FOUNDATION FIGHTING BLINDNESS
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Foundation Fighting Blindness
Brint Family Translational Research Program
Overview of Funding Opportunity

Request for Applications (Fiscal Year 2026 Cycle)

SUBMISSION AND REVIEW DATES AND TIMES

Request for Applications Release Date	April 25, 2025
Proposers Day	May 12, 2025; 11-12PM ET
Letter of Intent Due Date	June 12, 2025
Full Application Invites	August 18, 2025
Application Due Date	October 16, 2025
Review of Applications	October 2025 – March 2026
Anticipated Award Date	March 2026

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PROGRAM OVERVIEW:

Brint Family Translational Research Program (BFTRP) Funding Opportunity Purpose:
BFTRP is the Foundation's funding initiative aimed at accelerating preclinical translational research for inherited retinal degenerations (IRD) and dry age-related macular degeneration (dAMD). The program provides funding and strategic guidance to advance novel therapies from the laboratory toward clinical application (e.g., follow-on funding, FDA investigational new drug [IND] filing, clinical trials, etc.). By leveraging expert mentorship in drug development, regulatory strategy, intellectual property, and commercialization engagement, the BFTRP seeks to address the complexities and diversity of these retinal diseases, increasing the number of viable treatment options for our community.

Please review this entire document before preparing your full application as the information provided will help you correctly formulate your proposal to meet the requirements of this RFA.

Impact Expectations and Alignment with the Foundation's Mission:
Applicants must ensure that their proposed research project aligns with the Foundation's mission to drive treatments and cures for IRDs and dAMD. Projects should demonstrate a clear path toward clinical utility, with the goal of benefiting the low-vision patient community. The Foundation emphasizes that applicants should prioritize patient needs and consider the potential impact of their research on improving patient outcomes throughout the research process.

The proposal should present an integrative approach to research and develop and efficiently translate laboratory research findings into IND or investigational device exemption (IDE) applications to regulatory agencies for testing new therapeutic approaches.

This program does not solely support basic science, platform technologies, or isolated technology development. Instead, the goal is to generate preclinical data that will support a regulatory application (if applicable), ensuring that each project has a well-defined endpoint of developing a new therapy or device within a three-year timeframe. The steps toward this goal must be clearly delineated through milestones.

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Funding Information:

- The budget limit for this award is $1 million dollars distributed over a 3-year period.
- The Foundation aims to catalyze translational efforts (lead optimization R&D to IND-Enabling Studies) to accelerate discoveries and bring innovative therapies closer to patients. Researchers and institutions are encouraged to submit their applications, emphasizing rigorous scientific merit, feasibility, and potential impact.
- It is anticipated that the Foundation will make between five to seven awards for the FY2026 application cycle.
- The following are the allowable costs that should be reflected in the budget:
  - Personnel
  - Supplies (i.e., chemicals, reagents, tissue culture, etc.)
  - Travel Costs
  - Animal Costs
  - Patient Costs (itemized)
- The following are unallowable costs:
  - Facilities and Administrative Costs (also referred to as Indirect Costs)
  - These costs refer to the indirect costs that are incurred by an organization to support its research activities but are not directly attributable to a specific project.
  - Examples include, but are not limited to, (1) administrative support, (2) building and facility maintenance, (3) library services, (4) general office supplies, (5) institutional support services, (6) depreciation of research equipment and facilities.

NOTE: 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 (email: cjackson@fightingblindness.org). 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.

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PROGRAM OBJECTIVES:

BFTRP Funding Opportunity Goal(s):

1. **Advance Preclinical Research Toward Clinical Translation**: BFTRP supports high-impact translational research that moves promising IRD and dAMD therapies from preclinical discovery through IND-Enabling studies to regulatory engagement, accelerating their path to clinical application.
2. **Develop Next-Generation Gene and Drug-Based Therapies**: The program funds research in gene therapy, RNA-based approaches, small molecules, biologics, cell therapies, and restorative therapeutics (e.g., optogenetics, prosthetics, etc.), to name a few, with an emphasis on improving efficacy, delivery methods, and safety profiles.
3. **Advance IND-Enabling and Clinical Readiness Studies**: BFTRP supports projects that generate preclinical data necessary for regulatory approval, guiding researchers toward, the next developmental step and/or investigational new drug (IND) filings, first-in-human trials, and commercialization.
4. **Overcome Key Translational Barriers in Retinal Disease Research**: By providing strategic funding and expert mentorship, the program helps investigators navigate regulatory challenges, intellectual property considerations, and therapeutic scalability, facilitating real-world impact.
5. **Foster Multidisciplinary Collaboration for Innovation**: Recognizing the complexity of retinal degenerations, the program encourages cross-disciplinary efforts, integrating genetic technologies, regenerative medicine, bioengineering, and artificial intelligence to drive novel therapeutic strategies.

