

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Vision Research Program

Mentored Clinical Research Award

Announcement Type: Initial

Funding Opportunity Number: HT942524VRPMCRA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern time (ET), August 8, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, August 23, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, August 29, 2024
- **Peer Review:** October 2024
- **Programmatic Review:** December 2024

This program announcement must be read in conjunction with the General Application Instructions, version 901. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”

TABLE OF CONTENTS

I.	OVERVIEW OF THE FUNDING OPPORTUNITY.....	1
II.	DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY.....	3
II.A.	Program Description.....	3
II.A.1.	FY24 VRP Focus Areas	3
II.B.	Award Information	4
II.C.	Eligibility Information.....	6
II.C.1.	Eligible Applicants	6
II.C.2.	Cost Sharing.....	6
II.C.3.	Other	6
II.D.	Application and Submission Information.....	7
II.D.1.	Location of Application Package	7
II.D.2.	Content and Form of the Application Submission	8
II.D.2.a.	Step 1: Pre-Application Submission	8
II.D.2.b.	Step 2: Full Application Submission	9
II.D.2.c.	Applicant Verification of Full Application Submission in eBRAP	19
II.D.3.	Unique Entity Identifier (UEI) and System for Award Management (SAM)	19
II.D.4.	Submission Dates and Times.....	19
II.D.5.	Funding Restrictions.....	19
II.D.6.	Other Submission Requirements	20
II.E.	Application Review Information	21
II.E.1.	Criteria	21
II.E.2.	Application Review and Selection Process.....	23
II.E.3.	Integrity and Performance Information.....	23
II.F.	Federal Award Administration Information	24
II.F.1.	Federal Award Notices.....	24
II.F.2.	PI Changes and Award Transfers.....	25
II.F.3.	Administrative and National Policy Requirements	25
II.F.4.	Reporting	25
II.G.	Federal Awarding Agency Contacts.....	26
II.G.1.	eBRAP Help Desk.....	26
II.G.2.	Grants.gov Contact Center	26
II.H.	Other Information.....	26
II.H.1.	Program Announcement and General Application Instructions Versions.....	26
II.H.2.	Administrative Actions.....	27
II.H.3.	Full Application Submission Checklist	29
	APPENDIX 1: ACRONYM LIST	30

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

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

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

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

II.A.1. FY24 VRP Focus Areas

To meet the intent of the funding opportunity, applications to the FY24 VRP Mentored Clinical Research Award (MCRA) must address research in one of more of the following Focus Areas:

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

² Harvey MM, Justin GA, Brooks DI, et al. 2021. Ocular trauma in operation Iraqi freedom and operation enduring freedom from 2001 to 2011: A bayesian network analysis. *Ophthalmic Epidemiology* 28(4):312-321.

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

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

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

- Understand and treat eye injury or visual dysfunction as related to military exposure
- Diagnose, stabilize, and treat eye injuries in austere environments and prolonged care settings
- Restore visual function after military exposure-related vision loss or severe visual impairment

II.B. Award Information

The FY24 VRP MCRA is intended to support patient-oriented vision injury research and develop research expertise of highly motivated military or civilian clinicians in training. Research supported by the MCRA can be a standalone study of high impact to vision injury care or the generation of clinical research data in preparation for a more expansive study.

Each MCRA must be led by an established clinician or Ph.D. clinical scientist who will serve as Principal Investigator (PI) of the award. Key personnel must include a clinician in training (e.g., a fellow, resident, junior clinician, clinician in a Ph.D. program). The clinician in training should have sufficient time remaining in their training program to complete the research proposed under the MCRA. The clinician in training will conduct the proposed research under the mentorship of the PI, with support from supporting personnel as appropriate. While additional junior scientists or clinicians may participate in the research, ***only one clinician in training may be designated as mentee.*** A Letter of Organizational Support and Mentee Eligibility, signed by the Department Chair or appropriate organization official, and a Letter of Commitment, signed by the mentee, should be submitted as part of [Attachment 2: Supporting Documentation](#).

For the purposes of this award mechanism, clinical research is defined as research conducted with human subjects or research on material of human origin, such as tissues or specimens or data obtained from human subjects. **Documentation of Institutional Review Board (IRB)/ Ethics Committee (EC) approval or exemption by December 1, 2024, is required for an MCRA application to be considered for funding.** See [Attachment 2: Supporting Documentation](#) for additional detail.

