The views expressed in this presentation are those of the authors and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government.
CONGRESSIONAL PROGRAMS
- Manages extramural research programs directed by Congress since 1992
- FY20: 35 research programs, $1.2B total appropriation

DoD PROGRAMS
- Provides intramural/extramural research management support to Program Area Directorates (PADs)/Joint Program Committees (JPCs)

DIRECTOR
- COL Stephen J. Dalal

Website: cdmrp.army.mil
# FY20 CDMRP Funding

<table>
<thead>
<tr>
<th>Program</th>
<th>$M</th>
<th>Program</th>
<th>$M</th>
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<tbody>
<tr>
<td>Amyotrophic Lateral Sclerosis</td>
<td>$20.0</td>
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<td>Autism</td>
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<td>Bone Marrow Failure</td>
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<td>Peer Reviewed Cancer (14 Topics)</td>
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<td>Hearing Restoration</td>
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<td>Rare Cancers*</td>
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<tr>
<td>* New for FY20</td>
<td></td>
<td>TOTAL = $1.2B</td>
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</tbody>
</table>
Unique Public-Private Partnership

**Consumers**
- Demonstrate need
- Participate at all levels
- Bring passion and perspective

**Congress**
- Adds funds to budget
- Provides targeted guidance

---

**Researchers**
- Carry out research
- Peer review
- Subject matter experts

---

**DoD**
- Oversees program management
- Contracting actions
- Regulatory requirements
Challenges of Military-Relevant Vision Trauma Care

- Generate knowledge of vision trauma and translate knowledge into clinical application
- Save eyesight when ophthalmologists are not available
- Preservation of eyesight of Warfighters requires: *Clinically relevant mechanisms & therapeutics* + *Battlefield/en route care capability*
1. **Accelerate research in eye injury and vision dysfunction due to military-relevant trauma**
   - For example (more examples are provided in FTTSA PA):
     - Identification of significant changes in pathophysiology over time after trauma to inform targeted treatments
     - Elucidation of molecular, cellular, and biophysical mechanisms of a military-relevant trauma
     - Development or improvement of clinically relevant trauma models

2. **Advance diagnosis and treatment of eye injuries in both a forward operating environment and a prolonged field care setting**
   - Diagnostics and interventions that enable decision-making, triaging, stabilization, and management in austere conditions such as prolonged evacuation time and limited specialty care.
   - Research addressing #1 can inform those addressing #2
Vision Research Program

Vision - Transform visual system trauma care for our armed forces and the nation

Eye injury and visual dysfunction resulting from battlefield trauma affect a large number of Service members and Veterans. Surveillance data from the U.S. Department of Defense indicate that eye injury accounts for approximately 15% of all injuries from battlefield trauma sustained during the wars in Afghanistan and Iraq, resulting in more than 182,000 ambulatory patients and 4,000 hospitalizations between 2000 and 2011. In addition, traumatic brain injury (TBI), which affects more than 380,000 Service members between 2000 and 2018, can have significant impact on vision even when there is no injury to the eye. Research sponsored by the U.S. Department of Veterans Affairs showed that as many as 75% of Service members who had suffered a TBI had visual dysfunction.

The Vision Research Program (VRP) was established by Congress in fiscal year 2009 (FY09) to fund impactful military-relevant vision research that has the potential to significantly improve the health care and well-being of Service members, Veterans, their family members and caregivers, and the American public. The VRP’s program area aligns with the Sensory Systems task area of the Clinical and Rehabilitative Medicine Research Program, a core research program of the Defense Health Agency. The VRP was administered by the US Army Medical Research and Materiel Command’s Telemedicine and Advanced Technology Research Center from FY09 to FY12 and was transitioned to the Congressionally Directed Medical Research Programs (CDMRP) for administration starting with the FY13 program cycle.

Resources for Investigators:
- A Beginner’s Guide to Army Healthcare System
- Joint Health Services Publication JP 4-02
- Blast Term Dictionary and Guidance Documents for Blast Injury Research
- A Primer for Conducting DoD Funded Human Research with Military Populations

- What is austere environment?
- What is prolonged field care?
- What medical care capability is available in the military operational environment?
FY20 VRP Program Cycle

1. Creation and Release of Funding Opportunities

**Congressional Appropriation**

**Programmatic Panel**

- Vision Setting
- Funding Opportunities Released
- Pre-Application Receipt
- Pre-Application Screening and Invitation to Submit*
- Application Receipt
- Peer Review
- Programmatic Review/ Funding Recommendations
- USAMRDC Commanding General Approval
- USAMRAA Award Negotiations

**Awards Management**

- 14 awards anticipated

**Month/Year**

- 10/19
- 11/19
- 12/19
- 1/20
- 2/20
- 3/20
- 4/20
- 5/20
- 6/20
- 7/20
- 8/20
- 9/20
- 10/20
- 11/20
- 12/20
- 1/21
- 2/21
- 3/21
- 4/21
- 9/21
- 10/21
- 08/26