Preclinical Research Stages Eligible for Funding (Must be identified in application)

- **Early Preclinical Research – Lead Optimization**:
  - **Lead Optimization**: Chemical modifications (for small molecules) or vector engineering (for gene therapies) are performed to improve efficacy, safety, and bioavailability of retinal therapy.
  - Early toxicology screenings, assessing off-target effects in cell-based assays and initial small-animal models (e.g., zebrafish, rodents, etc.).
  - Studies that include blood-retinal barrier penetration, drug half-life, and mechanisms of action in disease-relevant pathways (e.g., complement system inhibition in dry AMD).

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- **Mid-Stage Preclinical Research – Proof of Concept in Animal or Acceptable Regulatory Models (e.g., retinal organoids)**:
  - The best-performing therapeutic candidates are evaluated in relevant animal models that mimic human retinal diseases.
  - **Efficacy Studies**: Gene therapies are delivered using AAV, lentivirus, or nanoparticles, and their ability to restore photoreceptor or RPE function is evaluated.
  - Small molecules are assessed for target engagement, disease modification, and biomarker response in retinal degeneration models.
  - Pharmacokinetics (PK) and Pharmacodynamics (PD): Dose-response relationships and retinal distribution are assessed to determine optimal dosing strategies. Studies evaluate the duration of therapeutic effect, including sustained release formulations for topical, intravitreal, subretinal, subchoroidal, etc. injections.
  - **Safety & Early Toxicology**: Off-target effects and toxicity in ocular tissues, as well as systemic exposure, are assessed in animal models.
  - If applicable, immune responses to gene therapy vectors (e.g., AAV neutralizing antibodies) are evaluated.
- **Late-Stage Preclinical Research – IND-Enabling Studies and Regulatory Safety Studies to meet FDA standards**:
  - **GLP-Compliant Toxicology Studies**: Long-term ocular and systemic toxicity studies in two species (typically rodents + non-human primates) to evaluate immune responses, inflammation, and dose-limiting toxicity.
  - Chronic exposure studies assess retinal structure (e.g., via OCT imaging) and functional endpoints (e.g., ERG recordings).
  - **Manufacturing & Scalability**: Good Manufacturing Practice (GMP) production is established for clinical-grade materials, including vector batch production for gene therapies.
  - Drug formulation, stability, and shelf-life studies ensure clinical readiness.
  - **Regulatory Readiness**: Data from pharmacology, toxicology, and efficacy studies.
  - Engagement with FDA, EMA, and other regulatory agencies helps define clinical trial design and endpoints.

If possible, the Foundation highly encourages applicants include a plan to submit or obtain an IND/IDE application, licensing effort, or transition their technology toward clinical implementation within the award period. The specific activities

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appropriate for the BFTRP phase will depend on the therapeutic or device under study and the available preliminary data.

Research Priority Areas: The BFTRP delineates three (3) of the six (6) Foundation research priority areas to guide funding toward preclinical projects with the highest potential to advance the development of treatment of IRDs and dAMD:

- **Genetic Technologies**:
  - **Objective**: To advance the manipulation and modification of gene expression to alter the biological properties of living cells and tissues, with the goal of developing therapeutic solutions for inherited retinal diseases IRDs and dAMD. This funding opportunity seeks to advance viral and non-viral gene delivery systems, improve gene and RNA editing techniques, and develop scalable manufacturing processes that align with regulatory requirements for clinical translation.
  - **Key areas of interest include, but are not limited to**:
    - **Enhancing Gene Therapy Delivery Methods**: Improve and advance delivery strategies by overcoming challenges associated with subretinal, intravitreal, and suprachoroidal injections through the development of clinically-relevant tools and solutions.
    - **Optimizing Retinal Cell Transduction**: Develop and refine tools—such as plasmids with cell type–specific promoters, novel viral capsids, or nanoparticles—that enable efficient and targeted gene delivery to all relevant retinal cell types, while also improving control over gene expression levels.
    - **Delivery of Complex Genetic Constructs**: Implement strategies for delivering large DNA sequences, gene editing tools, mRNA, or proteins to targeted retinal cells.
    - **Advancing RNA Editing Techniques**: Develop and refine RNA editing technologies to provide precise therapeutic modifications for IRDs and dAMD.
    - **Establishing Quantifiable Delivery Metrics**: Define metrics to measure and quantify the efficiency of both viral and non-viral gene delivery, as well as DNA/RNA editing, and demonstrate restoration of retinal function and vision.
    - **Scalable and Affordable Manufacturing Techniques**: Develop cost-effective and scalable manufacturing processes that adhere to regulatory requirements for clinical application.

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- **Exploring Novel Gene Therapy Platforms**: Advance research in plasmid or naked DNA, viral vectors, bacterial vectors, human gene editing technologies, patient-derived cellular gene therapy products, and innovative viral and non-viral gene delivery systems.

Key areas of interest must emphasize the advancement of therapeutic approaches with a clear trajectory toward clinical application. Proposals that focus solely on research without a defined plan for clinical relevance or therapeutic translation will be less competitive during the review process.

- **<u>Novel Medical Therapies</u>**:
  - **Objective**: The primary goal of this research priority area is to advance the development of therapies that enhance or retain retinal function and structure by optimizing drug efficacy, improving targeted delivery, and minimizing toxicity. Therapeutic categories include (1) Small Molecules, (2) Biologics, and (3) Alternative Therapies (research that falls outside of the stated research priority areas).
  - **Key areas of interest include, but are not limited to**:
    - **Enhancing Retinal Cellular Metabolism & Neuroprotection**: Advance therapies that enhance cellular metabolism in the diseased retina and demonstrating neuroprotective effects and/or stabilization or restoration of retinal function.
    - **Overcoming Challenges in Therapy Development for Complex Genetic IRDs**: Address barriers in developing therapies for genetically complex IRDs, including optimizing delivery systems to enhance efficacy and reduce retinal toxicity.
    - **Gut Microbiome as a Therapeutic Target**: Develop and evaluate therapeutic interventions that modulate the gut microbiome to alter the progression of IRDs and dAMD. Proposed strategies may include the use of antibiotics, defined bacterial consortia, or fecal microbiota transplantation. Projects should prioritize translational approaches with clear therapeutic endpoints and may explore systemic, immune, or metabolic pathways through which the gut microbiome influences ocular health and disease.
    - **Non-Drug Therapeutic Approaches**: Advance alternative therapeutic strategies, such as red-light therapy, for IRDs and dAMD.

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- **Non-Invasive Drug Delivery Modalities**: Advance non-invasive drug delivery systems (e.g., topical or systemic administration) that are particularly effective in early-stage disease intervention.

Key areas of interest must emphasize the advancement of therapeutic approaches with a clear trajectory toward clinical application. Proposals that focus solely on research without a defined plan for clinical relevance or therapeutic translation will be less competitive during the review process.

- **Restorative Therapies** (includes cell-based approaches, visual prosthetics and optogenetics):
  - **Objective**: To advance the development, regeneration, and application of human cells, tissues, and cellular/tissue-based products to restore retinal function and vision. The goal of this funding opportunity is to advance strategies that rescue or replace degenerating or dead retinal cells, optimize visual prostheses, and develop optogenetic approaches that confer light sensitivity to neuronal cells in the absence of functional photoreceptors.
  - **Key areas of interest include, but are not limited to**:
    - **Cell Transplantation Optimization**: Identify optimal preparation and purification methods for donor tissue, enhance cell survival and function post-transplantation, and establish effective immune suppression regimens.
    - **Endogenous retinal regeneration and/or reprogramming**: Develop and advance therapeutic strategies that activate or enhance the eye's intrinsic capacity to repair or regenerate retinal cells affected by IRDs and dAMD. Approaches may include reprogramming of resident retinal cells, stimulation of Müller glia or other endogenous cell types, or modulation of signaling pathways to promote cell survival, repair, or regeneration.
    - **Biomaterials & Transplant Integration**: Biomaterials transplantation of donor retinal pigment epithelium (RPE) and photoreceptors post-transplantation and evaluate the transplant survival and retinal function restoration.
    - **Optogenetic Approaches for Vision Restoration**: Identify and target the most effective retinal cells for optogenetic interventions that restore vision.