The MCRA may not be used to conduct preclinical research (including animal research) or clinical trials.

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

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

Studies that retrospectively analyze data generated from previously conducted clinical trial(s) are not considered a clinical trial.

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

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

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

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

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

CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

Applications involving collaborations among academia, industry, the military services, the U.S. Department of Veterans Affairs (VA), and other federal government agencies are highly encouraged.

Applicants may consult the following resource documents as applicable:

- [Blast Term Dictionary and Guidance Documents for Blast Injury Research](#)
- [A Primer for Conducting Department of Defense \(DOD\) Funded Human Research with Military Populations](#)
- [A Beginner's Guide to Army Healthcare System](#)

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

The types of awards made under the program announcement will be grants (31 USC 6304).

The anticipated **total costs** (including direct costs and indirect) costs budgeted for the entire period of performance for an FY24 VRP MCRA should not exceed **\$75,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

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

The CDMRP expects to allot approximately \$0.225M to fund approximately three VRP MCRA applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

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

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

II.C.1.b. Principal Investigator

Established clinicians or Ph.D. clinical scientists may be named by the organization as the PI on the application.

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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

II.D. Application and Submission Information

II.D.1. Location of Application Package

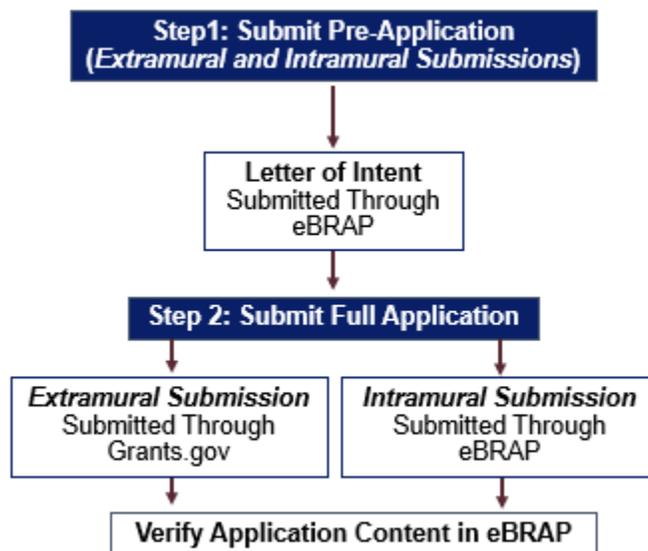
Submission is a two-step process requiring both a *pre-application* submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a *full application* (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission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

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

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

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

Application Submission Workflow



Extramural Submission: An application submitted by an [extramural organization](#) for an extramural or intramural PI working within an extramural or intramural organization. For

example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524VRPMCRA from Grants.gov (<https://grants.gov>). Full applications from extramural organizations *must* be submitted through Grants.gov.

Intramural Submission: An application submitted by an [intramural DOD organization](#) for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524VRPMCRA from the anticipated submission portal eBRAP (<https://ebrap.org>) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. *The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.*

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

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

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

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

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

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

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

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

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the focus area under which the application will be submitted.

LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review. An invitation to submit a full application is **NOT** provided after LOI submission and applicants are **NOT** required to have such an invitation in order to proceed to submitting a full application. ***Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.***

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

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

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

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

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

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

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

(b) Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 2.

- **Attachment 1: Project Narrative (four-page limit): Upload as “ProjectNarrative.pdf”.** The page limit of the Project Narrative applies to text and non-

