



# **CYSTIC FIBROSIS FOUNDATION**

## **Second Year Clinical Fellowship Application**

### **POLICIES AND GUIDELINES**

**December 7, 2016**

## I. SECOND YEAR CLINICAL FELLOWSHIP AWARD OVERVIEW

The mission of the Cystic Fibrosis Foundation (CFF) is to cure cystic fibrosis and to provide all people with the disease the opportunity to lead full, productive lives by funding research and drug development, promoting individualized treatment, and ensuring access to high-quality, specialized care. To meet this mission, various types of grants are offered to support meritorious research ranging from basic laboratory investigation to clinical management of cystic fibrosis (CF). For all awards, proposals are encouraged that involve collaboration between an approved CFF Care Center and an institution with basic and/or clinical research programs.

The CFF invites applications for the Second Year Clinical Fellowship award from physicians interested in chronic pulmonary and gastrointestinal diseases of children, adolescents, and adults with CF. The intent of this program is to encourage specialized training in the early career development stage and to prepare young, well-qualified candidates for careers in academic pulmonary or gastrointestinal medicine related to CF.

CFF generally prefers that the second year of training provides intensive experience in patient management, diagnostic, and therapeutic procedures combined with an introduction to CF research. A minimum of 30% of the trainee's total training time for a three-year period must be spent on research and so documented in the application. The second year clinical fellowship may include a research project for which additional funding is provided. The third, fourth, and fifth year clinical fellowships (see [www.cff.org](http://www.cff.org) for more information on these funding opportunities) each include funding for a research project.

### Eligibility and Requirements

- Applications are open only to those who have completed at least 3 years of training in an approved pediatric or internal medicine program and the first year of specialized fellowship training by the time the fellowship begins.
- Adult caregivers in CF are encouraged to apply.
- The applicant's institution must be U.S. based and accredited in pulmonary or GI medicine.
- Applicants must describe career goals related to a long-term commitment to CF Research and care.
- The institutional status of a fellow must correlate with the CFF fellowship award (e.g. Applicants who are not yet fellows in an accredited pulmonary or GI medicine program should apply for a first and second year clinical fellowship for the upcoming two years).
- Training must take place in one of the CFF recognized CF Care Centers of a Center-affiliated adult CF Program, and should provide a thorough grounding in diagnostic and therapeutic procedures, comprehensive care, and clinical research.
- Every fellow must have a Sponsor who will be responsible for the fellow's training and research activities. If the CF Center Director is not the Sponsor, then s/he must be listed as the Co-Sponsor. CFF can fund only one fellowship per subspecialty, per year, per Center. If more than one applicant is qualified to apply for the award, the Sponsor/Center Director must determine which applicant should apply.

## II. SUBMISSION INFORMATION & GENERAL TIMELINE

### Application Deadline: **February 15, 2017**

Applications must be submitted online through Proposal Central at <https://proposalcentral.altum.com/> by 5:00pm (Eastern). Email a PDF copy of the signed Face Page (see section VII.1. below) to [grants@cff.org](mailto:grants@cff.org) by the same date. Late applications will not be accepted and the deadline will not be waived. The Foundation reviews applications electronically, and only the documents submitted online will be reviewed.

### General Timeline

Application Deadline _____	February 15, 2017
Review by Professional Education Committee _____	mid-March 2017
Applicant Notified _____	April 1, 2017
Earliest Start Date _____	May 1, 2017

### III. AWARD DETAILS

Fellowships are not transferable to another trainee or sponsor, as the awards are made on the basis of individual and institutional merit.

- Training must take place in one of the CFF's accredited CF Care Centers or a Center-affiliated adult CF program.
- The applicant must describe career goals related to a long-term commitment to CF research and/or care.
- Each fellow must have a Sponsor who will be responsible for the fellow's training and, if applicable, research activities.

