

# **Program Announcement**

**for the**

**Department of Defense**

**Defense Health Program**

**Defense Medical Research and Development Program**

**Clinical and Rehabilitative Medicine Research Program**

**Joint Program Committee 8**

## **Vision Research Program Hypothesis Development Award**

**Funding Opportunity Number: W81XWH-13-CRMRP-VRP-HDA**

**Catalog of Federal Domestic Assistance Number: 12.420**

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

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), November 25, 2013
- **Invitation to Submit an Application:** December 23, 2013
- **Application Submission Deadline:** 11:59 p.m. ET, February 6, 2014
- **Peer Review:** March 2014
- **Programmatic Review:** May 2014

*This Program Announcement is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.*

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## **I. FUNDING OPPORTUNITY DESCRIPTION**

### **A. Program Description**

Applications to the Fiscal Year 2013 (FY13) Vision Research Program (VRP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The executing agents for this Program Announcement/Funding Opportunity are the Congressionally Directed Medical Research Programs (CDMRP) and the Telemedicine & Advanced Technology Research Center (TATRC).

The Clinical and Rehabilitative Medicine Research Program (CRM RP) is one of six major program areas within the Defense Medical Research and Development Program (DMRDP). The CRM RP is administered with oversight from Joint Program Committee 8 (JPC-8), which consists of Department of Defense (DoD) and non-DoD medical and military technical experts relevant to the program area. The CRM RP mission is to focus on definitive and rehabilitative care innovations required to reset our wounded warriors, both in terms of duty performance and quality of life. The VRP is administered by the CRM RP as part of this mission.

The VRP was established in FY09 to fund innovative research that has the potential to make a significant impact on improving the health and well-being of military Service Members, Veterans, and other individuals living with visual dysfunction. Congress has appropriated funds for FY13 to support vision research. As of the release date of this Program Announcement/Funding Opportunity, the FY14 Defense Appropriations Bill has not been passed and there is no guarantee that any additional funds will be made available to support this program.

The FY13 VRP challenges the scientific community to design innovative research that will foster new directions for and address neglected issues in the field of vision research. Applications from investigators within the military Services, and applications involving multidisciplinary collaborations among academia, industry, the military Services, the Department of Veterans Affairs (VA), and other Federal Government agencies are highly encouraged.

### **B. Award Information**

The FY13 VRP Hypothesis Development Award (HDA) mechanism supports conceptually innovative, high-risk/high-reward research that could ultimately lead to critical discoveries or major advancements that will drive the field of vision research forward. Research projects should include a testable hypothesis based on a strong scientific rationale. This award is not intended to support the continuation of existing studies or the next logical extension and/or incremental step. The HDA is designed to support innovative ideas with the potential to yield impactful data and new avenues of investigation.

**Important aspects of the HDA are as follows:**

- **Impact:** The proposed research is expected to make an important and original contribution to advancing the understanding of visual dysfunction and lead ultimately to improved outcomes for patients.
- **Innovation:** Research deemed innovative may represent a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities. Research may be innovative in study concept, research methods or technology, or adaptations of existing methods or technologies. Research that represents an incremental advance on previously published work is not considered innovative.

*The presentation of preliminary or published data relevant to one or more of the VRP HDA Focus Areas is encouraged, but NOT REQUIRED.*

*It is the responsibility of the Principal Investigator (PI) to clearly and explicitly articulate how the proposed research project is innovative.*

To meet the intent of the FY13 VRP HDA mechanism, all applications *must* specifically address one or more of the FY13 VRP HDA Focus Areas listed below. Applications proposing research outside of the Focus Areas listed below should *not* be submitted in response to this Program Announcement/Funding Opportunity.