text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background/Rationale:** Provide a sound scientific rationale for the proposed research. Describe why the proposed research is needed and in which ways it can address the need(s). Clearly stating the objective(s) to be reached and/or the hypothesis(es) to be tested. Present critical analysis of literature and, as available, preliminary data, to support the readiness of the objective(s), the soundness of the hypothesis(es), and the feasibility of the approach(es). Preliminary data are allowed but not required.
- **Specific Aims:** Concisely explain the project’s specific aims. Explain how the aims address the objective(s) and/or hypothesis(es) of the proposed research.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate randomization, blinding/masking, and controls. Provide sufficient detail so that the appropriateness and feasibility of the research strategy can be fully evaluated.
 - Describe the study population and include a detailed plan for the recruitment and retention of subjects or the acquisition of samples. Further details of research involving human subjects or human biological substances will be required in [Attachment 6: Human Subjects/Samples Acquisition and Safety Procedures](#), as applicable. *Clinical trials are not allowed.*
 - Describe the statistical plan and the rationale for the statistical methodology. Provide a sample size estimate and the method by which it was derived, including power analysis calculation, if applicable.
 - Describe measures to be taken to reduce bias and achieve reproducible and rigorous results, including controls, blinding, randomization, and data handling, as applicable.
 - Address potential problems that may arise and present alternative methods and approaches.
 - Explain how the research can be completed within the proposed period of performance.
- ❖ *If the proposed research requires IRB/EC approval, the application for IRB/EC review must be submitted prior to the FY24 VRP MCRA [application submission deadline](#).* The clinical protocol submitted to IRB/EC must cover the proposed research. Provide either a copy of IRB/EC

determination (i.e., approval or exemption) letter or a copy of the submitted IRB/EC application, including a copy of the approved/exempted/submitted protocol, in [Attachment 2: Supporting Documentation](#).

❖ *Applicants who are not able to submit a copy of IRB/EC determination (i.e., approval or exemption) letter as part of [Attachment 2: Supporting Documentation](#) must submit a copy to the CDMRP eBRAP Help Desk (help@eBRAP.org) by December 1, 2024, in order for the FY24 VRP MCRA application to be considered for funding.*

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

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

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- **Letter of Organizational Support and Mentee Eligibility (two-page limit is recommended):** Provide a letter signed by the Department Chair or appropriate organization official, confirming organizational support for the project and the mentee’s eligibility for the MCRA. The letter should include:
 - Laboratory space, equipment, and other resources available for the project.

- Mentee’s name, date the mentee completed their terminal clinical degree, and date the mentee is estimated to complete their training program.
- **Letter of Commitment (two-page limit is recommended):** Provide a signed letter from the mentee outlining qualification and commitment to the proposed research. Describe past training, experience, and expertise. Describe career goals and explain how the proposed project supports those goals. Describe the degree to which the mentee participated in the development of the proposed project and application preparation. Confirm commitment to conducting and completing the project if funded.
- **Documentation of IRB/EC approval, exemption, or application:** Provide either a copy of IRB/EC determination letter or a copy of the submitted IRB/EC application, including a copy of the exempted/approved/submitted protocol.
 - Applicants who submit a copy of IRB/EC *application* as part of Attachment 2: Supporting Documentation must submit a copy of IRB/EC *approval/exemption* letter to the CDMRP eBRAP Help Desk (help@eBRAP.org) by **December 1, 2024**, in order for the FY24 VRP MCRA application to be considered for funding.
- **Letters of Collaboration (if applicable) (two-page limit per letter is recommended):** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator’s involvement.
- **Intellectual Property:** Information can be found in the 2 CFR 200.315, “Intangible Property.”
 - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Data and Research Resource Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
- **Data Management Plan:** Describe the data management plan in accordance with Section 3.c Enclosure 3, [DoD Instructions 3200.12](#).
 - For Extramural Applications: Refer to General Application Instructions, Section III.A.2, Attachments Form, Attachment 2, Supporting Documentation, for more detailed information.

- For Intramural Applications: Refer to General Application Instructions, Section IV.A.1, Application Component – Attachments, Attachment 2, Supporting Documentation, for more detailed information.
- **Quad Chart:** Provide a Quad Chart for the proposed project. The format for the quad chart is available on the eBRAP “Funding Opportunities & Forms” web page at <https://ebrap.org/eBRAP/public/Program.htm>.
- **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.

Use of VA Resources (if applicable): Provide a letter of support signed by the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated non-profit corporation is not identified as the applicant organization for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. *Abstracts of all funded research projects will be posted publicly.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

Technical abstracts should include the following elements:

- **Research Idea/Rationale:** Present the ideas and scientific rationale behind the proposed research. Describe how the proposed research aligns with one or more of the [FY24 VRP Focus Areas](#).
- **Objective(s) and/or Hypothesis(es):** Clearly state the objective(s) to be reached and/or the hypothesis(es) to be tested.
- **Specific Aims:** State the project’s specific aims.
- **Study Design:** Briefly describe the study design, including appropriate controls.
- **Impact:** Explain how the proposed project, if successful, will advance the field of visual system trauma research, change the standard of care, improve the quality of life, contribute to the development or validation of evidence-based policy or

guidelines, or otherwise impact the visual health of Service Members, Veterans, and the American public.

