



## **THE FOUNDATION FIGHTING BLINDNESS**

### **INSTRUCTIONS FOR THE PREPARATION OF DIANA DAVIS SPENCER CLINICAL RESEARCH FELLOWSHIP AWARD APPLICATIONS**

This document provides instructions for the preparation of Diana Davis Spencer Clinical Research Fellowship Award (DDS CRFA) applications to the Foundation Fighting Blindness (the Foundation) via the online application portal. These instructions follow the sections of the online application portal.

#### **GENERAL INFORMATION AND KEY DATES**

**New Applications Accepted Fall 2021**  
**Application Due Date: October 21, 2021**  
**Notification Date: December 2021**  
**Earliest Start Date: June 2022**

The Foundation Fighting Blindness (the Foundation) is soliciting applications for Diana Davis Spencer Clinical/Research Fellowship Awards (DDS CRFA) from clinicians with a demonstrated interest in inherited orphan retinal degenerations. The program will provide funding for post-residency clinical fellowships in inherited orphan retinal degenerations. The goal of this program is to increase the number of clinician- scientists with expertise and commitment to provide clinical care to patients with inherited orphan retinal degenerations. With this goal in mind, the program is also designed to prepare fellows for careers in academic medicine, providing critical training in an environment that fosters research to develop preventions, treatments, and cures for inherited orphan retinal degenerations.

Since the focus of the program is to promote the emerging careers of newly trained, highly qualified specialists in the retinal degenerative diseases field, the candidates will undergo a careful selection process. Applications will be reviewed for their merit based on the criteria described below by the Foundation's Scientific Advisory Board. Selected applicants will be invited for

an interview to primarily discuss application materials and plans for the fellowship and the future.

## **ELIGIBLE INSTITUTIONS AND PRINCIPAL INVESTIGATORS**

Clinicians who possess an **M.D., D.O.**, or recognized **equivalent foreign degree** by the time the fellowship starts and will be eligible for subspecialty board certification at the completion of their training program are eligible to apply for a DDS CRFA.

- Ophthalmology residents or fellows with an interest in inherited orphan retinal degenerations could apply for both a fellowship position and a DDS CRFA in the final year of their residency program.
- Ophthalmology residents or fellows with an interest in inherited orphan retinal degenerations could apply for a DDS CRFA the year before applying for the fellowship position itself, allowing the applicant and institution to know about funding prior to the fellowship application.

Applications may be submitted on behalf of candidates by domestic and foreign, public and private, academic institutions, as well as hospitals and laboratories affiliated with such institutions. *In all cases, collaboration between the applicant and the fellowship mentor will be required to develop the application. If the candidate's situation is unique from what has been described here, applicants should contact the VP, Science and Awards Programs; the Foundation will work with individual applicants to address their personal situations.* Application instructions are below.

### **Sponsoring Institution Requirements**

The training environment for proposed DDS CRFAs will also be evaluated as part of the application process. Sponsoring institutions should provide formal endorsement from the Program Medical Director of the clinical setting with which the nominee will be affiliated for the duration of the DDS CRFA award. This endorsement should document a commitment to the proposed research training program's goals and provide assurance that the institution intends the program to be an integral part of its research and research training endeavor. The application should include a description of support (financial or otherwise) to be provided for the program, which could include, for example, space, shared laboratory facilities and equipment, funds for curriculum development, release time for both the Program Medical Director and participating faculty. While it is not required that the fellowship program be listed with the SF Match, it is desirable that it is in compliance with the Association of University

Professors of Ophthalmology Fellowship Compliance Committee (AUPO FCC).

### **The Mentor's Role**

As these fellowships are designed to provide advanced clinical training in the care of patients with inherited orphan retinal degenerations, identification of an appropriate mentor or mentors is essential. In addition, DDS CRFAs must include a significant clinical or basic research component. Ideal mentors should therefore be clinicians/clinician-scientists/scientists who have an established clinical practice in inherited orphan retinal degenerations and an established research program. Scientists with an established research program can serve as a co-mentor with a practicing clinician. Mentoring for the clinical and research components of the fellowship can be provided by a single individual or a team of mentors.

