

THE FOUNDATION FIGHTING BLINDNESS

REQUEST FOR PROPOSALS

TRANSLATIONAL RESEARCH ACCELERATION PROGRAM

Overview of Funding Opportunity

Program Announcement for the Foundation Fighting Blindness

Fiscal Year 2025 Translational Research Acceleration Program Award

SUBMISSION AND REVIEW DATES AND TIMES

•	Request for Proposals Release Date:	April 1, 2024
•	Proposers Day:	April 29, 2024 1-2PM ET
•	Letter of Intent Due Date:	June 04, 2024
•	Full Application Invites:	August 8, 2024
•	Application Due Date:	October 17, 2024
•	Review of Applications:	October 2024 – March 2025

Anticipated Award Date: March 2025

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 millions of people throughout the world. The Foundation is the world's leading private funding source for retinal disease research. We are committed to funding research until the entire spectrum of degenerative retinal disease is eradicated.

Translational Research Acceleration Program Funding Description

Here, the Foundation Fighting Blindness seeks proposals toward the Translational Research Acceleration Program. This unique award program accelerates preclinical translational research targeted at preventing, treating, or curing blindness resulting from inherited retinal degenerative disease (IRD) and dry age-related macular degeneration (dAMD). It leverages a proactive program management structure, including dedicated Project Mentors 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 degeneration (MOTE: 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 Translational Research Acceleration 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 the proposed research and/ or 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 IRDs. The approaches should seek relevant delivery to the biological site of interest, adequate target efficacy, and minimal toxicity. The goal is to enhance or retain retinal function and structure in retinal degenerative diseases through R&D efforts in 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, but are not limited to:
 - o 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 IRDs and dAMD. The goal is to find a viral or non-viral gene delivery and/or modification system(s). The application must also address a plan to evaluate efficacy and safety using relevant pre-clinical models in preparation for human clinical trials. Examples of interest areas are as follows, but not limited to:
 - Plasmid or naked DNA
 - Viral Vectors
 - o 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, but not limited to:
 - Stem cell therapies
 - Cell Delivery Systems (Combination Products)
 - Retinal Organoids

Eligibility Criteria

- <u>Proposed Translational Research Acceleration Program research must meet the</u> <u>following criteria</u>:
 - Proposals exploring therapeutic solutions for IRDs should focus on 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 or dAMD 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 a lead therapeutic, 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.).
 - $\circ\,$ 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. Also, include statement on marketplace impact as compared to current practices.
 - Applicants should provide an intellectual property (IP) and/or protection strategy for their technology.

- <u>Translational Research Acceleration Program applicants must meet the following</u> <u>criteria</u>:
 - 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 organization.
 - If you are applying as a company, please directly contact the Senior Director of the Preclinical Translational Research Program (<u>cjackson@fighitngblindness.org</u>). There are additional considerations that will need to be discussed before a full application is submitted.
 - A project shall have only a single Principal Investigator (PI; or single Program Director for a PPA), who is responsible for project oversight, fiscal 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.
 - Applicants must fully demonstrate all research and development personnel have the skillsets to execute proposed work.
 - Applicants 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.

Funding:

• The budget limit for this award is \$1 million dollars. The Foundation aims to catalyze translational efforts (hit-to-lead R&D to IND-Enabling Studies) to accelerate discoveries and bring innovative therapies closer to patients. Researchers and institutions are encouraged to submit their proposals, emphasizing rigorous scientific merit, feasibility, and potential impact.

Key Steps in Applying (and anticipated due dates)

- Proposers Day (April 29, 2024):
 - One day event that provides information to potential applicants on the objectives and program details of the Translational Research Award Program. The event will be held virtually, and advance registration will be required (<u>Register Here</u>)
- Letter of Intent (LOI) Due Date (June 04, 2024):
 - o LOIs are required prior to being invited to full application submission
 - Applicants should submit an LOI, which will be reviewed by the Foundation and its science advisory board to ensure program fit.
 - Applicants shall submit their Letter of Intent information through the JUMP application portal: (JUMP PORTAL)
 - Please include in the letter of intent:
 - (1) Project Title

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- (2) Research Priority Area
- (3) Project Abstract/Summary (500-word limit)
- (4) Overall Application Description
- (5) Stage of Development
- (6) Key Personnel
- (7) Estimated Budget and Performance Schedule
- (8) Applicant Curriculum Vitae
- (9) Supporting Figures
 - The letter of intent is not to exceed four (4) pages.
- References do not count toward page limit.
- Full Application Invites (August 8, 2024):
 - 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 17, 2024):
 - Application instructions are located on the Foundation website
- **<u>Review of Applications</u>** (October 2024 March 2025):
- Anticipated Award Date (March 2025)