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- **Visual Prostheses Development & Integration**: Advance the design and application of visual prostheses that interact effectively with remaining retinal cells and neural circuitry to restore vision.
- **Stem Cell Therapies & Retinal Organoids**: Develop and apply stem cell-based approaches, retinal organoids, and innovative cell delivery systems (combination products) to enhance retinal repair and function.

Key areas of interest must emphasize the advancement of therapeutic approaches with a clear trajectory toward clinical application. Proposals that focus solely on research without a defined plan for clinical relevance or therapeutic translation will be less competitive during the review process.

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.

Examples of previously funding preclinical translational awards are listed here:

- Foundation Funded Grants FY2024

Application Process Overview:

- Announcement of the Funding Opportunity: The process begins with the publication of a Request for Applications (RFA) to solicit proposals for specific

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scientific research areas aligned with the Foundation's mission. This RFA details the objectives, eligibility criteria, submission guidelines, and evaluation criteria. The Foundation strives to inform all relevant stakeholders and potential applicants of this funding opportunity.

- Submission of Letter of Intent (LOI): **Applicants are required to submit a LOI by a specified deadline (June 12, 2025)**. The LOI serves as an initial proposal overview and allows the Foundation to assess whether the proposed research aligns with the Foundation's mission and priorities. This step is required in order to be invited to submit a full application.
- Screening and Evaluation of LOIs: Upon receiving the LOIs, the Foundation's Scientific Advisory Board evaluates each submission. Applicants are notified if their application will move forward in the application cycle, and **top-scoring applicants are invited to submit a full application (Due Date: August 18, 2025).** This invitation is based on the LOI's scientific merit, feasibility, and alignment of the project with the Foundation's priorities.
- Submission of Full Application (**Due Date: October 16, 2025**): Invited applicants must submit a full, detailed application that expands on the information provided in the LOI. This includes a comprehensive research plan, detailed budget, timeline, and additional supporting materials such as biosketches, letters of support, and institutional endorsements.
- Comprehensive Review of Full Applications: The full applications are then subjected to a more in-depth evaluation process by the Foundation's Science Advisory Board. Three research priority area committees review the applications: (1) Novel Medical Therapy, (2) Genetic Technologies, and (3) Restorative Therapies.
- Funding Decision: The final funding decision is made by the Foundation's Executive Science Advisory Board and Board of Directors informed by the committee's review. A formal award notification is issued to the successful applicants, and funding agreements are negotiated and finalized.

Through this process, the Foundation ensures that only the most competitive and relevant research and development plans receive funding, and that each research project has the potential to make a meaningful impact in advancing scientific understanding or clinical solutions for IRD and dAMD therapeutics.

A Proposer's Day will be held on May 12, 2025, from 11-12PM ET, via ZOOM to review the program and answer questions (Register Here).

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Email questions to the Senior Director, Preclinical Translational Research Program at cjackson@fightingblindness.org.

Eligibility Criteria

- **Proposed BFTRP research must meet the following criteria**:
  - Proposals exploring therapeutic solutions for IRDs should focus on retinal degenerations with clear genetic disease drivers (e.g., ABCA4 disease) and/or take an agnostic approach to addressing IRDs.
  - The applicant **MUST** identify one of the three 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 include as a part of the Novel Medical Therapies and 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 for clinical use.
  - 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 (FDA, EMA, etc.) filing.
  - Applicants should demonstrate how their technology will potentially work in the clinic. Also, include statement on marketplace impact as compared to current practices. Consider including a Target Product Profile table to highlight.
  - Applicants should provide an intellectual property (IP) and/or protection strategy for their technology.