### **FFB CONTACT FOR INQUIRIES**

Direct inquiries regarding the application and review process and required application components and forms to [grants@FightingBlindness.org](mailto:grants@FightingBlindness.org)

### **DURATION OF AWARD AND LIMITATIONS ON BUDGET REQUESTS AND ALLOWABLE COSTS**

Up to **three** awards are available. In general, each one-year award will be for a total of **\$65,000**. 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 should be disclosed to the Foundation at the time of application. The DDS CRFA may be used for costs related to fellowship training, including stipend and fringe benefits.

**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**

### **Research and Clinical Training Components**

Award recipients must carry out a clinically focused research project and a clinical training program with didactic and other forms of training tailored to meet the individual needs of the award recipient. Research projects and clinical training activities must focus on inherited orphan retinal degenerative diseases. Support will not be provided for research and clinical training relating to dry or wet age-related macular degeneration (AMD), retinal detachment, or vitreoretinal surgery.

### **Research Project:**

The research project must:

- have a clinical focus and address one or more inherited orphan retinal degenerative diseases.
- have intrinsic value/research importance.
- serve as a suitable vehicle for learning or enhancing knowledge of the methodologies, practices, guidelines and requirements for the design, development and conduct of research involving human subjects.
- include timelines for each stage of the research project, i.e., design, implementation, completion and analysis, and, where appropriate, publication.

The types of research projects eligible for support include:

- clinical studies using human specimens, materials and/or data from diagnostic and other tests.
- participation in clinical trials to evaluate the safety and efficacy of

diagnostic, investigational therapeutic or preventive approaches/products.

- natural history studies
- evaluations of the validity and reliability of patient assessment tools
- translational research

### **Clinical Training Program**

For the purposes of this program, translational research is defined as the application of basic research discoveries to the diagnosis, management, treatment and prevention of human disease.

Award recipients must pursue a systematic clinical training plan that provides for a logical progression from prior clinical experience to enhanced training in clinical research related to inherited orphan retinal degenerative diseases and leading to research independence in this group of diseases. The Clinical Training Program must be tailored to the specific needs, level of training, experience, and career goals of the award recipient, and must include a schedule for the completion of all activities. Clinical training activities include formal courses and other forms of didactic training provided by the sponsoring institution and through other sources. Training activities may include a broad spectrum of topics, e.g.:

- the diagnosis, management, treatment and prevention of inherited orphan retinal degenerative diseases
- product development, including requirements for and sponsorship of Investigational New Drug (IND) Applications and Investigational Device Exemptions (IDEs)
- clinical protocol design, including hypothesis development, methodologies for statistical design and analysis, data and safety monitoring plans, and informed consent
- guidelines and regulatory requirements for the protection of human research subjects
- design and management of clinical research databases
- epidemiology and preventive medicine
- the responsible conduct of research
- grant writing
- publication of research results

### **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**: up to 5 pages each
  - **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 11:59 pm EST October 21, 2021.**

### **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, **11:59 pm EST October 21, 2021**.

### 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 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**.
- 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](mailto:blindness@onlineapplicationportal.com).**
- Your application status must appear as SUBMITTED **11:59 pm EST October 21, 2021**, in order for your application to be considered. Information on your application status may be found on the Online Application Portal home page.

## CRFA 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**

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.

In addition to the above, DDS CRFA applicants must also provide a brief statement from the candidate fellow of their long-term career goals and how this training will contribute to these objectives.

- **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 the Foundation's web site if the application is funded.

Include the following:

1. The research question(s) to be investigated.
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 the 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.

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

1. 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.

## 2. 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 Foundation. 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:

1. Specific Aims (Page Limit:1 page)
2. Research Strategy. (Page Limit: 5 pages)
  - a. Significance
  - b. 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); and,

- 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 a complete bibliography (or a bibliography of recent publications for DDS CRFA applicants). 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.**

### **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.