All CFF-supported Clinical Fellows in internal medicine, pulmonology, gastroenterology, family practice, and other specialties must submit a case study to be presented at the annual North American Cystic Fibrosis Conference (NACFC), at either the Pediatric Clinical Fellows session or the Adult care Clinical Fellows session. This involves submitting a one-page description of the case, including clearly defined discussion points prior to the conference. Please check the NACFC website at [www.nacfconference.org](http://www.nacfconference.org) for further details and specific deadlines.

### IV. AWARD AMOUNTS

The maximum award amount is **\$66,250 for Second Year Clinical Fellows and \$68,750 for Second Year Clinical Fellows with research project** in direct costs (no indirect costs will be paid to the institution). This includes:

- Base stipend: **\$65,000 for Second Year**
- Travel: **\$1,250** (e.g. required participation in NACFC)
- Up to **\$2,500** for research expenses (supplies) may be requested in the Second Year.

In addition, the CFF will underwrite the interest payments for educational loans for up to \$7,000 per year of CFF fellowship.

### V. CFF PAYBACK AGREEMENT

The applicant is required to sign the payback agreement provided online, and upload it as a PDF into the application. CFF expects that upon completion of a CFF fellowship, the recipient will engage in biomedical research, teaching, and patient care, or a combination of these activities, in an academic environment. Failure to commence these activities or sustain them for a period equal to that of CFF support will incur payback obligations for every fellowship year beyond the first. The payback amounts are \$23,500 for the second year of support, and \$33,000 additional for each year beyond.

Length of Support	Payback Amount
2 years	\$23,500
3 years	\$56,500
4 years	\$89,500
5 years	\$122,500

## VI. REVIEW AND AWARD

CFF's Professional Education Committee (PEC) will evaluate all applications. Funding of awards is based on the priority score awarded each application and the recommendations of the PEC. All awards including research are subject to observance of the regulations and policies of CFF related to that category of research support and are contingent upon the availability of CFF funds.

Applications will be evaluated in the following areas:

### 1. Candidate

- Competence in clinical activities and potential for a career in independent research related to CF
- Commitment to, or intent to pursue, a research career related to CF

### 2. Sponsor(s)

- Accomplishments in the clinical and basic science research area(s) related to CF
- Commitment of the primary Sponsor for the duration of the candidate's development and research plan
- Experience of the Sponsor in training individuals for clinical care

### 3. Environment

- Presence in the institution of highly trained faculty in clinical and basic sciences related to CF
- Institution's CF research and training programs
- Interaction between basic and clinical investigators
- Institution's commitment and ability to provide the opportunities and facilities necessary for the clinical and research career development related to CF

### 4. Training and Research Development Plan

- Feasibility and value of the proposed plan
- Specific didactic work to be required of the candidate
- Scientific and technical merit of the proposed research
- Ability of the proposed plan to develop research skill of the candidate
- Relationship to candidate's career development

***All applications will be reviewed and scored by the PEC. Applications receiving low scores, and/or those deemed nonresponsive to the program announcement, may be triaged and withdrawn before the review meeting. Applicants will be notified if their application has been triaged without discussion.***

Chief causes for assigning low priority scores to applications during review include the following:

- Insufficient information or documentation.
- Inadequate statement of hypothesis, experimental design or methods.
- Failure to demonstrate awareness of and plans for coping with key problems and pitfalls associated with the proposed research, e.g. insufficient numbers of potential study subjects, insufficient project duration to accomplish aims, or lack of documentation of access to necessary databases.
- Insufficient or improper controls, especially in human clinical studies.
- Failure to describe potential relevance of the proposed study to issues in CF.
- Failure to document the necessary skills/training to accomplish the proposal's goals.
- Failure to meet all of the criteria described in the policy statement for a given award.
- Failure to describe career development goals as they may be related to a long-term commitment to CF research.

- Insufficient evidence of Sponsor’s involvement in the development of the research plan.

