

# Vision Research Program

## Strategic Plan

### INTRODUCTION

The Congressionally Directed Medical Research Programs (CDMRP) represents a unique partnership among the U.S. Congress, the military, and the public to fund innovative and impactful medical research in targeted program areas.

In 2015, an ad hoc committee of the National Academies of Sciences, Engineering, and Medicine was assembled to evaluate the CDMRP's two-tier review process and its coordination of research priorities with the National Institutes of Health (NIH) and the Department of Veterans Affairs (VA). As part of their final report,<sup>1</sup> the committee recommended that each CDMRP program "... develop a strategic plan that identifies and evaluates research foci, benchmarks for success, and investment opportunities for 3–5 years into the future," and that these strategic plans "should specify the mission of the program, coordination activities with other organizations, research priorities, how those priorities will be addressed by future award mechanisms, how research outcomes will be tracked, and how outcomes will inform future research initiatives."

In response to these recommendations, this document presents the current strategy for the CDMRP's Vision Research Program (VRP). The VRP Strategic Plan identifies the high-impact research goals most important to its stakeholders while providing a framework that is adaptable to changes in the medical research environment to address those goals. This plan has been formulated to provide greater clarity of the program's goals over time to the public and other stakeholders. Funding for the VRP is Congressionally appropriated on an annual basis; therefore, there is no guarantee of future funding. The VRP Strategic Plan will be reviewed during the program's annual Vision Setting meeting and updated as necessary.

### VRP BACKGROUND AND OVERVIEW

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 (DoD) indicate that eye injury accounts for approximately 15% of all injuries from battlefield trauma sustained during the wars in Afghanistan and Iraq, resulting in more than 182,000 ambulatory patients and 4,000 hospitalizations between 2000 and 2011. In addition, traumatic brain injury (TBI), which affects ~380,000 Service members according to statistics from the Defense and Veterans Brain Injury Center, 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 (VA) showed that as many as 75% of Service members who had suffered a TBI had visual dysfunction.

The 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 (CRM RP), 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 CDMRP for administration starting with the FY13 program cycle.

### VISION AND MISSION OF THE VRP

**VISION:** Transform vision trauma care for our armed forces and the nation

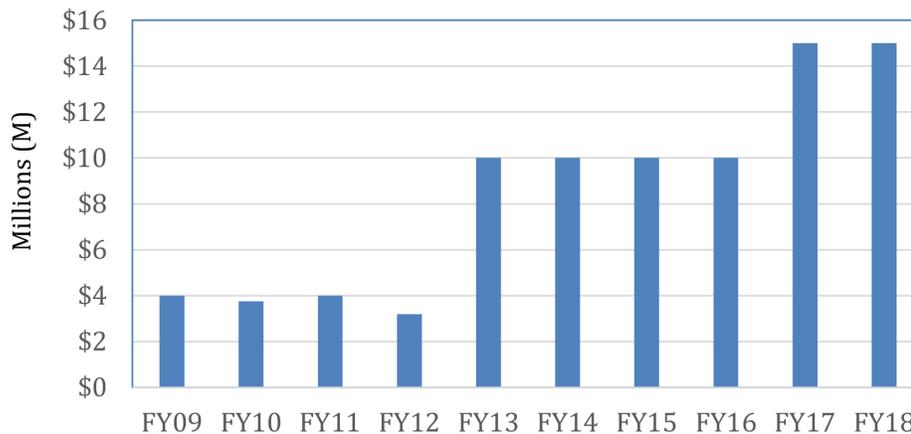
**MISSION:** Improve the health and readiness of military personnel affected by eye injuries and vision dysfunction by identifying clinical needs and addressing them through directed medical research



## FUNDING HISTORY

Congressional appropriations for the VRP from FY09 through FY18 totaled \$84.95 million (M) (Figure 1). Additional funds for VRP-released program announcements were provided by the Defense Medical Research and Development Program (DMRDP) and the Psychological Health/Traumatic Brain Injury Research Program (PH/TBIRP).

**Figure 1. VRP Appropriation, FY09-FY18**



## RESEARCH PORTFOLIO

A total of 85 grant applications submitted to VRP-released program announcements have been funded. Portfolio breakdowns by ocular system and care continuum are shown in Tables 1 and 2, respectively. Award data and abstracts of funded research proposals can be viewed on the CDMRP website (<http://cdmrp.army.mil>).

