP Programmatic Panel members can be found at http://cdmrp.army.mil/vrp/panels/panels18***.

- 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 FY18, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- 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 less than three or more than five research projects.

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

- The invited application does not propose the same research project described in the pre-application.
- PI 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 (R&R) Application for Federal Assistance **(Extramural submissions only)**	Complete form as instructed.	
Summary (Tab 1) and Application Contacts (Tab 2) **(Intramural submissions only)**	Complete these 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 and Military Relevance Statement: Upload as Attachment 6 with file name "Impact.pdf".	
	Translation Statement: Upload as Attachment 7 with file name "Translation.pdf".	
	Post-Award Transition Plan: Upload as Attachment 8 with file name "Transition.pdf".	
	Animal Research Plan: Upload as Attachment 9 with file name "AnimalPlan.pdf", if applicable.	
	Human Subjects/Sample Acquisition and Safety Procedures: Upload as Attachment 10 with file name "HumProc.pdf", if applicable.	
	Regulatory Statement: Upload as Attachment 11 with file name "Regulatory.pdf", if applicable.	
	Representations (Extramural submissions only): Upload as Attachment 12 with file name "MandatoryReps.pdf", if applicable.	
	DoD Military Budget Form(s): Upload as Attachment 13 with file name "MFBudget.pdf", if applicable.	
Research & Related Personal Data	Complete form as instructed.	

Application Components	Action	Completed
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget **(Extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Budget **(Intramural submissions only)**	Complete the DoD Military Budget Form and justification.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R&R 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
CDEs	Common Data Elements
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
DHA	Defense Health Agency
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
EAB	External Advisory Board
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FAQs	Frequently Asked Questions
FDA	U.S. Food and Drug Administration
FITBIR	Federal Interagency TBI Research
FSD	Federal Service Desk
FTTSA	Focused Translational Team Science Award
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GSA	General Services Administration
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
NINDS	National Institute of Neurological Disorders and Stroke
NPC	Non-Profit Corporation
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, Mathematics
TBI	Traumatic Brain Injury
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
VA	Department of Veterans Affairs
VRP	Vision Research Program