



**THE FOUNDATION FIGHTING BLINDNESS**

**LETTER OF INTENT GUIDANCE**

**TRANSLATIONAL RESEARCH ACCELERATION PROGRAM  
VIRAL-VECTOR INDUCED OCULAR INFLAMMATION PROGRAM PROJECT AWARD**

**LETTER OF INTENT**

**Translational Research Acceleration Program (TRAP)  
Viral-Vector Ocular Inflammation Program Project Award**

**Foundation Fighting Blindness Mission**

The mission of the Foundation Fighting Blindness (Foundation) is to drive the research that will lead to preventions, treatments and vision restoration for degenerative retinal diseases that affect more than 10 million Americans and millions more throughout the world. The Foundation is the world's leading private source for inherited retinal disease research funding. We are committed to funding research until the entire spectrum of retinal degenerative disease is eradicated.

**SUBMISSION AND REVIEW DATES AND TIMES**

- **Request for Proposals Release Date:** June 22, 2021
- **Proposers Day:** July 7, 2021
- **Letter of Intent Due Date:** July 22, 2021
- **Full Application Invites:** August 15, 2021
- **Application Due Date:** October 30, 2021
- **Review of Applications:** December 2021 – Jan. 2022
- **Anticipated Award Date:** March 2022

## **Translational Research Acceleration Program: Viral-Vector Ocular Inflammation Program Project Award Funding Description**

**Here, the Foundation Fighting Blindness seeks proposals toward the Translational Research Acceleration Program's (TRAP) Viral-Vector Ocular Inflammation Program Project Award.** The Foundation Fighting Blindness' unique TRAP program accelerates preclinical translational research targeted at preventing, treating, or curing blindness resulting from inherited retinal degenerative diseases and dry age-related macular degeneration. It leverages a proactive program management structure, including a hands-on advisory committee with expertise in drug development, retinal clinical therapies, commercialization, regulatory guidance, intellectual property, and partnerships, providing a catalyst that helps move technology into clinical use. People with inherited retinal degenerations need an increased number of personalized therapies to combat the diversity, complexity, and uniqueness of inherited retinal diseases and dry age-related macular degeneration (**NOTE: studies focused on wet AMD and diabetic retinopathy are not eligible** for support by the Foundation Fighting Blindness).

**This funding opportunity is slotted for a TRAP Program Project Award (PPA).** Retinal viral-vector therapy has the potential to cause ocular inflammation and may reduce the treatment's effectiveness. To mitigate the impacts of adverse immune reactions and ocular inflammation, this PPA is designed to support collaborative, multi-disciplinary, research studies that engage investigators with different expertise and resources to reduce or prevent ocular inflammation caused by viral-vector treatment. The PPA is intended to enable studies that are too large or complex for a single investigator to undertake in a reasonable amount of time and to address immunological gaps in our current knowledge or therapeutic options when treating retinal disease. The PPA must be unified around a single, well-articulated hypothesis and a clearly defined deliverable(s), relevant to the mission of the Foundation. The teams supported by a PPA must be tightly integrated and sharply focused, freely share data and creative ideas, and each must be essential to the common goal.

The PPA is not intended to support clinical research unless it is tightly integrated with the other projects, and the PPA is not intended to support research core facilities.

### **Research Priority Areas**

This TRAP PPA is interested in submissions related to one or more of the research priority areas listed below; **however**, research and technologies that fall outside of the scope of these areas may be considered with adequate preliminary data and justification. In the application, please highlight which research priority area(s) your research/technology falls within the defined outline:

- **Ocular Inflammation Pathways during Retinal Degeneration**
  - Priority to better understand the intrinsic inflammatory nature and immune activation consequent to inherited retinal disease-associated degeneration prior to gene therapy

- Priority to define, generate, and characterize appropriate animal models to study ocular inflammation due to viral vector based gene therapy
- Priority to explore and establish the relationship and conversion scale between small-globe intraocular inflammation and clinical intraocular inflammation
- **Viral-Vector Induced Ocular Inflammation, Activation, and Progression**
  - Priority to measure ocular and systemic inflammation, *in vivo*, during and after gene therapy at the cellular, tissue and organ level
  - Priority to understand the impact of ocular inflammation on the therapy (e.g. cells transduced, persistence of expression, safety signals, magnitude of activity/efficacy, etc.)
  - Priority to understand perturbations in biological-omics of ocular (and systemic) inflammation before, during, and after gene therapy
  - Priority to develop novel assays to measure inflammation that will inform use of gene therapies clinically
  - Priority to develop clinical imaging protocols and/or novel systems to monitor ocular inflammation *in vivo*, both clinical and subclinical
- **Ocular Inflammation Mitigation**
  - Priority to mitigate the impacts of inflammation before, during, and after gene therapy treatment
  - Priority to determine and develop preclinical testing regimen(s) to assess optimal, safe, and effective ocular immunosuppression
  - Priority to optimize prophylactic and symptomatic treatment of inflammation in clinical protocols
  - Priority to identify and develop novel or repurposed immune modulatory therapies beyond steroids
  - Priority to develop next-generation viral vectors and manufacturing practices

