THE FOUNDATION FIGHTING BLINDNESS

**PROPOSAL PREPARATION INSTRUCTIONS FOR
TRANSLATIONAL RESEARCH ACCELERATION PROGRAM AWARD**

This document provides proposal preparation instructions for the Translational Research Acceleration Program Award for the Foundation Fighting Blindness (THE FOUNDATION) via the online application portal. These instructions follow the sections of the online application portal.

Full Applications for the Translational Research Acceleration Program Awards may be submitted ONLY by those individuals who have submitted a Letter of Intent and have been invited by the FOUNDATION.

GENERAL INFORMATION AND KEY DATES

KEY DATES:
- **Application Due Date:** **October 17, 2024**
- **Review of Applications:** **October 2024 – February 2025**
- **Anticipated Award Date:** **March 2025**

ELIGIBLE INSTITUTIONS AND PRINCIPAL INVESTIGATORS

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. Applicants who are not U.S. citizens and reside and work outside the United States MAY APPLY.

THE FOUNDATION CONTACT FOR INQUIRIES

Direct inquiries regarding the application and review process and required application components and forms to:

Senior Director, Preclinical Translational Research Program
Tel: 404-310-0368, 1-800-683-5555
Email: grants@FightingBlindness.org

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 11:59PM (EST)
OCTOBER 17, 2024.**

How to begin online submission

First create an account on the site's homepage
(https://www.onlineapplicationportal.com/blindness) 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 **11:59 PM EST October 17, 2024**.

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,
   et cetera, 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** <u>each</u> 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. Information on your application status may be found on the Online Application Portal
   home page.

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**CATEGORIES, DURATION, AND LIMITATIONS ON BUDGET REQUESTS AND
ALLOWABLE COSTS FOR AWARD**

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Funding: This program specifically targets preclinically staged programs that hold immense
promise for treating and preventing blindness. **The budget limit for this award is $1 million**

dollars. The Foundation aims to catalyze translational efforts, 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. By supporting these preclinical initiatives, the Foundation strives to illuminate a path toward sight restoration and transform the lives of those affected by vision disorders.

Purchase of capital equipment is generally not supported by the Foundation. Capital 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 to submit an application proposing to purchase equipment. Contact the Foundation's Senior Director, Preclinical Translational Research Program for prior approval. In addition, if approval is granted to submit a request, all such equipment purchase requests must be well justified in the budget section of the application and in the description of proposed project.

Indirect and other costs: The Foundation does not pay any indirect or overhead charges, nor does the Foundation provide support for construction or renovation costs.

ANIMAL, RECOMBINANT DNA AND HUMAN SUBJECT ASSURANCES

THE FOUNDATION, like the National Institutes of Health (NIH), uses the "Just in Time" concept. Applicants may defer, until after completion of peer review and just prior to funding: certification of Institutional Review Board (IRB) and Institutional Biosafety Committee (IBC) approval of the application's proposed use of human subjects and proposed use of recombinant DNA; verification of Institutional Animal Care and Use Committee (IACUC) approval of the proposed use of live vertebrate animals; Health Insurance Portability and Accountability Act (HIPAA) compliance; and, evidence of compliance with the requirement for education in the protection of human research participants.

Evidence of IRB, IACUC, and IBC approval must be documented by submission of a signed THE FOUNDATION Institutional Agreement Form (IAF) at the time of award. If approvals are pending at the time of award, the FOUNDATION funding cannot be expended for research involving human subjects, recombinant DNA, and live vertebrate animals until the signed THE FOUNDATION IAF is submitted to document that the appropriate approvals have been obtained.

