



THE FOUNDATION FIGHTING BLINDNESS

REQUEST FOR PROPOSALS

TRANSLATIONAL RESEARCH ACCELERATION PROGRAM

Overview of Funding Opportunity

Program Announcement for the Foundation Fighting Blindness

Translational Research Acceleration Program (TRAP) Award Program

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

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.

Translational Research Acceleration Program Funding Description

Here, the Foundation Fighting Blindness seeks proposals toward the Translational Research Acceleration Program (TRAP). 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 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 a **priority** for support by the Foundation Fighting Blindness).

Research Priority Areas

The primary interest for the Foundation is to fund research and development efforts that are creating novel, clinically relevant treatments and cures. The TRAP program 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 your research/technology falls within according to the definitions outlined:

- **Novel Medical Therapies (NMT)** – Approaches that use chemistry, biology, and bioengineering to formulate new therapies that mitigate inherited retinal degenerations. The approaches should seek relevant delivery to the biological site of interest, adequate target efficacy, and minimal toxicity. The goal is to retain retinal function and structure in retinal degenerative diseases through the development of improved animal models of human disease, enhanced functional testing of drug effectiveness, and novel drug delivery systems. Examples of areas of interests are as follows:
 - Small Molecules
 - Biologics (excluding cells and tissues)
 - Optotherapies (e.g., optogenetic therapy)
 - Alternative therapies (research that falls outside of stated priority areas)

- **Genetic Technologies (GT)** – The manipulation and modification of human gene expression to alter the biological properties of living cells/tissues with the goal of providing therapeutic solutions that span inherited retinal degenerations and/or dry age-related macular degeneration. The goal is to find a viral or non-viral gene delivery and/or modification system(s) to treat retinal degenerative diseases. The application must also address a plan to evaluate efficacy and safety using relevant pre-clinical models in preparation for human clinical trials. The Foundation limits its funding to the development of the technology that will benefit overall retinal gene-therapy strategies. Examples of interest areas are as follows:
 - Plasmid or naked DNA
 - Viral Vectors
 - Bacterial Vectors
 - Human Gene Editing Technologies
 - Patient-Derived Cellular Gene Therapy Products
 - Viral and Non-Viral Gene Delivery Systems

- **Regenerative Medicine (RM)** – The development, regeneration, and employment of human cells, tissues, and cellular/tissue-based products for the restoration of retinal function and vision. The goal is to develop strategies to rescue or replace degenerating or dead retinal cells leading toward slowing, preventing or restoring vision loss. Technology interest areas are as follows:
 - Stem cell therapies
 - Cell Delivery Systems (Combination Products)
 - Retinal Organoids

TRAP Eligibility Criteria

- Proposed TRAP research must meet the following criteria:
 - Projects should address developing therapies for retinal degenerations with clear genetic disease drivers (e.g., ABCA4 disease)
 - Seek and identify one or more of the Research Priority Areas listed as the approach taken to provide a new IRD therapy. 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; however, it is not required if a proposal demonstrates that the project has already identified a target, developed lead therapeutics, and shows a plan toward optimization and development of a product
 - Clearly state how the proposed research project is geared toward developing a product to address inherited retinal degenerations and/or dry age-related macular degeneration and has the potential advance to the next stage of development (e.g., IND filing, venture capital, etc.)
 - Must use functional efficacy models/assays that are appropriate and relevant to regulatory filing

- Applicants should demonstrate how their technology will potentially work in the clinic and marketplace
- Applicants should provide an intellectual property (IP) and/or protection strategy for their technology
- TRAP applicants must meet the following criteria:
 - Applicants must hold a research leadership position (e.g., faculty position, director of research, etc.) at an accredited academic medical center, university, research institution, or company who can independently conduct research with full support of their institution
 - A project shall have only a single Principal Investigator (PI; or single Program Director for a PPA), who is responsible for project oversight, financial management, and reporting. The PI may engage collaborators, core labs or commercial CROs to execute any fraction of the project if it adheres to the awarded budget
 - Must fully demonstrate all research and development personnel have the skillsets to execute proposed work
 - Must 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
 - Any proposed research partnerships must be already established prior to application submission. This will be made clear with written confirmation provided to the Foundation at the time of proposal, and if applicable, a proposed cost sharing agreement
- Clearly identify the funding category they are applying to from the list below:
 - TRAP I (funding up to \$900K allocated over a three-year period):
 - Funds research covering early preclinical development from target validation to proof of concept up to develop of a lead therapeutic (Phase I)
 - Research lead by single PI
 - TRAP II (funding up to \$1.5M allocated over a three-year period):
 - Funds mid- to late-stage preclinical research covering lead optimization through drug candidate selection and IND enabling studies (Phase II)
 - Research lead by single PI
 - TRAP III (funding up to \$1M allocated over no more than a three-year period):
 - This flexible award funds late stage projects that need one or more critical experiments (e.g., lead candidate testing in non-human primates) to satisfy a transition requirement (i.e., FDA IND filing, Venture Capital investment, etc.)
 - Research lead by single PI

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. 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) a descriptive title of proposed activity
 - (2) name, address, and telephone number of the Principal Investigator
 - (3) names of other key personnel and collaborators
 - (4) participating institution(s)
 - (5) goals and impacts of project
 - (6) brief technical plan
 - (7) research team capabilities
 - (8) cost and schedule
 - 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.
 - Applicants should submit a Letter of Intent in PDF format to: <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):