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:** **March 30, 2023**
- **Proposers Day:** **May 12, 2023**
- **Letter of Intent Due Date:** **June 01, 2023**
- **Full Application Invites:** **August 10, 2023**
- **Application Due Date:** **October 05, 2023**
- **Review of Applications:** **October 2023 – March 2024**
- **Anticipated Award Date:** **March 2024**

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 ten (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 disease (IRD) and dry age-related macular degeneration (dAMD). 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 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:
    - 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) 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. Examples of interest areas are as follows, but not limited to:
    - 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, but not limited to:
    - Stem cell therapies
    - Cell Delivery Systems (Combination Products)
    - Retinal Organoids

TRAP Eligibility Criteria

- Proposed TRAP research must meet the following criteria:
    - Projects focused on IRDs 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 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.).
    - 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.

- 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 organization.
  - If you are applying as a company, please directly contact the Senior Director of the Preclinical Translational Research Program (cjackson@fighitngblindness.org). 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.

- 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 (May 12, 2023):
  - One day event that provides information to potential applicants on the objectives and program details of the TRAP. The event will be held virtually, and advance registration will be required (**Registration Link**)
- Letter of Intent Due Date (June 01, 2023):
  - 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.
  - **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
    - (2) Research Priority Area
    - (3) Project Abstract/Summary (500-word limit)
    - (4) Overall Application Description
    - (5) Stage of Development
    - (6) Key Personnel
    - (7) Cost and Schedule of Performance
    - (8) Applicant Curriculum Vitae
    - (9) Supporting Figures
  - The letter of intent is not to exceed four (4) pages.
- Full Application Invites (August 10, 2023):
  - 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 05, 2023):
  - Application instructions are located on the Foundation website
- Review of Applications (October 2023 – March 2024):
- Anticipated Award Date (March 2024)