



THE FOUNDATION FIGHTING BLINDNESS

REQUEST FOR PROPOSALS

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

Overview of Funding Opportunity

Program Announcement for the Foundation Fighting Blindness

**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 execute any fraction 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)
- 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
 - (5) Overall Application Description
 - (6) Stage of Development
 - (7) Names of Other Key Personnel and Collaborators
 - (8) Projected Cost and Timeline
 - (9) PI's CV
 - (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 does 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.

Program Overview

Project Leader

One of the senior investigators on the TRAP PPA proposal is required by the Foundation to assume the role of Project Leader. The Project Leader will be the primary contact with the Foundation, responsible for timely submissions and responses, overall scientific leadership and management of the award, and ensuring that progress and financial reporting requirements are met.

Program Information

Please provide a full title for the proposed program for which funding is being requested.

Overall Research Goals and Hypothesis

Define the overall research goal that addresses a targeted area of research relevant to the mission of the Foundation. Clearly state the central hypothesis of the program that will unify each project.

Therapeutic Development

If a therapeutic is being developed under this program, please complete the Target Product Profile section.

List of Investigators Included in the Program Project Award Application

Not including the Project Leader, provide the full name of EACH investigator that will serve as Principal Investigator of EACH Individual Project Proposal, include (Last Name, First Name, Middle Initial). For example:

If the Project Leader is Carol Washington **and** she is a project PI include the following:

Project 1: Smith, Jane, S

Project 2: Washington, Carol,

Project 3: Lowe, David, R

If Carol Washington is the Project Leader but **NOT** a project PI, do not include their information here.

Define each investigator's role in the PPA, and their institutional affiliation. The Foundation uses the following definitions for investigators:

- **Project Leader** is an investigator who will be responsible for overall scientific leadership and management of the PPA, ensuring that progress and financial reporting requirements are met and for submitting the PPA Application to the Foundation. The Project Leader may, if they wish, nominate a Principal Investigator as a Co-Project Leader to be responsible with the Project Leader for scientific leadership and management of the PPA. Salary requests up to 30% of the annual project budget are allowed for the Project Leader and co-Leader.
- **Principal Investigators** are those investigators who will be scientifically responsible for one or more of the individual projects listed. Salary requests up to 20% of the project budget are allowed for the PI of each component. Co-Investigators are investigators who may be responsible for a sub-component of a project or core.
- **Collaborators** are investigators who provide expertise, resources or services to a project or core. They do not receive Foundation funds from the project. The

collaborator must provide a letter to be submitted with the Full Application which describes the specifics of the collaboration.

Lay Summary

Provide up to a one-page summary of the Program Project Award application, written in lay terms for a non-scientific audience. The abstract should contain non-confidential material that can be posted publicly if the application is funded.

Please Include:

1. The goal of the research
2. The IRD population who might benefit
3. The clinical significance of the proposed research
4. What is novel and innovative about the proposed research
5. The nature of the collaboration(s) proposed and the strength it brings to the research

Include KEYWORDS at the bottom of the document to be uploaded.

Individual Project Proposals

A minimum of three research projects are required for consideration for the Program Project Award.

1. The fields below for **each project** should be completed by the Program Leader.
 - a. Title of Project
 - b. Personnel
 - i. List the investigators included in this Individual Project application. The number of rows in the table can be adjusted as required. Provide the full name of the investigator (Last Name, First Name, Middle Initial), that investigator's role in the project from the pull-down menu, and his/her institutional affiliation.
 - ii. Signatures of key personnel will be uploaded in the Facepage Upload section. A signature by that person on the proposal signifies that they agree to diligently carry out the responsibilities of the role assigned to them as described in the PPA proposal.
 - iii. Please note that the Foundation uses the following definitions for investigators:
 1. Principal Investigators are those investigators who will be scientifically responsible for one or more of the individual projects listed. Salary requests up to 20% of the project budget are allowed for the PI of each component.

2. Co-Investigators are investigators who may be responsible for a sub-component of a project or core. Collaborators are investigators who provide expertise, resources or services to a project or core. They do not receive funds from the project. The collaborator must provide a letter to be submitted with the Full Application which describes the specifics of the collaboration.
2. The Program Leader must provide the **Individual Project Proposal template** to each project PI to complete and return for upload (single PDF file). The completed Individual Project Proposal and related attachments should be returned to the Project Leader for uploading into the application (comprising upload of a single document for each individual project). The template includes the following items which are required for submission:
- a. **Individual Project Proposal template:**
 - i. **Scientific Abstract (maximum of 1 page)** - Background, Objectives, Summary of Research Plan, Anticipated Results and Outcomes
 - ii. **Research Proposal (maximum of 10 pages)**
 1. Background and Project Goal
 2. Preliminary Data
 3. Goals and Objectives
 4. Specific Aims and Hypothesis
 5. Technologies and Methodologies
 6. Project Time Plan
 7. Synergies with other Components of the Program
 8. List of References
 - a. Provide a complete list of relevant references for the preceding sections. The reference must include the full title of the paper. There is no page limit for the list of references.

