THE FOUNDATION FIGHTING BLINDNESS

INSTRUCTIONS FOR THE PREPARATION OF
CAREER DEVELOPMENT AWARD APPLICATIONS

This document provides instructions for the preparation of Career Development Award applications to the Foundation Fighting Blindness (FFB) via the online application portal. These instructions follow the sections of the online application portal.

GENERAL INFORMATION AND KEY DATES

KEY DATES:

Application Receipt Date: February 1, 2024
Review of Applications: February – March 2024
Earliest Anticipated Award Date: August 2024

ELIGIBLE INSTITUTIONS AND PRINCIPAL INVESTIGATORS

Clinician-scientists possessing an M.D., D.O., O.D. or recognized equivalent foreign degree and who are in their first, second, or third year of a junior faculty appointment are eligible to apply for a CDA. Applicants do not have to be U.S. citizens. **Application is not limited to the U.S. or U.S. citizens. Applicants who are not U.S. citizens and reside and work outside the U.S. may apply.**

FFB CONTACT FOR INQUIRIES

Direct inquiries regarding the application and review process and required application components and forms to grants@FightingBlindness.org

DURATION OF AWARD AND LIMITATIONS ON BUDGET REQUESTS AND ALLOWABLE COSTS

In general, each five-year award will be for a total of $375,000, received as five

annual payments of $75,000. Budgets can be tailored to address the situations of individual recipients. Applicants funded from other sources are eligible to apply. The source and nature of this funding must be disclosed to FFB at the time of application. The CDA may be used for partial support of the candidate's salary, postdoctoral and/or technical staff salaries and research supplies. No indirect costs are paid

ANIMAL, RECOMBINANT DNA AND HUMAN SUBJECT ASSURANCES

FFB, 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 FFB Institutional Agreement Form (IAF) at the time of award. If approvals are pending at the time of award, the FFB funding cannot be expended for research involving human subjects, recombinant DNA, and live vertebrate animals until the signed FFB IAF is submitted to document that the appropriate approvals have been obtained.

REVIEW CRITERIA

The Foundation Fighting Blindness (FFB) is soliciting applications for Career Development Awards (CDA) from clinical research scientists of superior dedication and talent. The award is for junior investigators to pursue vigorous research programs to drive the research to find the therapies and cures for retinal degenerative diseases (RDDs), i.e., inherited orphan retinal degenerative diseases and non-exudative age-related macular degeneration. The goal of this Program is to facilitate advances in laboratory and clinical research, to elucidate the mechanisms for the etiology and pathogenesis of RDDs and to develop innovative strategies to prevent, treat and cure these diseases.

Since the purpose of the program is to "jump-start" the careers of highly qualified junior investigators, the candidates will undergo a careful selection process. Consideration for funding will be determined by the Executive Scientific Advisory Board (ESAB) of FFB and applications will be reviewed for scientific and technical merit. However, the ESAB will also take into consideration other factors such as programmatic needs, balance and the support from an applicant's mentor(s) and institution. Selected applicants will be invited for an interview to discuss application materials and plans for the award and the future. The interview will occur virtually or in person at ARVO, schedule permitting.

As indicated above, the goal of this award is to support the career development of clinician-scientists in the field of retinal degenerations. Recipients of these awards must be clinicians who currently care for patients with RDDs. In addition, they should develop independent research programs directed toward providing therapies for RDDs. Research programs can be clinical or laboratory-based and must address one (or more) of the six designated FFB Priority Research Program Areas that are listed and described below:

Therapeutic Approaches

Gene Therapy (GT)
Develop and optimize viral and/or non-viral gene delivery systems for the treatment of dominant, recessive and X-linked retinal degenerative diseases. Demonstrate efficacy and safety using pre-clinical models in preparation for human clinical trials. **Gene-specific therapies are not eligible for funding support.**

Regenerative Medicine (RM)
Develop strategies that provide functional rescue or replacement of degenerating or dead retinal cells that can lead to the slowing and prevention of vision loss, or the restoration of lost vision.