- **BFTRP 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.

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- 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 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 the proposal, and if applicable, a proposed cost sharing agreement. NOTE: If working with a CRO, please consider addressing the following:
  - Project Management: Determine whether the project manager will be an internal team member or provided by the CRO. A dedicated project manager enhances communication and oversight, ensuring project milestones are met.
  - Data Management: Clarify how data accuracy, confidentiality, and security will be maintained. Ensure the CRO has robust data management systems and a history of compliance with data handling standards.
  - Contractual Agreements: Negotiate contracts that include clear milestones, confidentiality clauses, and payment terms. Consider structures where the CRO shares some project risks, aligning their incentives with project success.
  - Vendor Qualification: Provide cost estimates from potential CROs/Contract Manufacturing Organizations (CMOs) during the application process. Post-selection verifies these estimates and assesses the CRO's qualifications to ensure they meet regulatory requirements and have relevant experience.
  - Regulatory Compliance: If considering international CROs/CMOs, ensure they comply with U.S. State Department regulations and NIH

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policies. Be aware that using international vendors may require additional clearances and could delay project initiation.

Letter of Intent Guidelines

- The Letter of Intent is required prior to being invited to submit a full application.
- Only two (2) LOIs can be submitted per person, laboratory, company.
- Applicants shall submit their LOI information through the JUMP application portal: (https://www.onlineapplicationportal.com/blindness)
- LOI Due Date: June 12, 2025 (Close of Business, Eastern Standard Time).
- Please include in the LOI submission:
  - Project Title
  - Identify Research Priority Area (1. Genetic Technologies; 2. Novel Medical Therapies; 3. Restorative Therapeutics – Must Select One)
  - Project Abstract/Summary (600-word limit): It is recommended that the specific aims are listed, and rationale stated. Use the Overall Application Description section below to elaborate on the research plan and scientific approach.
  - Overall Application Description (1200-word limit):
    - Describe the research plan.
    - Include a brief statement that describes the research project's preclinical stage of development (e.g., Early Preclinical; 2. Mid-Stage Preclinical; 3. Late Stage Preclinical – the definitions of each stage can be found on pages 4 and 5 of this RFA).
    - Applicants MUST include a clear statement outlining the key scientific milestones that will define success for the proposed project. In addition, please describe the logical next steps for the research or technology if this funding results in positive outcomes. This should include potential follow-on funding sources that may be pursued to advance the future therapeutic.
    - We also encourage applicants to provide a forward-looking roadmap that outlines the regulatory and commercialization pathway, if applicable. This may include steps such as Investigational New Drug (IND) application planning, regulatory consultations, clinical trial readiness, or strategies for partnering and market entry.
    - Discuss the potential project challenges and risk mitigation strategies.

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  - Summarize the potential translational impact (e.g., how this leads to a therapy for IRD or dry AMD).
  - If supporting figures and references are to be included as an appendix, a maximum of 3 figures or tables can be uploaded separately to the Figures Upload page. Include Reference list in this field (please keep as brief as possible).
  - Names of Key Personnel, Collaborators, and Institutions
  - Cost and Timeline (budget categories are outlined in the Resource Download section: Application Instructions – Brint Family Translational Research Program Award).
  - Principal Investigator's Curriculum Vitae

- **LOI 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 limits specified refer to single-spaced format using the above formatting requirements.

- **LOI Due Date**: June 12, 2025 (Close of Business, Eastern Standard Time).

Full Application Guidelines

All applications must have been invited to submit full applications. Full applications must be submitted online. If attachments are required, they also must be submitted through the application portal.

NOTE: The complete full application must be SUBMITTED by 11:59PM (EST) OCTOBER 16, 2025, or will not be included in the application review cycle.

How to begin online submission:

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- First create an account on the site's homepage (blindness@onlineapplicationportal.com) 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 application in-progress as many times as you wish until it has been submitted. To be considered for the award, your online application must be complete and in SUBMITTED status no later than 11:59 PM EST October 16, 2025.
- How to enter information:
  - You may begin completing the application in any section. To begin, choose a section of the application from the left menu or click "Continue" at the bottom of the screen.
  - Text boxes will allow the allotted amount of text as specified in the submission instructions. 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.
  - 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.
  - 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.
- How to SAVE and SUBMIT your data:
  - 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.
  - 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.
  - If for some reason you need to make changes after your application is submitted, email blindness@onlineapplicationportal.com.
  - Information on your application status may be found on the Online Application Portal home page.