- **Mitigation and treatment of traumatic injuries, war-related injuries, and diseases to ocular structures and the visual system**
  - Understanding the mechanisms of and developing/evaluating treatments for injuries (blast, blunt, burn, ballistic, penetrating, etc.) to ocular structures and the visual system (including but not limited to pharmaceutical and biomaterial-based solutions for ocular surface and/or retinal damage, proliferative vitreoretinopathy neuroprotection, cell survival, axonal regeneration, etc.)
  - Early intervention and mitigation strategies to reduce injury and slow or stop vision loss
  - Novel drug delivery systems for the eye and adnexa
  - Treatments for eye movement and accommodation abnormalities resulting from trauma
  - Understanding the mechanisms of and developing/evaluating treatments for ocular pain and discomfort
  - Treatments for chronic diseases associated with traumatic ocular injury
- **Mitigation and treatment of visual dysfunction associated with traumatic brain injury (TBI)**
  - Screening, evaluation, and diagnosis of TBI-associated visual dysfunction
  - Treatments for TBI-associated visual dysfunction (including but not limited to photophobia, light sensitivity, disorders of ocular alignment and motility, disorders of

- accommodation, difficulties with stereopsis and spatial perception, decreases in visual acuity, visual field loss, visual attention and cognitive processing, and reading difficulties)
- Diagnostic methods and biomarkers for TBI-associated visual system injuries
  - Targeted therapies for gene expression profiles for different parts of the brain and visual system
  - Treatments for traumatic optic neuropathy
  - Novel models for visual dysfunction following blast and concussive trauma
  - **Vision restoration following traumatic injury**
    - Repair and/or restoration of function of visual components following injury
    - Regenerative medicine-based treatments for injury to or degeneration of the visual system
    - Visual prostheses for injury to or degeneration of the visual system
  - **Modeling and simulation of traumatic ocular injury**
    - Development of advanced and sophisticated mathematical and predictive modeling and simulation methods to characterize blast and ballistic effects on the eye, orbit, and optic nerve (including but not limited to advanced and sophisticated characterization of ocular and orbital tissue characteristics, capturing the wide spectrum and nature of ocular tissues and structures; characterization of blast wave propagation through the eye and orbit; effects of current military combat eye protection on blast wave characteristics; reactions of various ocular and orbital tissues to blast energies and forces).

***Research involving human subjects and human anatomical substances is permitted; however, studies must be exempt under Title 32 of the Code of Regulations, Part 219.101(b) (32 CFR 219.101(b)) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110).*** Exemption or expedited status is first determined by the Institutional Review Board (IRB) of record and then must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO). Investigators must review their institutional requirements and guidelines for filing with the IRB for exempt or expedited status. Studies that do not qualify for exempt or expedited status will be administratively withdrawn. ***Clinical trials are not allowed under this funding opportunity.*** For more information on clinical trials and clinical research overall, a Human Subject Resource Document is provided on the CDMRP eReceipt System at [https://cdmrp.org/Program\\_Announcements\\_and\\_Forms/](https://cdmrp.org/Program_Announcements_and_Forms/).

**Multi-Institutional Research:** Multi-institutional projects are encouraged when combining the resources of two or more organizations will strengthen the research application. If the proposed research is multi-institutional, plans for communication and data transfer between the collaborating institutions, as well as how data, specimens, and/or imaging products obtained during the study will be handled, must be included in the Project Narrative. A separate intellectual and material property plan agreed upon by all participating institutions is also

required for multi-institutional research. Participating institutions must be willing to resolve potential intellectual and material property issues, and to remove any barriers that may interfere with achieving high levels of cooperation to ensure successful completion of this award.

**DoD Collaboration and Alignment Encouraged:** Relevance to the health care needs of the Armed Forces, their family members, and/or the U.S. Veteran population 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. The following websites may be useful in identifying information about ongoing DoD areas of research interest:

Air Force Research Laboratory

<http://www.wpafb.af.mil/afrl>

Clinical and Rehabilitative Medicine  
Research Program

<https://crmrp.amedd.army.mil/>

Congressionally Directed Medical  
Research Programs

<http://cdmrp.army.mil>

Defense Advanced Research  
Projects Agency

<http://www.darpa.mil/>

Defense Medical Research and  
Development Program

<http://dmrdp.fhpr.osd.mil/home.aspx>

Defense Technical Information Center

<http://www.dtic.mil>

Naval Health Research Center

<http://www.med.navy.mil/sites/nhrc>

Naval Medical Research Center

[www.med.navy.mil/sites/nmrc](http://www.med.navy.mil/sites/nmrc)