- 28 Jul 2020
- *19 May 2020
- *1 Apr 2020
- *8 Sep 2020
- 18 Nov 2020

*Estimated
At Vision Setting each year, the Programmatic Panel recommends an investment strategy, considering factors such as:

- Congressional language
- Current research landscape
- Emerging technologies
- Research gaps
- Impact
- Portfolio composition
## FY20 VRP Investment Strategy

<table>
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<tr>
<th>Award Mechanism</th>
<th>Funding Level</th>
<th>Direct Costs</th>
<th>Number of Awards*</th>
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<td>FL2</td>
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<td>Translational Research Award (TRA)</td>
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<tr>
<td>Focused Translational Team Science Award (FTTSA)</td>
<td>N/A</td>
<td>$5.0M</td>
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</table>

*estimated
Program Announcement

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Vision Research Program

Investigator-Initiated Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-20-VRP-HRA

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

SUBMISSION AND REVIEW DATES AND TIMES

- Pre-Application Submission Deadline: 5:00 p.m. Eastern time (ET), July 28, 2020
- Invitation to Submit an Application: September 2020
- Application Submission Deadline: 11:59 p.m. ET, November 18, 2020
- End of Application Verification Period: 5:00 p.m. ET, November 23, 2020
- Peer Review: January 2021
- Programmatic Review: March 2021

General Application Instructions

Version 501

Department of Defense
Defense Health Program

Congressionally Directed Medical Research Programs

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This General Application Instructions document must be read in conjunction with the Program Announcement for this funding opportunity, which is available for downloading from Grants.gov and eBRAP.org

DoD FY20 Vision Investigator-Initiated Research Award

DoD General Application Instructions
Conceiving a Project

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FY20 VRP IIRA

» Supports studies that will yield highly impactful discoveries or major advancements.

» Funding Level 1 supports exploratory, high-risk/high-reward research in the earliest stages of idea development.
  » Research must have the potential to yield new avenues of investigation, such as new approaches, new research tools, or new paradigms.
  » While preliminary data are NOT required, applicants must provide solid rationale of the research idea.
  » The investigating team must have sufficient expertise to test the idea.

» Funding Level 2 supports the advancement of more mature research that has the potential to make significant advancements toward clinical translation.
  » Applications may focus on any phase of research from basic through translational.
  » Preliminary data supporting the readiness and feasibility of the proposed research are required.

» Research involving human subjects and human anatomical substances is permitted.

» Clinical trials are not allowed.

» Following selection of projects for VRP funding, the VRP may share FY20 IIRA applications and reviews with the NEI for independent funding consideration.
**VRP Award Mechanisms and the Research Pipeline**

**Building Hypothesis, Initial Ideas**
- Hypothesis Development Award (HDA) (FY11-14)
- Investigator-Initiated Research Award (IIRA), Funding Level 1 (FY18-20)
  - $260K/2-yr

**Developing Ideas, Knowledge, Technology**
- IIRA (FY11-12, FY18)
  - IIRA Funding Level 2 (FY18-20)
  - $750K/3-yr

**Translation**
- Translational Research Award (TRA) (FY13-14) with Pilot Clinical Trial Option (FY18-20)
- Technology/Therapeutic Development Award (TTDA) (FY15-17)
- Focused Translational Team Science Award (FTTSA) with Pilot Clinical Trial Option (FY18-20)

**Clinical Trial**
- Clinical Trial Award (CTA) (FY15-17)
- Expansion Award (EA) (FY18)
» Supports translational research that moves promising laboratory research into clinical applications.

» It is expected that an IND or IDE application will be submitted during or by the end of the period of performance.

» Preliminary data are required.

» May include, as a portion of the proposed research, a pilot clinical trial (PCT) component.

  » In contrast to full-scale clinical trials that are designed to determine safety or efficacy, the purpose of the PCT is generate preliminary data to inform the feasibility, rationale, and design of subsequent clinical trials through limited clinical testing of a novel intervention.

  » Applications that include a PCT as part of the proposed research will have additional submission requirements (Pilot Clinical Trial Plan, Regulatory Strategy) and review criteria.