## VII. INSTRUCTIONS FOR COMPLETING SPECIFIC APPLICATION COMPONENTS

- Font: Times New Roman 12 or Arial 11 font
- Margins: Standard ½”
- When all the documents have been uploaded to Proposal Central, the system will compile them into a single PDF file in the correct sequence

### FACE PAGE

The Face Page is populated automatically with data entered in the online application (applicant’s name, institution, title of application, etc.). The Face Page can be downloaded after completing the application and clicking on the “Validate” button (Proposal Section 12). The Face Page must be signed by the Principal Investigator and Authorized Institutional Official. Co-Principal Investigators, if any, are not expected to sign the Face Page. However, signed letters of collaboration from Co-Principal Investigators should be provided in the Appendix. Scan and email the signed Face Page to [grants@cff.org](mailto:grants@cff.org) by the deadline. No hardcopy is required.

#### 1. SPONSOR’S RESULTS OF PAST AND CURRENT CFF/CFFT SUPPORT (For applicant to upload)

Use the form provided for download on Proposal Central. Sponsors are requested to identify the results of past and current CFF/CFFT support (e.g., subsequent funding from other sources, journal articles, and invited presentations) and the CFF/CFFT grant/award from which they resulted for the past three to five years. Please note that the following information must be included with each research project identified:

- CFF/CFFT Account #
- Principal Investigator (PI)
- CFF/CFFT Project Title
- Applicant’s Title on Project
- Project Start/End Dates
- Total CFF/CFFT Award Amount
- Results of Support

#### 2. SPONSOR’S LIST OF PREVIOUS FELLOWS (For applicant to upload)

Download the provided template for the Sponsor(s) to list all previous fellows under his/her supervision over the past 10 years, including the fellows’ source(s) of support.

#### 3. BUDGET AND JUSTIFICATION

Complete the online budget summary in addition to a detailed budget and budget justification (templates provided online in Proposal Section 10) for each year of Phase I and/or Phase II. Be sure the detailed budget matches the online budget summary. A detailed budget and justification are not required for Phase III until that portion of the award is activated.

##### Detailed Budget – Direct Costs Only

**Personnel** - List the name and title of the applicant. Indicate dollar amounts separately for salary and fringe benefits. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all sponsors. The total salary and fringe benefits charged to the CFF Clinical Fellowship cannot exceed \$65,000 for the second year.

**Equipment** –Computers, laptops, and/or other computer equipment are not allowable expenses on a fellowship grant.

**Supplies** –Second Year Only: Up to \$2,500 may be requested for supplies to support a research project. Justify all items. Itemize supplies e.g. glassware, chemicals, animals, in separate categories and give the estimated cost of each category. If animals are involved, state the number, unit purchase cost, and unit care cost.

**Travel** - A maximum of \$1,250 may be requested for travel to NACFC. Expenses for travel outside the North American continent are not allowable.

**Other Expenses** – Expenses such as duplication costs, publication costs, etc. are not allowable expenses on a fellowship grant.

**Indirect Costs** - Indirect costs are not allowable for Physician Scientist Training Awards.

**Maximum level of support:** \$65,000 (Second Year) Total of Salary + Fringe Benefits, if applicable  
\$1,250 Travel to NACFC  
\$2,500 Research Expenses (with approved Second Year Research Plan)

#### **Budget Justification**

Describe costs listed in the Detailed Budget. Use major categories, such as Personnel, Supplies, and Travel.

#### **4. BIOGRAPHICAL SKETCH**

Complete and upload an NIH Biographical Sketch for all key project personnel, beginning with the Applicant/Principal Investigator (fellow) and the Sponsor(s). (CFF defines “key project personnel” as any individual with an advanced degree that will play an instrumental role in the accomplishment of the research project.) Do not exceed five (5) pages per person. A sample NIH Biographical Sketch is available for download on Proposal Central.

#### **5. OTHER SUPPORT**

Complete and upload an Other Support form, for all key project personnel, beginning with the Applicant/Principal Investigator (fellow) and the Sponsor(s). (CFF defines “key project personnel” as any individual with an advanced degree that will play an instrumental role in the accomplishment of the research project.) There is no page limitation.

#### **6. LETTERS OF REFERENCE**

**Letters of Support and Reference are weighted heavily** in the review. **Please activate the process promptly** in Section 6 of the application as these letters involve a multi-step process.