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

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

- Clearly describe the rationale, objective, and aims of the application.
- Describe the anticipated short-term and long-term outcomes of the proposed research. Explain how the outcomes will impact the field of visual system trauma research and/or care.

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

For the MCRA mechanism, refer to the “Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work” for guidance on preparing the SOW. Use the “Suggested SOW Format” to develop the SOW for the proposed research. Submit as a PDF.

All DOD-funded clinical research must be reviewed and approved by the USAMRDC Office of Human Research Oversight (OHRO) prior to research implementation. This administrative review requirement is in addition to the local IRB or EC review. **When assembling the MCRA SOW, include tasks/subtasks associated with obtaining the OHRO approval.** Allow *up to 3 months* to complete the OHRO regulatory review and approval process following submission of ***all required and complete*** documents to the OHRO. Refer to https://mrhc.health.mil/index.cfm/collaborate/research_protections/hrpo for more details.

- **Attachment 6: Human Subjects/Samples Acquisition and Safety Procedures (no page limit): Upload as “HumProc.pdf”.** Include the components listed below as applicable.
 - **Study Population and Recruitment Process:** Describe the study population (i.e., Service Members/Veterans/civilians, approximate number, age ranges, sex/gender, racial and ethnic groups, and other pertinent demographic characteristics), criteria for

inclusion/exclusion, and the methods that will be used for recruitment/accrual/retention of human subjects.

- Describe the rationale for the selection of subjects. Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender.
- **Women and Minorities in the Study:** Consistent with the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects,” and congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research.
 - ❖ Describe the strategy for the inclusion of women and minorities as appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.
 - ❖ Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The Public Health Service (PHS) Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.
- Demonstrate that the research team has access to the proposed study population. If applicable, discuss past efforts in recruiting human subjects from the target population for previous clinical studies. Address any potential barriers to accrual and plans for addressing unanticipated delays.
- Describe how the subject-to-group assignments process will be conducted (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable.
- Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
- ***For clinical studies proposing to recruit military personnel, refer to the General Application Instructions, Appendix 1, for more information on recruitment process and considerations, payment, and confidentiality. If a non-military***

population will be used for the proposed clinical study, explain how results obtained will be applicable to military personnel.

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

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

- **Human Samples:** Describe the types and source(s) of specimens, records, or data to be collected and evaluated. Include information about specimen storage (i.e., location, duration, special handling conditions). Describe the identifiers that will be associated with the human specimens and data, and provide a list of who has access to subjects' identities. Describe how individually identifiable private information will be protected.
- **Attachment 7: Researcher Development Plan (two-page limit): Upload as “ResearcherDev.pdf”.** The individualized Research Development Plan should clearly describe a strategy for the mentee to develop research expertise through conduction of the proposed project.
 - Describe the PI’s background and experience in clinical research.
 - Describe the PI’s track record in mentoring junior clinical researchers.
 - Explain how the mentee will develop research expertise through the proposed project. Describe the mentee’s background, experience, and role in the proposed project. Identify specific areas of growth.
 - Provide details on the amount and types of planned interactions between the mentee and the PI.
 - Explain how the Researcher Development Plan is supported by the environment; this should include a description of ongoing vision injury research at the organization. Include resources available and opportunities for the mentee to interact with other vision injury researchers through collaborations, seminars, workshops, and other interactions.

- **Attachment 8: Relevance to Military Health Statement (one-page limit): Upload as “Military.pdf”.** Explain how the proposed research is responsive to the healthcare needs and quality of life of Service Members and Veterans with eye injury and/or visual impairment and/or to their Family members and caregivers.