Appendices

- Letters of Collaboration – There is no page limit for the letters of collaboration.
- Up to Five Key Publications and Submitted Manuscripts (Note: These items should NOT be included in the final Individual Project Proposal PDF; submit these separately to the Project Leader).

Program Budget:

- Application Budget Applicants must use the Foundation's TRAP Program Project Award Budget Form. This form is provided as an Excel template and can be downloaded on the application webpage.

- Provide an itemized program budget for each individual project in the Excel worksheet, and the relevant budget justification text on the Budget justification form. Complete the tables with a single dollar amount per year for each of the following categories: Personnel, Supplies, Animals, Patients, Travel and Other.

Budget Limitations:

- Requested budgets must not exceed \$1,500,000.00 distributed evenly over a three-year timeframe.
- The support requested for the Project Leader and co-Leader must not exceed twenty percent (20%) of the total annual budget.
- The Program coordinator/manager should be included in the Program Cost budget and not in the Individual Project budget
- The support requested for the Principal Investigator must not exceed twenty percent (20%) of the total annual project budget.
- The award may be used to support the salaries of research trainees (graduate students, postdoctoral or clinical fellows), technical staff and research supplies.
- Purchase of significant equipment is generally not supported by the Program Project Awards. Significant equipment is defined as permanent or semi-permanent apparatus, devices or systems costing more than \$5,000 per item or system. Applicants must obtain prior approval from the Foundation Fighting Blindness to submit an application proposing to purchase equipment. All such equipment purchase requests must be well justified in the budget section of the application and in the description of proposed project.
- The Foundation Fighting Blindness does not pay indirect or overhead charges, nor does the Foundation provide support for building construction or renovation.
- Final approved budgets may be restructured post-award based on reviewer recommendations and funding availability.

Budget Application:

- Personnel support, listed by name and degree with percent effort, salary, and fringe benefits requested;
- Supplies, itemized by general category, e.g. glassware, molecular biology reagents;
- Patient Costs, itemized by number of patients and per patient cost;
- Animal Costs, itemized by number, type, and length of housing;
- Travel funds up to \$2,000 may be requested for meetings and conferences;
- Other costs should be clearly itemized.

Program Cost:

The final section of the budget worksheet is for Program Budget costs not covered in the Individual project section:

- Salaries of program coordinator/manager
- Travel and meetings
- Other cost
 - The following cannot be paid from Foundation PPA funding:
 1. Indirect costs such as overhead or infrastructure

2. Entertainment or hospitality costs
3. Activities by researchers not part of the application

Budget Justification

Upload a detailed budget justification in the following upload fields for the budget requests made on the “FFB PPA 2021 FULL APPLICATION – Budget – PROJECTLEADERNAME” Excel workbook. Provide a justification for each of the submitted sections of the application in the following order:

- Program costs
- Individual Projects – provide a separate section for each project

For “Personnel Support” justification:

- List all scientific and technical personnel involved in the proposed project;
- Clearly designate roles of all personnel;
- Clearly identify key personnel and co-investigators;
- For each person identified as key personnel provide information on all other sources of financial support, including both current and proposed projects. For each source (federal, private or commercial) provide:
 - Title of grant/award;
 - Grant/award number;
 - Percent effort;
 - Funding amount;
 - Budget period;
 - A short description of the project’s goals.
- Include a section for each project, detailing the budget request. Provide a justification for the budget requested for each category: Personnel, Supplies, Patients, Animals and Other.

Appendices

In the fields below provide a list of all the file attachments supplied with the Budget documentation, such as quotations, letters of commitment, and Statements of Work.

Overall Program Description

This section must be prepared and submitted by the Project Leader. Within the limit of ten pages, provide an overview of the program. Provide a background of current knowledge relative to the proposed research, with reference to relevant publications. Summarize the objectives of the proposal, and state why they are important and are novel. Describe the established and planned collaborations and provide a rationale why this application fits the criteria for the TRAP PPA. Explain how interrelated and synergistic the projects are in their work towards a common goal. The overall program must have the potential to achieve much more than the simple sum of its component projects. Describe how the program provides a valuable research training environment for students and fellows.