» Following selection of projects for VRP funding, the VRP may share FY20 TRA applications and reviews with the NEI for independent funding consideration.
VRP Award Mechanisms and the Research Pipeline

**Building Hypothesis, Initial Ideas**
- Hypothesis Development Award (HDA) (FY11-14)
- Investigator-Initiated Research Award (IIRA), Funding Level 1 (FY18-20)

**Developing Ideas, Knowledge, Technology**
- IIRA (FY11-12, FY18)
- IIRA Funding Level 2 (FY18-20)

**Translation**
- Translational Research Award (TRA) (FY13-14) with Pilot Clinical Trial Option (FY18-20)
- Technology/Therapeutic Development Award (TTDA) (FY15-17)
- Focused Translational Team Science Award (FTTSA) with Pilot Clinical Trial Option (FY18-20)

**Clinical Trial**
- Clinical Trial Award (CTA) (FY15-17)

- Expansion Award (EA) (FY18)

$1.0M/3-yr
» Supports a team initiative that leverages the strengths of investigators specializing in different fields to address an overarching scientific challenge or question and fundamentally advance the understanding and treatment of military-relevant vision trauma.

» Overarching Challenge
  » Consider barrier(s) to and/or gap(s) in the understanding, prevention, diagnosis, mitigation, and/or treatment of eye injury or visual dysfunction associated with a military-relevant trauma and envision what may be achievable in 10 to 15 years.
  » Identify, based on the long-term vision, what should and can be achieved in the near term.
  » Design projects and research teams around these considerations.

» Research Projects
  » 3-5 distinct research projects, each representing a unique approach to address the overarching challenge
  » Individual projects must be capable of standing on their own scientific merits and not dependent on the success of any other project.
  » Preliminary data to support the feasibility of each project are required.
  » Synergy between project will advance a solution beyond what would be possible through individual efforts.
  » May include, as a portion of the proposed research, a pilot clinical trial component that collects preliminary data to inform the feasibility, rationale, and design of subsequent clinical trials.

» Research Team
  » The overall lead PI: Associate Professor or above, with experience in leading large collaborative research projects; a minimum of 20% effort.
  » Each project leader, including the overall lead PI, may lead only one project.
  » Must have a detailed Implementation Plan for participating research groups to coordinate efforts, facilitate collaboration, and create synergy.
## VRP Award Mechanisms and the Research Pipeline

<table>
<thead>
<tr>
<th>Building Hypothesis, Initial Ideas</th>
<th>Developing Ideas, Knowledge, Technology</th>
<th>Translation</th>
<th>Clinical Trial</th>
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<tr>
<td>• Hypothesis Development Award (HDA) (FY11-14)</td>
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<td>• Clinical Trial Award (CTA) (FY15-17)</td>
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<td>• Investigator-Initiated Research Award (IIRA), Funding Level 1 (FY18-20)</td>
<td>• IIRA Funding Level 2 (FY18-20)</td>
<td>• Technology/Therapeutic Development Award (TTDA) (FY15-17)</td>
<td></td>
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</table>

- **Focused Translational Team Science Award (FTTSA) with Pilot Clinical Trial Option (FY18-20)**
- **$5.0M/4-yr**
- **Expansion Award (EA) (FY18)**
FY20 VRP Program Cycle

2. Pre-application and Application Submission

- Pre-application Receipt
- Pre-application Screening and Invitation to Submit*
- Programmatic Review/Funding Recommendations
- Application Receipt
- Peer Review
- USAMRDC Commanding General Approval
- USAMRAA Award Negotiations
- Congressional Appropriation

- 14 awards anticipated

- Vision Setting
- Funding Opportunities Released
- 1 Apr 2020
- 19 May 2020
- 28 Jul 2020
- *8 Sep 2020
- 18 Nov 2020

*Estimated
### Pre-Application Screening Criteria

<table>
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<tr>
<th>IIRA</th>
<th>TRA</th>
<th>FTTSA</th>
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<tr>
<td>Research Idea/Rationale (Including alignment to FY20 VRP Focus Areas)</td>
<td>Research Idea/Rationale (Including alignment to FY20 VRP Focus Areas)</td>
<td>Overarching Challenge</td>
</tr>
<tr>
<td>Objectives/Hypothesis(es), Specific Aims, and Approaches</td>
<td>Objectives/Hypothesis(es), Specific Aims, and Approaches</td>
<td>Research Strategy</td>
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<tr>
<td>Impact</td>
<td>Translational Potential: How well the proposed research presents a clear path to transform a promising discovery into new drugs, devices, or clinical practice guidelines that are ready for definitive testing in clinical trials.</td>
<td>Projects ↔ overarching challenge</td>
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<td>Personnel</td>
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<td>Objectives/Hypothesis(es), Specific Aims, and Approaches</td>
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<td>Synergy</td>
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<td>Research Team</td>
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<td></td>
<td></td>
<td>Leverage strengths of investigators specializing in different fields</td>
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<tr>
<td></td>
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<td>Have sufficient expertise</td>
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<td>Interaction and collaboration</td>
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» Applicants do not receive feedback on pre-application

» Submission of full application is by invitation only
## Full Application Submission Content