As applicable, include the element(s) below:

- Identify any element(s) or special consideration(s) related to the applicability of the ultimate outcome of the research in the military operational environment (e.g., battlefield, Battalion Aid Stations, Forward Support Medical Battalions). Applicants may consult [A Beginner’s Guide to Army Healthcare System](#) and the [Joint Health Services Joint Publication 4-02](#) for descriptions of health services across the range of military operations.
 - If active-duty military, Veteran, or military Family member population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed research, and the feasibility of using the population.
 - If applicable, provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to both benefit the civilian population and address a military need.
- **Attachment 9: Representations (Extramural Submissions Only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
 - **Attachment 10: Suggested Intragovernmental/Intramural Budget Form (if applicable): Upload as “IGBudget.pdf”.** If an [intramural DOD organization](#) will be a collaborator in performance of the project, complete a separate budget using the “Suggested Intragovernmental/Intramural Budget Form”, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The *total* costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

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

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

submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- **PI Biographical Sketch (six-page limit):** Upload as “Biosketch_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.
 - **PI Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf”.
 - **Key Personnel Biographical Sketches (six-page limit each):** Upload as “Biosketch_LastName.pdf”.
 - Include mentee’s biographical sketch.
 - (If applicable) Include key collaborator’s and co-mentor’s biographical sketch.
 - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf”.
 - Include mentee’s previous/current/pending support.
 - (If applicable) Include key collaborator’s and co-mentor’s previous/current/pending support.
- (e) **Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.
- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.
- (f) **Project/Performance Site Location(s) Form:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.
- (g) **Research & Related Subaward Budget Attachment(s) Form (if applicable, Extramural Submissions Only):** Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.
- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.

- **Intramural DOD Subaward:** Complete a separate “[Suggested Intragovernmental/Intramural Budget Form](#)” for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 10.

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

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

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

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

II.D.4. Submission Dates and Times

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

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

II.D.5. Funding Restrictions

The maximum period of performance is **18 months**.

The application’s total costs (including direct costs and indirect costs) budgeted for the entire period of performance should not exceed **\$75,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 18 months.

For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary support for supportive personnel (e.g., research coordinator, research nurse, statistician, etc.).
- Costs for the mentee to travel to one scientific/technical meeting during the entire period of performance. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the VRP FY24 MCRA.

Must not be requested for:

- Salary support for mentor or mentee
- Equipment over \$5,000
- Costs typically covered as part of routine care

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DOD or other federal agency is not allowed except under very limited circumstances. Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

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

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Research Idea/Rationale**
 - To what extent the proposed research addresses an important need(s), is supported by a rationale, critical analysis of the literature, and as applicable, preliminary data.
- **Impact**
 - To what extent the proposed research will advance the field of visual system trauma research, change the standard of care, improve the quality of life, contribute to the development or validation of evidence-based policy or guidelines, or otherwise impact the visual health of Service Members, Veterans, and the American public.
- **Research Strategy**
 - To what extent the specific aims are appropriate to address the objective(s) and/or hypothesis(es) of the proposed research.
 - How well the clinical study is designed to achieve the study objectives, including description of and access to the study population(s) or sample(s); plans for subject recruitment, consent, screening and retention; and plans for addressing ethical and regulatory considerations.
 - If applicable, whether the strategy for the inclusion of women and minorities is appropriate for the proposed study.
 - To what extent the statistical plan, including sample size estimate, is appropriate.
 - To what extent the experimental methods and analyses are appropriate and feasible.
 - How well the proposed research is designed to reduce bias and achieve reproducible and rigorous results.
 - How well the application acknowledges potential problems and addresses alternative approaches.
 - Whether the research can be completed within the proposed period of performance.

- **Personnel**
 - To what extent the backgrounds, expertise, and past accomplishments of the PI, mentee, and other key personnel are appropriate for the proposed research.
 - Whether the levels of effort by the PI, mentee, and other key personnel are appropriate for the proposed research.
 - To what extent the mentee is qualified and committed to conduct the proposed research.
 - To what extent the PI has a track record of successful mentorship, is committed to researcher development, and is committed to overseeing the completion of the proposed research.
 - To what extent the Researcher Development Plan will support the development of research expertise of the mentee and successful conduct of the proposed research.
- **Environment**
 - To what extent the scientific environment is appropriate for the proposed research.
 - How well the research requirements are supported by the availability of and access to facilities and resources (including collaborative arrangements).
 - To what extent the quality and level of organizational support are appropriate for the proposed research.