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- **BFTRP Application Components**:
  - 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 (Includes Experimental Plan and Methods): 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 Face Page of the application must be signed by both the Principal Investigator and an authorized institutional official who is legally permitted to sign on behalf of the applicant institution. Before submitting the application, applicants must print the completed Face Page, obtain the required signatures, and upload the signed document to the designated Face Page Upload section of the application portal. Applications submitted without the appropriate signatures will be considered incomplete.
- **Abstract** (limit: 1 single-spaced page, see Application Formatting Instructions)
  - Provide an abstract of the proposed research project, written in lay terms 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 in the abstract**:
      - The research question(s) to be investigated and/or will lead an advancement to the next stage of preclinical development.
      - The significance of the proposed project in terms of accelerating the advancement of therapeutic and preventive approaches for IRDs and dAMD into the clinic, and how the proposed research directly supports the mission of the Foundation.

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  - A brief lay description of all specific aims, including experimental approaches, and a listing of all diseases/patient populations to be studied.
  - The expected accomplishments and outcomes for each specific aim.
- **Specific Aims and Rationale** (limit: 1-2 single-spaced pages, see Application Guidelines and Components):
  - 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 each 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 aims identified in the application.
  - Describe the potential clinical value of the proposed research in terms of developing therapeutic and preventive interventions for IRDs and dAMD, including the feasibility of applying the anticipated results to the development of new or improved interventions.
  - 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 and Supporting Data** (limit: 2 single-spaced pages, see Application Guidelines and Components):
  - 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 Guidelines and Components):
  - Experimental Plan and Methods: (limit: 5 single-spaced pages, see Application Guidelines and Components)
    - 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,

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feasibility, and importance for advancing a therapeutic strategy for IRDs and dAMD.
    - Applications proposing research using human samples must provide the information delineated below.
    - **NOTE**: If IRB approval is not required 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 (if applicable)**:
            - **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.
            - **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.
            - **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).
- **Milestones and Timelines**: A clear delineation of *SMART* milestones (Specific, Measurable, Achievable, Relevant, and Time-bound) is a critical aspect of this program.
    - Each application must propose a well-defined series of milestones, including key experiments, manufacturing (if applicable) and product development objectives. Applicants are strongly encouraged to include

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contingency plans to proactively address potential delays in meeting these milestones.
    - Prior to awarding funding, program staff will collaborate with the applicant to refine and finalize the proposed milestones. These agreed-upon milestones will be incorporated into the terms and conditions of the award and will serve as the basis for evaluating project progress.
    - Please consider using a Gnatt chart when formulating this information for the application.
- **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.
- **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.
- **Technology Protection and Transition Plan**: During the project, it is possible that new intellectual property (IP) may be developed. Applicants must provide a detailed plan outlining how any IP generated during the funding period will be protected. In addition, one of the goals of this program is to advance research to the next stage of development, which may include technology transition activities such as licensing, forming a startup (newco), or other commercialization efforts. Please describe any past, current, or planned efforts related to the transition or commercialization of the proposed technology included in this application.
- **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.

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  - Add all key scientific and technical personnel involved in the proposed project. Designate researchers who are co-investigators.
  - Provide current and pending sources of ALL research support. For each source (federal, private, or commercial) provide (a) title, (b) grant number, (c) percent effort, (d) funding amount, and (e) budget period. This information should include total support for all current and proposed projects.
  - 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:
  - Track the technical progress of the project.
  - 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.
  - 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:
  - 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.
  - Supplies: (Itemized by category, e.g., glassware, molecular biology reagents, not by individual items within the category).
  - Patient Costs: (Itemized)
  - Animal Costs: (Itemized)
  - 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.
  - Other Costs: (Itemized).

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  - Applicants MUST use the standard Foundation Budget format provided as an Excel template which can be downloaded within the application portal or on the BFTRP website (LINK). 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**: As previously stated, the Foundation Fighting Blindness does not provide support for indirect costs associated with scientific research projects. Only direct project costs are eligible for funding.
- **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.
- **Reprints**: 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.