**Table 1. VRP Portfolio Breakdown by Ocular System, FY09-FY17**

Ocular System	# Awards	Funding*
Anterior Segment	15	\$21.9M
Posterior Segment	29	\$26.2M
Central Visual Pathway	16	\$12.3M
Other/Multiple	25	\$24.6M

\* Funding sources include the VRP, PH/TBIRP, and DMRDP

**Table 2. VRP Portfolio Breakdown by Care Continuum, FY09-FY17**

Care Continuum	# Awards	Funding*
Battlefield/En Route Care	18	\$19.1M
Acute Care	38	\$40.9M
Chronic Care	19	\$13.8M
Other/Multiple	10	\$11.3M

\* Funding sources include the VRP, PH/TBIRP, and DMRDP

## RESEARCH AND FUNDING ENVIRONMENT

### STATE OF THE SCIENCE

Vision science has seen rapid and exciting developments in both basic and clinical research over the past decade. These developments have translated into new or improved diagnosis and/or treatment methods for visual system diseases and injuries. For example, gene therapy to treat a rare form of inherited blindness was approved by the U.S. Food and Drug Administration (FDA)—the first FDA-approved gene therapy for any genetic disease. Stem cell therapies to treat age-related macular degeneration are in clinical trials. Several types of retinal prosthesis are at various stages of clinical trials or applications, transforming the lives of blind patients. Optical coherence tomography (OCT) has revolutionized ophthalmic imaging.

Vision care in the military has also made significant progress. The FY08 National Defense Authorization Act (NDAA) authorized the establishment of the DoD Vision Center of Excellence (VCE) to address the full scope of military vision care, including prevention, diagnosis, mitigation, treatment, research, and rehabilitation of military eye injuries and diseases, including visual dysfunctions related to TBI. Since then, the VCE has played a unique and critical role in promoting the vision health of Service members and Veterans through a myriad of activities, such as education, training, information management, and development of clinical practice



guidelines. The FY09 NDAA authorized establishment of the VRP, which has since become a magnet for military-relevant vision research projects, for example:

- A novel reversible adhesive to manage ocular trauma<sup>2</sup>
- A hand-held OCT with remote wireless web-based interactive control capability<sup>3,4</sup>
- The time course of visual dysfunction and pathology after blast exposure<sup>5</sup>
- Extracellular matrix technology to protect and repair injured retinas and optic nerves<sup>6</sup>
- Comprehensive modeling of ocular alkali injury<sup>7</sup>

While military and civilian vision care share many common goals and both benefit from advancements in diagnostic imaging, retinal regeneration, visual prosthetics and other technologies, military vision care also faces some unique challenges. Substantial barriers and gaps remain that must be overcome to preserve the eyesight of Warfighters, who more frequently face traumatic injuries such as those caused by blast, open globe rupture, thermal and chemical burn, directed energy weapons, ionizing radiation, and polytrauma. Moreover, treatment of ocular trauma in a military combat or mass casualty setting may be more austere, demanding specially adapted or specially developed methods, technologies, and clinical guidelines.

## RESEARCH FUNDING LANDSCAPE

Funding across all types of vision research comes from a variety of federal and private sources (Figure 2). The primary funder of vision research is the National Eye Institute (NEI). In FY18, the NEI invested \$655.9M and \$86.1M in extramural and intramural research, respectively, in six program areas: retinal disease; corneal disease; lens and cataract; glaucoma and optic neuropathies; strabismus, amblyopia, and visual processing; and low vision and blindness rehabilitation. The NEI is also a participant in the NIH Brain Research through Advancing Innovative Neurotechnologies (BRAIN) and NIH Regenerative Medicine Initiatives.

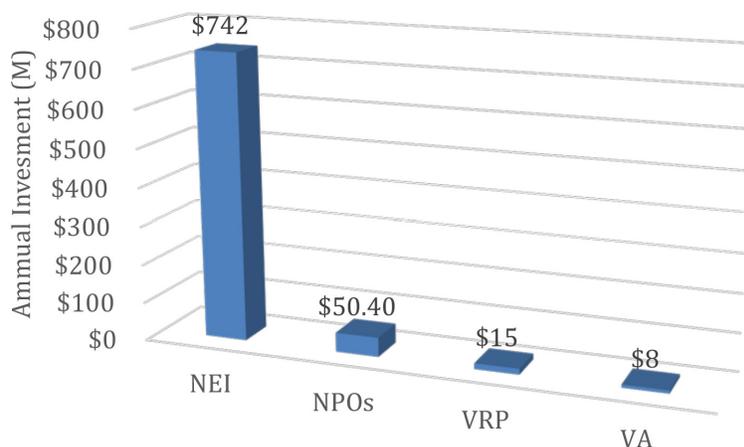
There are 13 non-profit organizations (NPOs) that provide significant funding (i.e., greater than \$1M annually) to vision research. Annual investment by the largest three NPOs (Foundation Fighting Blindness, JDRF, and Research to Prevent Blindness) exceeds \$10M each. In 2015, the 13 NPOs collectively invested \$50.4M, with the largest investments going into age-related macular degeneration (\$25.2M), diabetic retinopathy (\$11.7M), and glaucoma (\$5M).

The VA Rehabilitation Research and Development Service (RR&D) sponsors vision research as part of its Sensory Systems/Communication Disorders portfolio, which encompasses hearing, speech, and vision research projects. In FY17, the VA RR&D invested \$8M to fund 42 awards focused on vision research.