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

- **Budget**
 - Whether the total costs exceed the allowable total costs as published in the program announcement.
 - Whether the budget is appropriate for the proposed research.
- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers

- Relevance to the priorities of the Defense Health Program and FY24 VRP, as evidenced by the following:
 - Adherence to the intent of the funding opportunity, including alignment with at least one of the FY24 VRP Focus Areas.
 - Relative impact
 - Relevance to military health
 - Contribution to program portfolio

II.E.2. Application Review and Selection Process

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

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

II.E.3. Integrity and Performance Information

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

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. The federal

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

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

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

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

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

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

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

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

II.F.2. PI Changes and Award Transfers

Unless otherwise restricted, changes in PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

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

Refer to the General Application Instructions, Appendix 7, Section F, for general information on organization or PI changes.

II.F.3. Administrative and National Policy Requirements

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

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

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

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

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee, IRB, or EC review. Refer to the General Application Instructions, Appendix 6, for additional information.

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

II.F.4. Reporting

Annual progress reports and quad charts as well as a final progress report and quart chart will be required.

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

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

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

Email: support@grants.gov

II.H. Other Information

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

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 901b. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- Letter of Intent was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Human Subject Recruitment and Safety Procedures is missing.

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

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

- An FY24 VRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation. *A list of the FY24 VRP Programmatic Panel members can be found at <https://cdmrp.health.mil/vrp/panels/panels24>.*
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.health.mil/about/2tierRevProcess>).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.

- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- The application proposes preclinical research (including animal research) or clinical trial.
- The PI does not meet the eligibility criteria.
- Key personnel do not include a mentee who is a clinician in training (e.g., a fellow, resident, junior clinician, clinician in PhD program).
- The mentee does not have sufficient time remaining in their training program to complete the research proposed under the MCRA.
- The applicant fails to provide documentation of IRB approval or exemption for the proposed project by December 1, 2024.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance <i>(Extramural submissions only)</i>	<input type="checkbox"/>
Summary (Tab 1) and Application Contacts (Tab 2) <i>(Intramural submissions only)</i>	<input type="checkbox"/>
Attachments	
Project Narrative – Attachment 1, upload as “ProjectNarrative.pdf”	<input type="checkbox"/>
Supporting Documentation – Attachment 2, upload as “Support.pdf”	<input type="checkbox"/>
Technical Abstract – Attachment 3, upload as “TechAbs.pdf”	<input type="checkbox"/>
Lay Abstract – Attachment 4, upload as “LayAbs.pdf”	<input type="checkbox"/>
Statement of Work – Attachment 5, upload as “SOW.pdf”	<input type="checkbox"/>
Human Subjects/Samples Acquisition and Safety Procedures – Attachment 6, upload as “HumProc.pdf”	<input type="checkbox"/>
Researcher Development Plan – Attachment 7, upload as “ResearcherDev.pdf”	<input type="checkbox"/>
Relevance to Military Health Statement – Attachment 8, upload as “Military.pdf”	<input type="checkbox"/>
Representations <i>(Extramural submissions only)</i> – Attachment 9, upload as “RequiredReps.pdf”	<input type="checkbox"/>
Suggested Intragovernmental/Intramural Budget Form <i>(if applicable)</i> – Attachment 10, upload as “IGBudget.pdf”	<input type="checkbox"/>
Research & Related Personal Data	<input type="checkbox"/>
Research & Related Senior/Key Person Profile (Expanded)	<input type="checkbox"/>
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	<input type="checkbox"/>
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	<input type="checkbox"/>
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	<input type="checkbox"/>
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	<input type="checkbox"/>
Research & Related Budget <i>(Extramural submissions only)</i>	<input type="checkbox"/>
Include budget justification	
Budget <i>(Intramural submissions only)</i>	<input type="checkbox"/>
Include budget justification	
Project/Performance Site Location(s) Form	<input type="checkbox"/>
Research & Related Subaward Budget Attachment(s) Form <i>(if applicable)</i>	<input type="checkbox"/>
Additional Application Components	<input type="checkbox"/>
Confidential Letters of Recommendation	<input type="checkbox"/>

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FITBIR	Federal Interagency TBI Research Information System
FY	Fiscal Year
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MB	Megabytes
MCRA	Mentored Clinical Research Award
MIPR	Military Interdepartmental Purchase Request
OHARO	Office of Human and Animal Research Oversight
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TBI	Traumatic Brain Injury
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs
VRP	Vision Research Program