Novel Medical Therapies (NMT)
Develop drug therapies that retain retinal function and structure in retinal degenerative diseases. This includes the creation and development of improved animal models of human disease, better functional testing of drug effectiveness, and novel drug delivery systems.

Basic Research

Genetics (GE)
Identify disease-causing mutations in inherited retinal disorders, in part by integrating comprehensive genetic testing into routine clinical care. Identify inherited risk factors for age-related macular degeneration (AMD) and the relative contributions of associated genetic and non-genetic factors (e.g. lifestyle), sufficient to incorporate into treatment and preventions.

Cell and Molecular Mechanisms of Disease (CMM)
Basic research that improves our understanding of the nature and cause of disease in inherited retinal degenerations so that improved therapies for the prevention of vision loss can be developed.

Clinical Research

Clinical: Structure and Function (CL)
Clinical research that develops improved technology and standardizes processes to establish relationships between clinical retina function and retina structure in retinal degenerative diseases and enables early disease detection. N.B.: Applicants should select the appropriate therapeutic research category, e.g., RM, GT, NMT, for research proposals that focus on therapeutic intervention strategies.

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.
  - **CANDIDATE STATEMENT**: up to 2 pages
  - **ABSTRACT:** up to 1-single-spaced page
  - **DETAILED PROJECT DESCRIPTION**
    - **Mentor's Proposal for Training:** up to 5 pages

- **Applicant's Research Proposal:** up to 6 pages (excluding references)
  - **Specific Aims:** up to 1 page
  - **Research Strategy:** up to 5 pages
  - **Appendix:** no page limit
  - **CV'S AND BIOSKETCHES:**
  - **LETTERS OF SUPPORT**
  - **BUDGET and BUDGET JUSTIFICATION:** up to 2 pages

APPLICATION SUBMISSION INSTRUCTIONS

All applications must be submitted online. Attachments are required and must be submitted through the application portal.

NOTE: The complete application must be SUBMITTED by 2/1/2024.

Online submission

First create an account on the site's homepage by selecting "Applicant Registration-start here" underneath the FFB 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 **2/1/2024 11:59 pm EST**.

How to enter information:
- 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.
- 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.**
- 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 <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.
- 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**.
- 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.
- Your application status must appear as SUBMITTED **by 2/1/2024 11:59 p.m. EST** in order for your application to be considered. Information on your application status may be found on the Online Application Portal home page.

CAREER DEVELOPMENT AWARD APPLICATION COMPONENTS

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.

CANDIDATE STATEMENT
(limit: 2 single-spaced page, see Application Formatting Instructions)

The candidate statement should outline the applicant's long-term vision and goals in the field of clinical career investigation and their future commitment to clinical/patient research. CDA applicants should list and describe no more than

three of their most important scientific/clinical accomplishments deemed most relevant to this award and its purpose.

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 FFB's web site if the application is funded.

Include the following:
- The research question(s) to be investigated.
- 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 FFB.
- A **brief lay** description of **all specific aims**, including experimental approach (es), and a listing of all diseases/patient populations to be studied.
- The expected accomplishments and outcomes for each specific aim.

DETAILED PROJECT DESCRIPTION
(limit: **11** single-spaced pages, see Application Formatting Instructions)

Mentor(s)' Proposal for Training (In Addition to Mentor's Letter)
(5 Pages Max)
Must include a plan for how the mentor(s) will ensure the development of the candidate into an independent clinician-researcher. The mentor(s) must state the number of hours he/she will commit to the investigator's training each week. This part of the proposal should also describe any formal courses and training programs developed and offered by the sponsoring institution for the training of clinical investigators that would be included in the applicant's curriculum.
Applicant's Research Proposal
(6 Pages Max, excluding references)
The level of detail in a NIH investigator-initiated research project grant application is not required by the FFB. However, the research proposal, including references, should concisely outline the aim(s) of the proposed research project(s), the significance of the research goals, the plan of research proposed and the experimental designs, strategies and methods to be used in

the conduct of the research. This should also include, where applicable, biostatistical methods used for design and analysis.