REVIEW CRITERIA

The goal of the FOUNDATION Translational Research Acceleration Award Program is to accelerate preclinical translational research focused on preventing, treating, or curing blindness resulting from inherited retinal degenerative diseases and dry age-related macular degeneration toward patient use. Reviewers will evaluate proposals on their (1) Significance, (2) Approach, (3) Innovation, (4) Investigators, and (5) Environment. In their written critiques, reviewers will use the criteria listed below to assess the likelihood that the proposed research will have a substantial impact on the pursuit of this goal. Each of these criteria will be addressed and considered in assigning the overall score (1 [best] through 5 [no interest in funding]), weighting them as appropriate for each application.

1. **Significance**
   a. Does the study address an important problem? Does the study substantially add to existing knowledge and data in the field in a therapeutically relevant manner?
   b. If the aims of the application are achieved, how will scientific knowledge, preclinical or clinical development be advanced?
   c. What will be the effect of the study on the concepts, methods, technologies, treatments, services, or preventive interventions that drive the field?
   d. What is the feasibility/plan to take the proposed studies/treatments to the clinic?
2. **Approach**
   a. Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well-reasoned, well supported by preliminary data, and appropriate to the aims of the project?
   b. Does the applicant acknowledge potential problem areas and provide alternative tactics?
   c. Are the annual timelines realistic and feasible for achieving the specific aims of the proposed project?
3. **Innovation**
   a. Is the proposed research original and innovative? **For example**, does the proposed research project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field?
   b. Does the proposed research project develop or employ novel concepts, methodologies, tools, or technologies for this area?
4. **Investigators**
   a. Are the investigators appropriately trained and well suited to carry out this research?
   b. Is the research proposed appropriate for the experience level of the Principal Investigator and other researchers?
   c. Does the investigative team bring complementary and integrated expertise to the project?
5. **Environment.**
   a. Does the scientific environment in which the research will be done contribute to the probability of success?
   b. Does the proposed study benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?
   c. Are plans for collaborations with other FOUNDATION-supported investigators adequate with respect to sharing methodologies/technologies, animal models, patient assessment tools and results, and both positive and negative findings?

TRANSLATIONAL RESEARCH ACCELERATION PROGRAM AWARD APPLICATION COMPONENTS

APPLICATION FORMATTING 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.)
- Use a 1" margin

- Type density, including characters and spaces, must not exceed **15** characters per inch.
- Type may be no more than **six lines** per inch.
- All page limits specified refer to **single-spaced** format using the above formatting requirements.
  - **ABSTRACT:** up to 1-single-spaced page
  - **SPECIFIC AIMS/RATIONALE:** up to 2 single-spaced pages
  - **PRELIMINARY/SUPPORTING DATA:** up to 2 single-spaced pages
  - **DETAILED PROJECT DESCRIPTION:** up to 9 single-spaced pages
  - **KEY PERSONNEL:** Up to 1 single-spaced page per person
  - **MANAGEMENT PLAN:** Up to 1 single-spaced page
  - **BUDGET and BUDGET JUSTIFICATION:** up to 2 single-spaced pages

APPLICATION FACE PAGE

The application Face Page must be signed by the Principal Investigator and the responsible institutional individual. Prior to submitting the application, print the face page, obtain the appropriate signatures and upload as instructed on the application portal Face Page Upload page.

ABSTRACT (limit: 1 single-spaced page, see Application Formatting Instructions)

Provide an abstract of the proposed research project, written <u>in lay terms</u> for a non-scientific audience. The abstract should contain non-confidential material that can be posted on FOUNDATION's web site if the application is funded.

Include the following:
1. The research question(s) to be investigated and/or will lead an advancement to next stage of preclinical development.
2. The significance of the proposed project in terms of accelerating the advancement of therapeutic and preventive approaches into the clinic, and how the proposed research directly supports the mission of FOUNDATION.
3. A brief lay description of all specific aims, including experimental approach(es), and a listing of all diseases/patient populations to be studied.
4. The expected accomplishments and outcomes for each specific aim.