This section must include details of the following:

1. Work Plan: describe the management and oversight of the PPA; how will each PI contribute to the fulfillment of the project objective; what is the expectation for publications
2. Communication Plan: how will the Director communicate with the PIs and how often; how and when will the PIs communicate with each other
3. Data Sharing Plan: what is the mechanism of data sharing (research tools, model organisms, GWAS data sharing); how will the data be stored, curated and accessed; how will the data access and sharing be maintained beyond the end of the award

In regard to overlapping projects and funding sources, describe commitments made by any of the sponsoring institutions associated with this project that will be essential for the successful performance of this program, including the role of other partners or funders. Disclose relevant commitments made by and to those partners, for example, to give the partner preferred access to use a resource. State whether these commitments (collaborative and/or financial) are secured, requested but not yet secured, or are planned but not yet requested. Finally, describe the specifics of how this proposal fits with, integrates and synergizes with another program or activity at any of the sponsoring institutions. Provide a summary of the overlapping program's goals and participants.

Program Budget Summary

Use the 3rd tab of the Foundation Program Project Budget Award Form, called "5-YEAR OVERALL BUDGET SUMMARY", and copy that content into the fields on this form.

Key Publications

Upload all key publications and submitted manuscripts directly related to the application. There is a limit of 5 key publications per project.

Curriculum Vitae

All program applicants (Project Leader, Principal Investigators, and Co-Investigators) with the exception of collaborators, are required to submit a CV (NIH biosketch acceptable). CVs can be combined into a single PDF document and uploaded.

Face Page

The Face Page must be signed by the Principal Investigator and the responsible Institutional official. Prior to submitting the application, print the face page, obtain the appropriate signatures and upload as instructed.

Application Formatting Instructions

Use the specified character limit as your guide for portal fields.

When uploading pdfs follow these instructions:

- Use an Arial typeface and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.)
- Type density, including characters and spaces, must not exceed 15 characters per inch.
- Type may be no more than six lines per inch.
- Use 1" margins

- All page limits specified refer to single-spaced format using the above formatting requirements.
- **LAY SUMMARY:** up to 1-single-spaced page
- **SCIENTIFIC ABSTRACT:** up to 1-single-spaced page
- **RESEARCH PROPOSAL:** up to 10 single-spaced pages
- **TABLES & FIGURES:** up to 5 single-spaced pages included in appendices

APPLICATION SUBMISSION INSTRUCTIONS

All applications must be submitted online. Attachments are required and must be submitted through the application portal.

NOTE: The complete full application must be SUBMITTED by October 30, 2021 (11:59PM EDT).

Online submission

First create an account on the site's homepage by selecting "Applicant Registration-start here" underneath the Foundation logo. If you have previously created an account, this step is not necessary.

You may log out and return to your in-progress application as many times as you wish until it has been submitted. In order to be considered for the award, your online application must be complete and in SUBMITTED status no later than **by 11:59 p.m. EDT.**

A. How to enter information

1. You may begin completing the application at any section. To begin, choose a section of the application from the left menu or click "Continue" at the bottom of the screen.
2. Text boxes will hold only a limited amount of text. Where longer answers are permitted, the number of available characters will be indicated. **Before submitting, we suggest you print and examine a hard copy of your application to be certain your responses are complete and accurate.**
3. The information you provide will be saved exactly as entered. Therefore, fill out the form carefully, paying attention to spelling, case (**do not use all caps**), punctuation, etc., and give special consideration when entering your contact information.
4. Begin typing all answers at the extreme left-hand side of the response area or box; do not leave a space or indent at the beginning of your answer.

B. How to SAVE and SUBMIT your data

1. You must **SAVE each time you leave a screen.** If you do not click on SAVE or SAVE & CONTINUE, anything entered since you last hit SAVE on that screen will be lost (any work from a previous session will be retained, but any new entries will be lost). The SAVE and SAVE & CONTINUE buttons are at the bottom of your screen.
2. You may work on your application over as many sessions as you wish, and the status of your application will be **IN PROGRESS** until you submit it. Once you are satisfied that your application is complete, you must go to the "Submit Application" screen and select **SUBMIT APPLICATION.**

3. When you have completed your application, we strongly suggest that you print and read it before submitting, to be sure there are no further revisions you wish to make. **If for some reason you need to make changes after your application is submitted, email blindness@onlineapplicationportal.com.**
4. Your application status must appear as SUBMITTED **by 11:59 p.m. EDT** in order for your application to be considered. Information on your application status may be found on the Online Application Portal home page.

PLEASE USE YOUR OWN E-MAIL ADDRESS IF POSSIBLE WHEN SUBMITTING THE LETTER OF INTENT SO THAT WE CAN INFORM YOU IN A TIMELY FASHION IF YOUR APPLICATION HAS BEEN SELECTED FOR SUBMISSION OF A FULL PROPOSAL. IN ADDITION, PLEASE ADVISE US AS SOON AS POSSIBLE OF CHANGES IN E-MAIL ADDRESSES.