The following format is suggested for the Detailed Project Description:

- Specific Aims (Page Limit:1 page)
- Research Strategy. (Page Limit: 5 pages)
    - Significance
    - Approach (including Preliminary Studies): For each specific aim, describe the experimental design, strategies and methods to be used in the conduct of the research. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work. Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. Include any courses that you plan to take to support the research training experience.

The following items should be included in an Appendix (not included in the page limit, include in Research Proposal pdf):

- Additional figures
- Institutional Review Board (IRB) approvals, if required (do not include protocols)
- A biohazard/safety statement if applicable

CV'S AND BIOSKETCHES
(limit: 5 pages per CV)

Candidate Biosketch/CV
(Page Limit: 5 Pages)
This should include education and training information, research and professional experience, and <u>a complete bibliography (or a bibliography of recent publications for CRFA applicants)</u>. The bibliography should be annotated to explain the applicant's role in the work reported in each paper. Comments should be limited to one sentence for each publication. A 5-page NIH biosketch format is also acceptable.

Mentor/Supervisor Biosketch/CV
(Page Limit: 5 Pages per Biosketch)

This should include a biographical sketch and bibliography of recent publications (not to exceed two pages). A list of pending and current funding should be included . A 5-page NIH biosketch format is also acceptable

Project Collaborators Biosketch/CVs

(Page Limit: 5 Pages per Biosketch)

The application must provide CVs for the candidate and for any proposed research project collaborators. Limit CVs to 5 pages (NIH Biosketch is also acceptable,) include qualifications, expertise and experience relevant to training of M.D.s and M.D./Ph.D.s in general and with respect to clinical research related to inherited orphan retinal generative diseases, and include qualifications, expertise and experience relevant to the proposed research project.

LETTERS OF SUPPORT

Chair/Dept. Head
Letter from Chair/Head of Department(s)

A letter from the head/chair of the department(s) in which the applicant is appointed should confirm the department's willingness to support the candidate's research efforts and guarantee a significant amount of protected time for research required to fulfill the terms of the award.
This appointment should not be contingent upon the applicant securing funding.

Letter from Mentor

The Mentor(s) should evaluate the applicant's qualifications for the proposed research project and assess their potential for successful independent research. The mentor(s) must guarantee that the awardee is under no obligation to any industrial ties or obligations the mentor may have.

LETTERS OF REFERENCE

These should include letters from qualified sources that can assess the applicant's professional experience in: medical school, residency program and/or fellowship training periods. The quality and depth of these letters will be pivotal in deciding the candidate's suitability.

Three (3) letters of reference addressing the capabilities and potential of the candidate for a **career in clinical research on inherited orphan retinal degenerative diseases**.

Three letters of recommendation should be submitted by their authors through the online portal. It is the applicant's responsibility to secure a commitment from each person who will write a recommendation.

Instructions for Requesting a Recommendation:
- Please select the "Request a Recommendation" button and complete the required information in the window that opens.
- After you have entered the necessary information, select the "Send E-mail to Recommender" button.
- An e-mail request will be sent to the recommender with instructions on how to complete the online recommendation form.
- After sending the requests, the recommender's name will appear in the Recommender box below, with the "Status" of the letter itself.
- Please Note: You must enter your recommenders into the system from the page before they can log into the Online Reference Portal. Please do not ask them to access the system until you have done this.

BUDGET (limit: **1-2** pages)

Applicants MUST use the standard FFB Budget format provided as an **Excel template** in the Career Development Award Application Package which can be downloaded within the application portal [below]. If you are unable to download the files, contact the FFB to obtain the form. Applicants are to submit the proposed budget in U.S. dollars.

BUDGET TEMPLATE
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.
- **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**)
- **Other Costs:** (Itemized).

BUDGET SUMMARY
(Page Limit: 1 Page)

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

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.