SPECIFIC AIMS AND RATIONALE (limit: **1-2** single-spaced pages, **see Application Formatting Instructions**)

1. Describe the overall goal(s) and rationale for the proposed project. Numerically list the specific aims and describe the anticipated results to be achieved in <u>each</u> year of the project. **Note** that successful applicants will be required to participate in monthly technical update meetings (with meeting materials [e.g., PowerPoint slides]) and submit Annual Progress Reports that detail accomplishments for each of the specific aim identified in the application.

2. Describe the potential clinical value of the proposed research in terms of developing therapeutic and preventive interventions for inherited orphan retinal degenerative

diseases and dry age-related macular degeneration, including the feasibility of applying the anticipated results to the development of new or improved interventions.

3. Briefly discuss how you envision the Foundation's funding of this proposed research to promote, supplement, or complement future support from the NIH and/or other funding agencies, organizations, private companies, etc.

PRELIMINARY/SUPPORTING DATA (limit: 2 single-spaced pages, see Application Formatting Instructions)

Describe existing experimental data or prior clinical research that support(s) the soundness and feasibility of the proposed experiments. Include evidence of *in vitro* and/or *in vivo* experiments, if applicable, that demonstrate the relevance of the proposed experiments for advancing therapeutic and preventive interventions

DETAILED PROJECT DESCRIPTION (limit: 9 single-spaced pages, see Application Formatting Instructions)

1. **Experimental Plan and Methods: (limit: 5 single-spaced pages, see Application Formatting Instructions)**
   For each specific aim, describe the experimental design, procedures and methods to be used. The level of detail in a NIH investigator-initiated research project Award application is not required by the FOUNDATION. However, applicants must include sufficient information so that reviewers can understand the proposed experiment, its soundness, feasibility and importance for advancing the study of inherited retinal degenerative diseases and dry age-related macular degeneration.

   Applications proposing research using human samples must provide the information delineated below.

NOTE: If IRB approval is not required in order to conduct the proposed clinical study using human samples, then such projects are considered non-clinical and applicants are not required to provide the information/materials listed below.

Clinical Research Requirements:

   A. *Study Description*: A description of the proposed clinical study, including: (a) hypothesis and study objectives; (b) study population(s) and relevance of the proposed study to clinical disease/patient outcome; (c) study design, methodologies, and the scientific rationale, including supporting data from completed basic, preclinical and clinical research, and the feasibility and appropriateness of applying such supporting data to the design and execution of the proposed clinical study; (d) statistical analysis plan; and, (f) plan for receipt and storage of human samples.

   B. *Human Samples*: Documentation of the ability to acquire human samples prospectively or retrospectively, including obtaining samples from planned, ongoing or completed clinical studies/trials sponsored by any source. This should include written agreements between the applicant institution, the clinical trial sponsor, and the

Investigational New Drug (IND) or Investigational Device Exemption (IDE) sponsor, if not one of the above, for the conduct of the proposed study.

    C. *Informed Consent*: A copy of the approved or proposed informed consent form to be used for collection of patient samples (include in Appendix Materials, Reprint Section; does not count against 9-page proposal limit).

2. **Milestones and Timelines:** Delineate key milestones and timelines for the proposed research project. Milestones are intended to define the specific stages and/or steps involved in accomplishing the stated aims, and are to incorporate timelines for the initiation, execution and completion of each specific stage or step. The number of types of milestones will vary depending on the goals and intended outcomes of the proposed research project. This information may be shown in a Gantt chart.

3. **Collaborative Plan:** Include plans for collaboration with other investigators to share research materials, methodologies/technologies, animal models, patient assessment tools and results, and both positive and negative findings.

4. **Future Relevance:** If the aims of the application are achieved, **describe how scientific knowledge or clinical practice will be advanced**. Include a brief discussion on the anticipated effect of the study on the concepts, methods, technologies, treatments, services, or preventive interventions that drive the field of research on inherited retinal degenerative diseases and dry age-related macular degeneration.