**At least five (5) Letters of Support/Reference are required** as follows:

- **The Sponsor(s) for this award** – A Letter of Support from the current Sponsor(s) should clearly identify the merits of the applicant and must include a description of CF-specific and other training the applicant will receive while working under the Sponsor’s direction (i.e., seminars, new techniques, professional development, etc.).
- **The Applicant’s Division or Section Chief**, if s/he is not the Center Director should detail career and faculty development plans and opportunities, as well as institutional resources available and relevant to the applicant.

- **The CF Center Director(s) at the sponsoring (or nearby) institution** (if s/he is not a Sponsor, should be listed as a Co-Sponsor) should describe the types of CF learning experiences, tools, and resources to support the fellow.
- **At least two other individuals who were closely associated with the applicant during his/her medical training**

### **Names and Addresses of References**

A template is provided online. List the names, titles, and contact information of the individuals who have been asked to submit Letters of Reference on the applicant's behalf. A PDF copy of the completed form should be uploaded.

### **Invite Referees to Submit Letters of Reference through Proposal Central**

Letters of Reference must be submitted electronically ONLY. To "invite" Referees, go to the "Letters of Reference" section of the online application, and enter the email addresses of the individuals you have asked to submit letters. This will generate automated emails (with instructions) sent to each Referee through the Proposal Central website.

The applicant should inform Referees to submit the letters at least one (1) week prior to the application deadline. This helps to ensure that the letters have been uploaded before the application is submitted. Once the application has been submitted, no documents can be added.

Letters uploaded to Proposal Central should not be password protected or otherwise encrypted. Such encryption will cause errors in assembling a single-print PDF of the application. The applicant should inform the individuals writing letters to not include password protection on their documents.

### **7. PERSONAL STATEMENT (PREVIOUS TRAINING AND FUTURE PLANS)**

Upload a brief description of the first year of the applicant's clinical fellowship and a summary of future plans in CF-related research and/or clinical care. The personal statement is weighted heavily in the review.

### **8. TRAINING PLAN *limited to five (5) pages***

Using the template provided, the applicant, in conjunction with the Sponsor(s), should provide a brief summary of the applicant's previous research and/or clinical fellowship training, including the reasons for entering the fields related to CF research and care. In addition, the applicant and sponsor(s) should develop a training plan that outlines skills and techniques that will be learned during this fellowship period as well as CF-specific training that will be available to the applicant, including participation in supplemental course work and special seminars should be included. Further, this section should clearly indicate plans for introducing the applicant to research study planning and design, statistical methods, data management, etc. This plan should address the applicant's long-term career goals and include training and professional development activities that will facilitate the applicant's transition to the next phase of their career.

### **9. SECOND YEAR RESEARCH PLAN**

If research funding is requested, a research plan must be uploaded.

**Page limit:** Five (5) single-sided pages, not including the Literature Cited. Applications exceeding this page limit will not be reviewed. At the top of each page, type the PI's name. Each page must be sequentially numbered at the bottom. Include sufficient information to permit effective review without reference to previous applications. Information should be presented in a clear and concise manner, while being specific and informative.

**Abstract (Scientific):** No more than 250 words (up to 2,000 characters max, including spaces)

**Hypothesis and Specific Aims.** State concisely and realistically the intent of the proposed research and the hypothesis to be tested. The specific aims should be relevant to the mission of the Cystic Fibrosis Foundation. Do not exceed one (1) page.

**Background and Significance.** Briefly describe the background. Critically evaluate existing knowledge and specifically identify the gaps that the project is intended to fill. Concisely state the importance and rationale of this research by relating the specific aims to longer-term objectives. This section should also show the potential importance of the proposed work to CF. In addition, describe the relationship of the proposed work to your long-term career goals. Preference will be given to applicants who express an interest in a long-term career in CF-related research.

**Experimental Design and Methods.** Provide a concise discussion of the experimental design and methods to be used to accomplish the specific aims. Discuss the data expected to be obtained and the means by which data will be analyzed and interpreted. If clinical studies are involved, provide details of the methods for patient selection and care. Discuss potential difficulties and/or limitations of the proposed procedures and alternative approaches to achieve aims.