Finally, other investments in vision research within the DoD have included the CRMRP, PH/TBIRP, Medical Technology Enterprise Consortium (MTEC), and the CDMRP's Joint Warfighter Medical Research Program and Peer Reviewed Medical Research Program.

It is worth noting that, while the total annual investment across federal and private funders, including the VRP, exceeds \$800M, the VRP is the only funder with a focus on ocular trauma and trauma-related visual dysfunction.

**Figure 2. Approximate Annual Vision Research Investment\* from NEI, NPOs, VRP and VA.**



\* Showing FY18 investments from the NEI and VRP, FY17 investment from the VA, and 2015 investments from NPOs.



## STRATEGIC DIRECTION

The VRP developed its near-term (5-year) strategic direction based on recommendations from the VRP Programmatic Panel, which includes program officials from the VCE, NEI, VA, and other government entities; ophthalmologists and optometrists with first-hand experience of serving Warfighters; academic scientists; Veterans with vision loss; and other program stakeholders. To set the VRP's strategic direction and pursue promising scientific opportunities while coordinating research funding, initiatives, and priorities across organizations, the VRP Programmatic Panel members considered the state of the science, including major unanswered questions and emerging technologies, the funding landscape, NEI programs and research priorities,<sup>8</sup> and the vision research initiatives and outcomes of other entities such as the CRM RP, MTEC, and PH/TBIRP.

### STRATEGIC GOALS

The VRP has identified two near- and medium-term program priorities and set the following goals to address them:

► **Accelerate research in eye injury and vision dysfunction due to military-relevant trauma**

The VRP is uniquely focused, as well as uniquely positioned, to promote research that addresses current and anticipated battlefield-related eye and vision injuries. To preserve the eyesight of injured Warfighters, we must achieve a better understanding of the biological, physical, and mechanical mechanisms by which military-relevant trauma damages the ocular system and impairs vision, as well as develop more effective preventive and treatment approaches.

► **Advance diagnosis and treatment of eye injuries in both a forward operating environment and a prolonged field care setting**

It is anticipated that the future battlefield will require more advanced eye injury management and treatment options to accommodate austere conditions such as prolonged evacuation time and limited specialty care. To preserve eyesight in an austere environment, we must develop diagnostics and interventions that enable decision-making, triaging, stabilization, and management by forward casualty caregivers who are as close to the point of injury as possible.

With these strategic goals, the VRP expects to reduce the near- and long-term impact of military-relevant trauma on eye and vision; minimize the impact of ocular/vision injury on force readiness; and improve the health and quality of life of Service members, Veterans, and the American public. While these goals are expected to be stable for the next 3-5 years, they will be reviewed during the VRP's annual Vision Setting meetings and revised/updated as needed.

### NEAR- AND MEDIUM-TERM FOCUS AREAS

To achieve the strategic goals identified above, the VRP will focus its investment on the understanding, prevention, diagnosis, mitigation, and treatment of battlefield-related eye injury and vision dysfunction over the next 3-5 years. The VRP will solicit and support research to prevent, diagnose, and treat battlefield-related injuries to the ocular system that are caused by existing and new/anticipated weapons or environments. Additionally, the VRP will solicit and support research to prevent, diagnose, and treat blast- and TBI-related progressive visual dysfunctions. Finally, the VRP will solicit and support research to advance effective vision injury diagnosis and treatment as far forward on the battlefield as possible to help injured Warfighters in austere environments.

## INVESTMENT STRATEGY

For each fiscal year, the specifics of the VRP's investment strategy, including award mechanisms, focus areas, and funding levels, will be determined at the annual Vision Setting meetings, taking into account the most current state of the science and available Congressional appropriations.

In FY18, the VRP is offering three award mechanisms. The Focused Translational Team Science Award mechanism is intended to support highly collaborative and translational team initiatives that will fundamentally advance the understanding and treatment of eye injuries and/or visual dysfunction that result from a military-relevant traumatic event. The Investigator-Initiated Research Award mechanism is intended to support innovative studies that will yield highly impactful discoveries or major advancements in research and/or patient care of eye injury and/or visual dysfunction as related to military-relevant trauma. Finally, the Expansion Award mechanism will support continued investigation and further development of highly impactful research projects that were previously funded by the VRP.



## MEASURING PROGRESS

The VRP will measure its near-term success based on its impact on research activity, as well as scientific output in the aforementioned priority areas. Program evaluation will be conducted on an ongoing basis using a multitude of parameters. Some examples are provided below.

### ASSESSING RESEARCH ACTIVITY

- Quantity and quality of grant applications received
- Awards funded in each priority area
- Investigators and institutions that engage in VRP-sponsored research projects

### ASSESSING SCIENTIFIC OUTPUT

- Publications
- Presentations
- Patent applications and patents

The long-term success of the VRP will be evaluated by the scientific and clinical returns on its investment, including therapeutic agents identified and/or tested, therapeutic devices designed and validated, diagnostic tools and methods developed, Investigational New Drug/Investigational Device Exemption applications submitted to and approved by the FDA, and clinical trials resulting from VRP-funded projects.

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