Navy and Marine Corps Public  
Health Center

<http://www.nmcphc.med.navy.mil/>

Office of Naval Research

<http://www.med.navy.mil/>

Office of the Under Secretary of Defense  
for Acquisition, Technology and  
Logistics

<http://www.acq.osd.mil/>

Telemedicine & Advanced Technology  
Research Center (TATRC)

<http://www.tatrc.org/>

U.S. Army Institute of Surgical Research

[http://www.usaisr.amedd.army.mil/ocular\\_t  
rauma.html](http://www.usaisr.amedd.army.mil/ocular_trauma.html)

U.S. Army Medical Research  
Acquisition Activity

<http://www.usamraa.army.mil>

U.S. Army Medical Research and  
Materiel Command

<https://mrmc.amedd.army.mil>

U.S. Army Research Laboratory

<http://www.arl.army.mil>

U.S. Naval Research Laboratory

[www.nrl.navy.mil](http://www.nrl.navy.mil)

U.S. Department of Veterans Affairs,  
Office of Research and Development

[www.research.va.gov](http://www.research.va.gov)

**Use of Military and VA Populations or Resources:** If the proposed research involves access to military and/or VA population(s) and/or resource(s), the PI is responsible for establishing access. If possible, access to target military and/or VA patient population(s) should be confirmed at the time of application submission. A letter of support, signed by the lowest ranking person with approval authority, should be included as part of Attachment 2 for studies involving Service Members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases. See Section II.C., Application Submission Content and Form, Supporting Documentation.

**Data Sharing:** 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. The FITBIR Informatics system is a free resource to the research community designed to accelerate comparative effectiveness research on brain injury diagnosis and treatment. Data reporting to FITBIR is an opportunity for investigators to facilitate their own research and to collaborate with others doing similar research. While use of the informatics system has no direct cost to the user, a project estimation tool (<https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp>) is available to help estimate indirect cost and manpower needs for PIs. To contribute to FITBIR, researchers should contact the FITBIR Operations Center ahead of time to arrange for data entry support and to ensure all data have been made compatible with the system. 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/) (<http://fitbir.nih.gov/>).

FITBIR allows for de-identification and storage of data (medical imaging clinical assessment, environmental and behavioral history, etc.) of various types (text, numeric, image, time series, etc.). Use of FITBIR's Global Unique Identifier (GUID) system facilitates repeated and multi-user access to data without the need to personally identify data sources. FITBIR encourages collaboration between laboratories, as well as interconnectivity with other informatics platforms. Such community-wide sharing requires common data definitions and standards.

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 the 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.

**Reporting Guidelines:** Proposed research projects should adhere to a core set of reporting standards for rigorous study design. The CRM RP strongly encourages investigators to follow the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines (<http://www.nc3rs.org.uk/page.asp?id=1357>). While these standards are written for animal studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies and should be applied to those projects as well.

***The CRM RP intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity 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 4, Section K.***

### C. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations. Both intramural (i.e., U.S. Federal Government agency, department, laboratory, medical treatment facility, or a U.S. Government activity embedded within a civilian medical center) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

### D. Funding

- The maximum period of performance is **2** years.
- The maximum allowable total (direct and indirect) costs for the entire period of performance are **\$250,000**.
- All direct and indirect costs of any subaward (subgrant or subcontract) 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 **2** years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable total costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.***

In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel costs for the PI(s) to attend one program review per year during the award period of performance. For planning purposes, it may be assumed that these program reviews will be held in the National Capital Region for approximately 2 days.

May be requested for (not all-inclusive):

- Salary of non-Government personnel (includes contract research personnel at Government facilities)
- Research supplies
- Support for multidisciplinary collaborations

- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings (in addition to the required meeting described above)

Intramural (DoD) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. As required of all applicants to this Program Announcement, if PIs from federal agencies submit full applications, they must submit through Grants.gov. Therefore, federal applicants must be familiar with Grants.gov requirements, including the need for System for Award Management (SAM) and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (cooperative agreements and grants). Awards to intramural organizations will be executed through a Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Direct transfer of funds from the recipient to a federal organization or agency is not allowed except under very limited circumstances.