**Take advantage of Application Submission Checklist**

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<td>Attachments</td>
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<tr>
<td>Personal Data</td>
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<tr>
<td>Senior/Key Person Profile</td>
<td>Biographical Sketch, Previous/Current/Pending Support</td>
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<td>Budget (Extramural only)</td>
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<tr>
<td>Subaward Budget Attachments</td>
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FY20 VRP Program Cycle
3. Review Process

Congressional Appropriation

Programmatic Panel

Awards Management

USAMRAA Award Negotiations
14 awards anticipated

USAMRDC Commanding General Approval

Programmatic Review/ Funding Recommendations

Vision Setting

Funding Opportunities Released

Pre-Application Receipt

Pre-Application Screening and Invitation to Submit*

Application Receipt

Peer Review

28 Jul 2020

*19 May 2020

1 Apr 2020

*8 Sep 2020

18 Nov 2020

Month/Year

*Estimated
Goal of the Two-Tier Review Process

To find *scientifically meritorious* proposals and fund those that *best fulfill program goals*
First Tier: Peer Review

» How the evaluation process works
  » Technical merit assessment based on an ideal application
  » Criteria-based evaluation of entire application

» Peer reviewers
  » Scientists, clinicians, consumers, specialists (e.g., statisticians and tech transfer specialists)
  » No standing panels
  » Recruited based on expertise needed
  » Identities are unknown to applicants; contact between applicants and reviewers are not permitted
## Peer Review Criteria

<table>
<thead>
<tr>
<th>Scored (Equal Importance)</th>
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<th>TRA</th>
<th>FTTSA</th>
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<td>Data and Resource Sharing</td>
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<td>Application Presentation</td>
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# Writing Proposals with Reviews in Mind

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

- **Background/Rationale:** Provide a sound scientific rationale for the proposed research.

- **Funding Level 1:** Describe the idea that the proposed research will explore and develop, clearly stating the objective(s) to be reached and/or the hypothesis(es) to be tested. Present sufficient literature to support the rationale for testing the idea. Explain how the proposed research has the potential to yield new avenues of investigation, such as new approaches, new research tools, or new paradigms. *Preliminary data are allowed but not required.*

II.E. Application Review Information

- **Research Idea**
  - **Funding Level 1:**
    - To what extent the idea of the proposed research, including the objective(s) and/or hypothesis(es), is based on sound rationale and critical analysis of literature.
    - To what extent the proposed research has the potential to yield new avenues of investigation.
Second Tier: Programmatic Review

» How the evaluation process works
  » Comparison-based
  » Strong scientific merit
  » Program relevance
    » Adherence to award mechanism’s intent
    » Impact
    » Relevance to military health
    » Consideration of portfolio composition

» Programmatic reviewers
  » VRP Programmatic Panel
  » Ad hoc reviewers

Outcome: Funding Recommendations

Involvement of Programmatic Panel member in the design or performance of the proposed project is PROHIBITED and would result in ADMINISTRATIVE WITHDRAWAL.
Programmatic Review Criteria

» Ratings and evaluations of the peer reviewers
» Relevance to the mission of the DHP and FY20 VRP, as evidenced by the following:
  » Adherence to the intent of the award mechanism
  » Relative impact
  » Relevance to military health
  » Program portfolio composition

Check out Resource Document!
Funding Opportunities Beyond the VRP

» Small Business Innovative Research (SBIR) Program
  » SBIR topics posted on DoD SBIR/STTR Portal

» Broad Agency Announcement (BAA)
  » Posted on Grants.gov
  » Current active BAA: W81XWH18SBAA1 (closing date September 30, 2022)
  » Check Appendix 1 for Research Areas of Interest

» Request for Information (RFI) / Request for Project Proposals (RPP)
  Example: a portable ocular diagnostic device/system RFI, posted April 18, 2019

Subject: JUST RELEASED! FY19 DoD USAMMDA RFI

This email is to notify the medical research and development (R&D) community of a recently released Fiscal Year 2019 Request for Information (RFI) for the Department of Defense (DoD) U.S. Army Medical Materiel Development Activity (USAMMDA) for a portable ocular diagnostic device / system. This RFI is issued solely for information and planning purposes.

The USAMMDA develops and delivers quality medical capabilities to protect, treat, and sustain the health of our Service Members. The USAMMDA enhances the DoD by facilitating further development of promising industry and academic efforts and reviews a broad spectrum of R&D efforts on an ongoing basis.

A detailed description of this RFI and the submission requirements can be found at the following website:

https://www.fbo.gov/index?s=opportunity&mode=form&id=3f13f034debc370664a49db195b242a8&tab=core&cview=0

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  » https://cdmrp.army.mil/pubs/video/CDMRP_overview

» VRP Homepage
  » https://cdmrp.army.mil/vrp/default

» DoD SBIR/STTR Portal
  » https://www.dodsbirsttr.mil/submissions/login

» MTEC
  » https://www.mtec-sc.org/