5. **Technology Protection and Transition Plan:** During the course of the effort, it is possible that new intellectual property will be generated. Therefore, please provide in detail the plan to protect any intellectual property generated during the funding period. Also, it is a goal of the program to get the research effort to the next stage of development, which often means transitioning (e.g., licensing, newco startup, etc.) technology. Please provide any former, current, or proposed interactions regarding the transition of the proposed technology in this application.

6. **References:** Provide a list of references and abstracts for: (a) publications relevant to the data cited to support the science for the proposed research; and, (b) up to five pertinent reprints representing the applicant's research. Copies of the reprints can be uploaded on the REPRINT page. This information does not count against the page limits for the Detailed Project Description.

KEY PERSONNEL

Each Individual Investigator Research Award Application must be directed by a single Principal Investigator who is responsible for the conduct and management of the project. Co-Investigators are allowed and must be identified.

1. Add all key scientific and technical personnel involved in the proposed project. Designate researchers who are co-investigators.

2. Provide current and pending sources of ALL research support. For each source (federal, private or commercial) provide: title, grant number, percent effort, funding amount, and budget period. This information should include total support for all current and proposed projects.
3. Provide abbreviated CVs (5-page limit) for all key personnel (NIH biosketch is acceptable), listing ONLY RELEVANT publications from the last three years and representative publications prior to that. DO NOT include Abstracts.

MANAGEMENT PLAN (limit: 1 page)

All awarded projects must present a management plan that details the activities of all key scientific and technical personnel involved in the proposed project.

The PI and the Senior Director of the Preclinical Translational Research Program at the Foundation Fighting Blindness will hold monthly progress meetings to:
1. Track the technical progress of the project
2. Reports and briefing material will also be required as appropriate to document progress in accomplishing project metrics and milestones – a PowerPoint template will be provided
3. This meeting will also provide an opportunity to address any program delays or potential rescoping ideas

BUDGET (limit: 1-2 pages)

For each year of support requested, provide a detailed, itemized budget and budget justification for each of the categories listed below.

1. **Personnel:** Listed by name with percent effort, salary, and fringe benefits requested. **Salary Support for the Principal Investigator of up to twenty (20) percent of the total annual budget is permitted. There is no salary cap.**
2. **Supplies:** (Itemized by category, e.g. glassware, molecular biology reagents, not by individual items within the category).
3. **Patient Costs:** (Itemized)
4. **Animal Costs** (Itemized).
5. **Travel Costs (limits):**
- **$2,000** per annum (**U.S**., **Canada**)
- **$2,500** per annum (**Europe**)
- **$3,000** per annum (**e.g. South America**, **Australasia**, **India**, **Japan, China**)
- **$2000** will be added to the budget for travel to the Program's Biennial In-Person meeting.
6. **Other Costs:** (Itemized).

Applicants MUST use the standard FOUNDATION Budget format provided as an Excel template which can be downloaded within the application portal. If you are unable to download the files, contact the FOUNDATION to obtain the form. Applicants are to submit the proposed budget in U.S. dollars.

Note: The FOUNDATION no longer allows an annual 'cost of living' increase.

The budget WILL NOT convert to PDF and therefore WILL NOT be visible to you in the copy of your completed application. THE FOUNDATION will receive the excel file of the submitted budget.

LETTERS OF COLLABORATION

Upload, if appropriate, letters of collaboration for all proposed collaborators (Word or PDF format). There is no limit on letters of collaboration.

REPRINT

Upload up to five pertinent reprints representing the applicant's research individually in PDF format. Upload each reprint as a separate PDF document. Do not combine the reprints into one document.

PRINT & SUBMIT APPLICATION

Before submitting, we suggest you examine the final copy of your application to be certain your responses are complete and accurate. The budget will not convert to PDF and therefore will not be visible to you in the final copy. Unlike the Face Page sections of the application a physical signature is not required when submitting your full application. Follow the instructions listed on the Print &Submit Application page to "sign" and submit your fully reviewed and completed application.