**Literature Cited.** References should be numbered in the sequence that they appear in the text and listed at the end of the Research Plan. Each citation must include the names of authors, the name of the journal or book, volume number, page number and year of publication (titles are optional).

## 10. ORGANIZATION ASSURANCES & CERTIFICATIONS

### Research Involving Human Subjects

CFF policy pertaining to the protection of individuals as research subjects requires that for each proposal submitted, the applicant institution certify in writing that an Institutional Review Board (IRB) has reviewed and approved the procedures for the use of human subjects, or human organs, tissues and body fluids, in the proposed research, in accordance with Department of Health and Human Services policies. This certification should accompany the application and must be received prior to activation of any grant. If the IRB approval is pending, give the date when it is expected. The approved certification should be submitted as soon as it is available.

### Research Involving Recombinant DNA

All research involving recombinant deoxyribonucleic acid (DNA) techniques and human gene transfer supported by CFF must meet the requirements contained in the document NIH Guidelines for Research Involving Recombinant DNA Molecules. This publication and announcements of modifications and changes to the NIH Guidelines may be accessed at [http://oba.od.nih.gov/rdna/nih\\_guidelines\\_oba.html](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html). The purpose of these guidelines is to specify practices for the construction and handling of: (i) recombinant deoxyribonucleic acid (DNA) molecules, and (ii) organisms and viruses containing recombinant DNA molecules. As defined by those guidelines, recombinant DNA molecules are either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or (ii) molecules that result from the replication of those described in (i) above.

Many types of studies involving recombinant DNA are exempt from the NIH Guidelines while others are prohibited. The applicant organization is required to establish and implement policies that provide for the safe conduct of the research in full conformity with the NIH Guidelines. This responsibility includes establishing an Institutional Biosafety Committee to review all recombinant DNA research to be conducted at or sponsored by the applicant organization, and to approve those projects it finds are in conformity with the Guidelines.

CFF policy pertaining to recombinant DNA research requires that the applicant institution certify in writing that an institutional committee has reviewed and approved the procedures involving recombinant DNA in accordance with the NIH Guidelines. Applicants that do not have institutional committee approval must submit a recombinant DNA application to the applicant institution BEFORE the CFF application deadline. Certifications need not accompany the application, but all required certifications should be available upon request by CFF.

### **Research Involving Animals**

Grant applications submitted to CFF involving the use of animals must meet the guidelines of the National Institutes of Health, U.S. Public Health Service, which require that all proposed studies be reviewed and approved by an Institutional Animal Care and Use Committee (IACUC). In addition, CFF grantee institutions and laboratories must be accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC) and/or have other verifiable assurances that the institution and laboratory meet appropriate standards. Applicants that do not have institutional committee approval must submit an IACUC application to the applicant institution BEFORE the CFF application deadline. Certifications need not accompany the application. Applicants must be able to provide copies of all required certifications upon request by CFF.

## **11. VERIFICATION OF APPLICANT INSTITUTION'S TAX STATUS**

Per Internal Revenue Service (IRS) stipulations for grant-making organizations, CFF's Grants and Contracts Office must have a copy of the applicant institution's current W9 **and** 501(c)3 letter, or other documentation verifying its Federal tax status, on file. CFF's Grants and Contracts Office will not issue Award Letters to Grantees if these documents are not on file.

Applicants from for-profit organizations must submit a copy of the applicant institution's W9 **and** IRS Form 147C, or other documentation verifying the organization's Federal tax status. Awards are not issued prior to having these documents on file with the CFF Grants and Contracts Office.

## **12. APPENDICES**

Appendices are restricted to the following two (2) categories:

- If applicable, certification of IRB approval, or statement indicating that such approval is pending and the date when such approval is expected.
- Up to three (3) reprints of the applicant's work relating to the general area of research in the grant proposal may be uploaded in PDF format.

No other types of Appendices will be reviewed.