*The CRMRP JPC-8 expects to allot approximately \$2.5M of FY13 VRP and Psychological Health/TBI appropriations to fund approximately 10 FY13 VRP HDA applications, depending on the quality and number of applications received. Of the \$2.5M, approximately \$1.5M will be allocated to support research focused solely on TBI-associated visual dysfunction. In addition to the FY13 appropriations, it is anticipated that up to \$1M in FY14 funds may be available to fund approximately 4 additional VRP HDA awards. As of the release date of this Program Announcement/Funding Opportunity, the FY14 Defense Appropriations Bill has not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this Program Announcement/Funding Opportunity is approximate and subject to realignment. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of federal funds for this program.*

## **II. SUBMISSION INFORMATION**

Submission is a two-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (<https://cdmrp.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

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

### **A. Where to Obtain the Application Package**

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-13-CRM RP-VRP-HDA.

## B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (<https://cdmrp.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.

PIs and organizations 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@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.

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

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

FY13 VRP Panel members should not be involved in any pre-application or application. For questions related to FY13 VRP Panel members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP at [help@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.

- **Required Files – Tab 4**

**Preproposal Narrative (one-page limit):** The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. 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 application.

**Note:** *At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.*

The Preproposal Narrative should include the following:

- **Rationale:** State the ideas and reasoning on which the proposed research is based. Describe the rationale to support the research idea. State how this project meets the intent of the award mechanism.
- **Focus Area:** Note specifically what FY13 VRP HDA Focus Area(s) the proposed work addresses.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Research Strategy:** Concisely state the project's specific aims and ultimate endpoints. Describe the proposed methods and how they will accomplish the project's aims.

- **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the described research.
- **Military Benefit:** Describe how the proposed work would impact the health care needs of Service Members and/or U.S. Veterans recovering from traumatic injury as well as their families, caregivers, and/or communities.

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application are limited to:

- **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, 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 used in the Preproposal Narrative.
- **Key Personnel Biographical Sketches (four-page limit per individual).**
- **Quad Chart:** The Quad Chart template is a one-page PowerPoint file that must be downloaded from the CDMRP eReceipt System at [https://cdmrp.org/Program\\_Announcements\\_and\\_Forms/](https://cdmrp.org/Program_Announcements_and_Forms/), completed, and saved as a PDF file using Adobe Acrobat Reader.
- **Submit Pre-Application – Tab 5**  
This tab must be completed for the pre-application to be accepted and processed by the CDMRP.
- **Other Documents Tab**  
No additional documents are required.

## 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, CRM RP, and VRP, pre-applications will be screened based on the following criteria:
  - **Alignment with Focus Areas:** How well the project addresses at least one of the FY13 VRP HDA Focus Areas.
  - **Research Plan:** How well the proposed research addresses the intent of the award mechanism and the program. To what degree the rationale, objectives, and specific aims support the research idea. How the endpoints are appropriate for the proposed study. Whether the proposed methodology is appropriate.
  - **Personnel:** How the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed research.

- **Military Benefit:** How the proposed work would benefit the health care needs of Service Members and/or U.S. Veterans recovering from traumatic injury as well as their families, caregivers, and/or communities.
- **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 on the [title page](#) of this Program Announcement/Funding Opportunity.

### C. Application Submission Content and Form

*Applications will not be accepted unless the PI has received notification of invitation.*

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

**Grants.gov application package components:** For the FY13 VRP HDA, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
2. **Attachments Form**
  - **Attachment 1: Project Narrative (five-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, etc.) 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 will result in administrative withdrawal of the application.  
  
Describe the proposed project in detail using the outline below. *The presentation of preliminary data is not required.*
    - **Background:** State the relevance of the research to at least one of the FY13 VRP HDA Focus Areas and explain the applicability of the proposed findings. Present the ideas and reasoning behind the proposed work. Cite relevant literature. Describe research team’s expertise and previous experience most pertinent to this project.
    - **Objectives/Specific Aims/Hypotheses:** State the question/concept to be tested or the objective to be reached.

- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for peer review. Address potential problem areas and present alternative methods and approaches. Describe the statistical plan, if appropriate for the research proposed. As applicable, include plans for communication and data transfer between collaborating organizations, as well as how data, specimens, and/or imaging products obtained during the study will be handled. ***Research proposed to involve human subjects or anatomical substances must be exempt under 32 CFR 219.101(b) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110).***
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or 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 Patent Abstracts (five-document limit):** Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included in Attachment 2. Extra items will not be reviewed.
  - **Letters of Organizational Support (two-page limit per letter):** Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project.
  - **Letters of Collaboration (if applicable) (two-page limit per letter):** 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.
  - **Letter(s) of Support for Use of Military and VA Populations or Resources (if applicable) (two-page limit per letter):** Provide a letter(s) signed by the lowest

ranking person with approval authority for studies involving military Service Members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases.

- Intellectual and Material Property Plan (if applicable):
  - Provide a list of all background intellectual property relevant to the project. Identify any proprietary information that will be provided to the Government and whether the applicant will require a waiver of Government purpose rights; *and/or*
  - Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about expectations for making data and research resources publically available. Include plans for utilizing the NINDS TBI CDEs (see <http://www.commondataelements.ninds.nih.gov>). If the proposed research is not compatible with the required CDEs, the investigators must supply a justification as to why these measures will not be incorporated into the research. Additionally, reporting is required via the FITBIR (<http://fitbir.nih.gov/tbi-portal/>) data repository quarterly. The Government reserves the right to identify additional data sharing requirements and/or repositories for submission of data for archive.
- Current Quad Chart: Provide a current Quad Chart in the same format as in the pre-application. If no changes have been made to the project, the same Quad Chart submitted with the pre-application may be used.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”

Use the outline below. (Proprietary or confidential information should *not* be included.)

  - Background: State how the proposed research addresses a FY13 VRP HDA Focus Area. Present the ideas and reasoning behind the proposed work.
  - Objective/Hypothesis: State the concept/question to be tested. Provide evidence or rationale that supports the objective/hypothesis.
  - Specific Aims: State the specific aims of the study.
  - Study Design: Briefly describe the study design, including appropriate controls.
  - Military Benefit: Briefly explain how the proposed project will have an immediate or potential long-term impact on the health and well-being of Service Members, Veterans, and/or their family members.
- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.”

Lay abstracts should be written using the following outline. (Proprietary or confidential information should *not* be included.)

- Describe the objectives and rationale for the application in a manner that will be readily understood by readers without a background in science or medicine.
  - Do not duplicate the technical abstract.
- Describe the ultimate applicability and potential impact of the research.
  - What types of patients will it help, and how will it help them? (Include the current available statistics to the related injury/condition.)
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected timeline it may take to achieve the expected patient-related outcome?
- Briefly describe how the proposed project will benefit Service Members, Veterans, and/or their family members.
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information, including guidance on appropriate SOW formats.
- **Attachment 6: Military Benefit (one-page limit):** Upload as “MilBen.pdf.”
  - Describe how the proposed study is responsive to the health care needs of Service Members and/or Veterans living with visual dysfunction. Provide information about the incidence and/or prevalence of the disease or condition to be studied in Service Members and/or Veterans, if appropriate and available. Show how the proposed study complements ongoing DoD and VA areas of research interest.
- **Attachment 7: Innovation Statement (one-page limit):** Upload as “Innovation.pdf.” Summarize how the proposed research project is innovative. Investigating the next logical step or incremental advancement on published data is not considered innovative.

*Although not all-inclusive*, the following examples are ways in which the proposed research project may be innovative and are intended to help PIs frame the innovative features:

- Study concept: Investigation of a novel idea and/or research question.
- Research method or technology: Use of novel research methods or new technologies, including technology development, to address a research question.
- Novel method or technology: Development of a novel method or technology for preventing, detecting, diagnosing, or treatment.
- Existing methods or technologies: Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.

- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information.
  - PI Biographical Sketch (four-page limit): Upload as “Biosketch\_LastName.pdf.”
  - PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
  - Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch\_LastName.pdf.”
  - Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
  - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

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

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines will result in application rejection.