Review Process and Evaluation Criteria

Review Process: The Foundation's science team and Scientific Advisory Board will review the Letter of Intent. The reviewers will be grading the LOIs on the research's (1) significance, (2) approach, (3) innovation, (4) investigators, and (5) environment. If found adequate for the award program and addresses the criteria listed above, the applicant will be invited to submit a full application. The email will contain the application and guidance.

The Foundation Fighting Blindness is committed to a rigorous and impartial scientific review process, ensuring that funding decisions are based solely on scientific merit, feasibility, and potential impact. We actively work to mitigate bias related to race, ethnicity, gender, institutional affiliation, geographic location, and career stage. Our review panels are composed of diverse experts who evaluate proposals based on objective criteria, fostering an equitable and inclusive

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selection process that prioritizes the advancement of innovative therapies for IRDs and dAMD.

Structure:

This program will utilize a milestone-driven BFTRP mechanism. Applicants are strongly encouraged, if funded and in collaboration with the Foundation, to implement project management principles to facilitate milestone achievement and ensure translational success.

Non-Responsiveness Criteria

- The following types of applications will be considered non-responsive and will be withdrawn prior to review:
  - Applications that do not align with the mission and strategic priorities of the Foundation Fighting Blindness
  - Applications that do not propose milestone-driven BFTRP research objectives.
  - Applications focused solely on basic research or technology development without a clear translational goal.
  - Applications proposing development of general research infrastructure.
  - Clinical trial applications, including:
    - Phase I (first-in-human) trials
    - Multi-site clinical trials
    - Basic Experimental Studies in Humans (BESH)

Additional Resources:

- 2024 Proposers Day Recording: https://www.youtube.com/watch?v=a0gmpoffJYs
- Brint Family Translational Research Award website: https://www.fightingblindness.org/translational-research

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APPENDICES:

Foundation Fighting Blindness Mission:

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The mission of the Foundation Fighting Blindness (Foundation) is to drive research toward 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.

About the Brint Family Translational Research Program:
David and Betsy Brint became passionate volunteers and supporters of the Foundation Fighting Blindness shortly after their son, Alan, was born blind from Leber congenital amaurosis. David became a Foundation National Trustee in 2000 and a Board Director in 2004. He served as the Foundation's Board Chair from 2016 to 2024. David has always taken a strong interest in understanding and communicating the complex science of retinal diseases and related emerging therapies.

David and Betsy Brint also co-founded the Foundation for Retinal Research, an organization that merged with the Foundation Fighting Blindness in 2016, significantly contributing to the Foundation's mission and maximizing the impact on the rapidly advancing effort to cure blindness caused by retinal degenerative diseases.

Choosing the Right Animal Models:
Selecting an appropriate animal model is a critical step in preclinical research for IRDs and dAMD. The right model ensures that the biological mechanisms under investigation accurately reflect the human condition, increasing the likelihood that therapeutic interventions will translate effectively to clinical settings. Inadequate, poorly matched, and/or unsubstantiated models can lead to misleading results, wasted resources, and, delays in bringing treatments to patients. Furthermore, regulatory agencies like the FDA increasingly expect preclinical data to be generated using models with established relevance to human disease. Thoughtful model selection strengthens the scientific rigor of a project, supports meaningful outcome measures, and improves the likelihood of regulatory acceptance and downstream clinical success.

<u>Please consider the following guidance when selecting a model for research</u>:

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- **Alignment with Human Pathology:** Choose models that closely replicate the human disease's key features, such as drusen formation, RPE atrophy, and photoreceptor degeneration.
- **Regulatory Acceptance:** Utilize models that have been previously employed in studies leading to FDA-approved therapies, ensuring a smoother translational pathway.
- **Genetic Relevance:** For IRDs, select models with genetic mutations analogous to those found in human conditions, enhancing the relevance of findings.
- **Model Limitations:** Be aware of each model's limitations, such as differences in ocular anatomy between species, which may affect the extrapolation of results.
- **Ethical Considerations:** Ensure that the use of animal models complies with ethical guidelines and justifies the scientific benefits derived from the research.

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