**TRAP PPA Eligibility Criteria:**

- Principal Investigators must hold a research leadership position (e.g., faculty position, director of research, etc.) at an accredited college, university, medical school, other public or private research institution/facility, or company who can independently conduct research with the full support of their organization.

- Application is not limited to the U.S. or U.S. citizens. Applicants who are not U.S. citizens and reside and work outside the U.S. may apply.
- A project shall have only a single Program Leader for each PPA who is responsible for project oversight, financial management, and reporting. The Project Leader may engage collaborators, core labs or commercial CROs to aspects of the project if it adheres to the awarded budget.
- A minimum of three research projects are required for consideration for the Program Project Award.
- The PPA team must fully demonstrate all research and development personnel have the skillsets to execute proposed work and show that the location(s) where the work is to be conducted has the adequate space, equipment, tools, protocols, safety and regulatory measures to execute research.
- The proposed research partnerships must have been already discussed and tentatively agreed upon prior to application submission. This will be made clear with written confirmation provided to the Foundation at the time of proposal.
- Proposals must identify one or more of the Research Priority Areas listed as their main focus to elucidate and mitigate the impact of viral-vector induced ocular inflammation. However, if outside the scope of the listed Research Priority Areas please indicate in the proposal and provide adequate background and/or preliminary results to justify funding.
- Research should be hypothesis driven.
- Clearly state how the proposed research project is geared toward better understanding the basis and the impact of viral vector-induced ocular inflammation in developing a product to address inherited retinal degenerations and/or dry age-related macular degeneration.
- Applicants should provide an intellectual property (IP) and/or protection strategy for their technology if efforts produce technology with commercial potential.

### **Key Steps in Applying (and anticipated due dates)**

- Proposers Day (July 7, 2021):
  - One day event that provides information to potential proposers on the objectives and program details of the TRAP and TRAP PPA. The event will be held virtually, and advance registration will be required ([https://fightingblindness-org.zoom.us/webinar/register/WN\\_uaa\\_lyQbQMumo6s4y7cJMQ](https://fightingblindness-org.zoom.us/webinar/register/WN_uaa_lyQbQMumo6s4y7cJMQ)). Please check the Foundation website or email [grants@fightingblindness.org](mailto:grants@fightingblindness.org) for more information.
- Letter of Intent Due Date (July 22, 2021):
  - LOIs are required prior to being invited to full application submission

- Applicants should submit a Letter of Intent (LOI), which will be reviewed by the Foundation and its science team to ensure fit to the program.
- Please include in the letter of intent:
  - (1) Contact Information
  - (2) Project title
  - (3) Research Priority Areas
  - (4) Project Abstract/Summary (500-word limit)
  - (5) Overall Application Description (600-word limit)
  - (6) Stage of Development
  - (7) Names of Other Key Personnel and Collaborators
  - (8) Projected Cost and Timeline
  - (9) Project Leader and PI CVs
  - (10) Figures to Upload (3 figures maximum)
- The letter of intent is not to exceed four (4) pages. It will be reviewed by the Foundation's science team and if found adequate for potential funding, an email with the application and guidance will be sent to the Principal Investigator. PI's CV and figures do not count against page limit.
- Applicants should submit their Letter of Intent information through the JUMP application portal: <https://www.onlineapplicationportal.com/blindness>
- Full Application Invites (August 15, 2021):
  - The Foundation will inform the Principal Investigator by email of its decision to accept a full application Full Applications: Application instructions will be provided at the time of invitation.
- Application Receipt Date (October 30, 2021):
  - Application instructions are located on the Foundation website
- Review of Applications (December 2021 – January 2022):
- Anticipated Award Date (March 2022):

**Foundation Contact for Inquiries:**

Direct inquiries regarding the application and review process and required application components and forms to [grants@FightingBlindness.org](mailto:grants@FightingBlindness.org).