## **VIII. ELECTRONIC SUBMISSION GUIDELINES**

**Application Deadline: February 15, 2017** at 5:00pm (Eastern Time).

Online registration required, and all applications must be submitted online to Proposal Central at: <https://proposalcentral.altum.com>. Late applications will not be accepted and the deadline will not be waived. A PDF copy of the signed Face Page should be emailed to grants@cff.org) by the same date. Please do not mail any hardcopy to CFF.

The opening screen, after logging in to Proposal Central, includes multiple grant opportunities organized by Grant Maker and Program. If this screen does not appear, click on the gray tab labeled "Grant Opportunities"

found in the upper right hand side of the page. Scroll down to the Cystic Fibrosis Foundation and click on the “Apply Now” button that appears on the far right next to the program name for which you are applying.

Instructions and templates are provided for review/download in related sections of the application. If you need technical support, please use the contact information that is provided on each screen.

Applicants may stop at any point, each time remembering to click the SAVE button before exiting, and continue/revise until clicking the SUBMIT button. When logging in to continue, click on the blue tab, “Manage Proposals,” and then the “Edit” button next to the application’s title.

Access may be designated to another registered individual, such as an assistant, do so in Section 3, “Enable Other Users to Access This Proposal.” Enter the full name and email address and in the Permissions column select the type of access allowed from the drop down menu.

An application will be considered incomplete if it fails to comply with instructions, or if the submitted material is insufficient to permit adequate review. CFF reviews applications electronically, and only documents submitted online at Proposal Central will be reviewed. Late applications will not be accepted, and the deadline will not be waived.

Upon validating your application, follow the prompts to print the system-generated face page. Please click on the SUBMIT key to complete the application process. Sign, scan and email the Face Page to [grants@cff.org](mailto:grants@cff.org) by the deadline date.

An email confirming successful upload will be sent from Proposal Central, not CFF. This email will be the only acknowledgment that the application was successfully uploaded. If this acknowledgement is not received, please contact Proposal Central for assistance.

**For technical support with the online application:**

Proposal CENTRAL at [pcsupport@altum.com](mailto:pcsupport@altum.com) or

800-875-2562 on weekdays, 8:00 a.m. to 5:00 p.m. (Eastern)

**For program/content information:**

CFF Grants & Contracts at [grants@cff.org](mailto:grants@cff.org) or 301-841-2614

## IX. ELECTRONIC APPLICATION CHECKLIST

Application Deadline: **February 15, 2017** at 5:00pm (Eastern Time)

Applications must be submitted at Proposal Central: <https://proposalcentral.altum.com/>. A PDF copy of the signed Face Page should be emailed to CFF ([grants@cff.org](mailto:grants@cff.org)) by the same date. The complete application must be submitted online, and no other documents will be reviewed.

### Face Page which includes:

- Signatures
  - Principal Investigator (Co-PI's are not required to sign)
  - The Official authorized to sign on behalf of the Sponsoring Institution
- Applicant/PI information (online)
- Complete Institution and PI Contact information, including correct mailing address (online)
- Organization Assurances (online)
  - Human Subjects Certification
  - Recombinant DNA Biosafety information
  - Research Involving Animals information

### Research Plan, Supporting Documents and Appendix:

- Sponsors' Results of Past and Current CFF/CFFT Support
- Sponsor's List of Previous Fellows
- Budget and Budget Justification
- Biosketches for all key personnel (NIH Format)
- Other Support for all key personnel (NIH Format)
- Letters of Reference
  - Names and Addresses of References must be provided
  - Letters are electronically submitted by each Referee through the Proposal Central website
- Research Plan
  - Abstract
  - Hypothesis and Specific Aims
  - Background and Significance
  - Experimental Design and Methods
  - Literature Cited (not included in Research Plan page limitation)
- Personal Statement
- Training Plan
- Applicant Institution Tax Status forms
  - W-9, **and**
  - 501(c)3 letter **or** IRS Form 147C
- Appendices
  - If applicable, certification of IRB approval, or statement indicating a pending approval and anticipated date
  - Up to three copies of the applicant's work relating to the general area of research in the proposal