#### **E. Other Submission Requirements**

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

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

### **III. APPLICATION REVIEW INFORMATION**

#### **A. Application Review and Selection Process**

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes

recommendations for funding to the Office of the Assistant Secretary of Defense for Health Affairs, based on technical merit, the relevance to the mission of the DHP, CRM RP, and VRP and the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess.shtml>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a non-disclosure 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 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 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 Title 18 United States Code 1905.

## **B. Application Review Criteria**

- 1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:
  - **Innovation**
    - To what extent the proposed research project is innovative in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
    - How well the proposed research project represents more than an incremental advance upon published data.
  - **Research Strategy and Feasibility**
    - How well the scientific rationale supports the research project and its feasibility, as demonstrated by a critical review and analysis of the literature and logical reasoning.
    - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project and how well they address the need(s) described.
    - How well the PI acknowledges potential problems and addresses alternative approaches.
    - How well the PI has outlined a plan for management and sharing of research data as appropriate for the type of study.
  - **Military Benefit**
    - How the study is responsive to the health care needs of Service Members and/or Veterans living with visual dysfunction.

- The potential immediate or long term benefit and usability of the proposed research on the health and well-being of Service Members, Veterans, and/or their families or communities.

- **Personnel**

- How the background and expertise of the PI and other key personnel demonstrate their ability to perform the proposed research.
- How the levels of effort by the PI and other key personnel are appropriate to ensure success of this project.

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

- **Environment**

- How the scientific environment is appropriate for the proposed research.
- How the research requirements are supported by the availability of and accessibility to facilities and resources.
- How the quality and extent of institutional support are appropriate for the proposed project.

- **Budget**

- Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- **Application Presentation**

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

**2. Programmatic Review:** To make funding recommendations, the following criteria are used by programmatic reviewers:

- **Ratings and evaluations of the peer reviewers**

- **Relevance to the mission of the DHP, CRM RP, and VRP as evidenced by the following:**

- Adherence to the intent of the award mechanism
- Military relevance
- Program portfolio composition
- Relative impact and innovation

### **C. Recipient Qualification**

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

## **D. Application Review Dates**

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

## **E. Notification of Application Review Results**

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

## **IV. ADMINISTRATIVE ACTIONS**

After receipt of pre-applications from the CDMRP eReceipt System or applications from Grants.gov, the following administrative actions may occur:

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

### **B. Modification**

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

## **C. Withdrawal**

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

- A FY13 VRP 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 document. A list of the FY13 VRP Panel members can be found at <http://cdmrp.army.mil/dmrdp/panels/VRPpanel13.shtml>.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Total costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- 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).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The proposed research project does not qualify for exempt status under Title 32, Code of Federal Regulations, Part 219, Section 101(b) (32 CFR 219.101[b]) or is not eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110).

## **D. Withhold**

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution 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.

## **V. AWARD ADMINISTRATION INFORMATION**

### **A. Award Notice**

Awards will be made no later than September 30, 2014. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

### **B. Administrative and National Policy Requirements**

Refer to the General Application Instructions, Appendix 4, Section D, for general information regarding administrative and national policy requirements.

## **C. Reporting**

Refer to the General Application Instructions, Appendix 4, Section E, for general information on reporting requirements.

Quarterly technical progress reports and quad charts will be required.

In addition to written progress reports, oral briefings may be requested.

## **D. Award Transfers**

The institutional transfer of an award is discouraged. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 4, Section F, for general information on organization or PI changes.

## **VI. AGENCY CONTACTS**

### **A. CDMRP Help Desk**

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through the CDMRP eReceipt System 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@cdmrp.org](mailto:help@cdmrp.org)

### **B. Grants.gov Contact Center**

Questions related to application submission through the 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

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

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

## VII. APPLICATION SUBMISSION CHECKLIST

<b>Grants.gov Application Components</b>	<b>Action</b>	<b>Completed</b>
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Military Benefit (MilBen.pdf) as Attachment 6.	
	Upload Innovation Statement (Innovation.pdf) as Attachment 7.	
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	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	