



Award Type: First/Second Year Clinical Fellowship 2023

Brief Program Overview/Description: This award is part of the Cystic Fibrosis Foundation’s Physician Training Program and is designed to support First Year and/or Second Year Clinical Fellows pursuing training in CF relevant subspecialties. The intent of this program is to encourage specialized training in the early career development stage, provide exposure to CF research and patient care, and to prepare well-qualified candidates for careers related to CF.

Funding Amount: The maximum award amount ranges from \$62,000 for the First Year to \$69,500 for the Second Year. Indirect costs are not allowable.

Eligibility:

- Applicants may be either U.S. citizens, permanent residents, or non-U.S. citizens. International applicants must have the ability to obtain the appropriate visas, as applicable.
- Applicants must have completed at least three (3) years of training in an approved pediatric and/or internal medicine program by the time the fellowship begins. International applicants must be certified by the Educational Commission for Foreign Medical Graduates (ECFMG) and be able to fulfill the eligibility requirements of the Accreditation Council for Graduate Medical Education (ACGME) for entry into an accredited fellowship.
- The institutional status of a fellow must correlate with the CFF fellowship award to which the applicant is applying.

Key Dates:

Published	December 7, 2022
LOI Submission Deadline	NA
LOI Applicant Notified	NA
Full Application Deadline	March 1, 2023
Committee Review Date	Late- May 2023
Notification to Applicants	June 2023
Earliest Project Start Date	July 1, 2023

Table of Contents:

- I. [About the Cystic Fibrosis Foundation](#)
- II. [Program and Award Overview](#)
- III. [Funding Amounts](#)
- IV. [Eligibility](#)
- V. [Mentorship Requirements](#)
- VI. [Goals of Research Currently of Interest to CFF/Priority Areas](#)
- VII. [Review and Award](#)
- VIII. [Submission Information](#)
- IX. Letter of Intent Guidelines
- X. [Full Application Guidelines](#)
- XI. Other Information
- XII. [Contact Information](#)
- XIII. [Electronic Application Checklist](#)

I. About the Cystic Fibrosis Foundation

The mission of the Cystic Fibrosis Foundation (CFF) is to cure cystic fibrosis (CF) and to provide all people with CF the opportunity to lead long, fulfilling lives by funding research and drug development, partnering with the CF community, and advancing high-quality, specialized care.

To achieve this mission, various types of grants and awards are offered to support meritorious research in CF.

Diversity, Equity, and Inclusion

Cystic fibrosis affects people of different racial and ethnic backgrounds. Diversity, equity, and inclusion (DEI) are core to our ability to make a meaningful difference in the lives of all people with CF. Improving the representation of people of color within the CF community – including those in the CF research workforce – and addressing health disparities that exist within these groups is critical to the Foundation’s mission of serving all people with CF. Making clinical trial design and engagement more inclusive of people of color with CF will be critical for improving treatment options and health outcomes for these groups; Black and Hispanic people with CF account for nearly 40 percent of individuals with rare mutations that are not candidates for available treatments addressing the underlying cause of the disease. As PIs prepare application materials, we strongly encourage the consideration of how to support inclusion of diverse participants, including plans for building trust with community members and ensure adequate recruitment of people from diverse backgrounds.

CF Foundation Resources

The Cystic Fibrosis Foundation supports the development of a number of helpful tools and resources to assist the research community in accelerating the progress toward new scientific knowledge of and new therapies for cystic fibrosis. For more information on Tools and Resources for the CFF research community, please visit: <https://www.cff.org/for-researchers>

CFF Patient Registry Data

The CF Foundation Patient Registry collects information on the health status of people with cystic fibrosis who receive care in CF Foundation-accredited care centers and agree to participate in the Registry. This information is used to create CF care guidelines, assist care teams providing care to individuals with CF, and guide quality improvement initiatives at care centers. Researchers also use the Patient Registry to study CF treatments and outcomes and to design CF clinical trials.

The Cystic Fibrosis Foundation Patient Registry is an invaluable tool for researchers who are interested in conducting studies about people with CF in the United States. About 50,000 individuals have been followed in the Registry, and many have been included for over 20 years. In addition, we recently linked the CF Foundation Patient Registry with the Pediatric Health Information System (PHIS) database. Investigators at PHIS sites can request to use these linked data. Instructions on how to request CFFPR data for your research project is included in the application instructions below.

If you intend to request access to CFFPR data for this award, you are strongly encouraged to reach out to the PO, Elizabeth Yu, to ensure best timing and other practices are observed.

CFF Biorepository

Cystic fibrosis biological samples are available to qualified researchers to help develop promising new studies that will support CF research and aid in drug development and drug discovery. Biorepository samples come in many different forms: blood, urine, stool, tissue, and other material. These samples are stored under appropriate conditions that ensure they are preserved for future analysis.

Since 2006, the Cystic Fibrosis Foundation has collected and stored samples from a variety of clinical trials. The CF Foundation has developed a database that combines information from these samples with data from CF clinical trials and the CF Foundation Patient Registry to create a unique and specific sample profile. Instructions on how to request CFF Biorepository samples for your research project is included in the application instructions below.

Community Voice

The CF Foundation is committed to ensuring that the CF community's voice is heard in all of our activities. In December 2014, the CF Foundation created Community Voice, formerly known as the CF Adult and Family Advisors group, to serve as a consultative body and partner to the Foundation on various activities. Research Voice, a sub-committee within Community Voice, consists of people with CF and their family members who undergo special training on the basics of clinical research to provide insight and feedback to the research community.

Opportunities to partner with the community occur throughout the stages of a research project. Recently, several CFF funded investigator-initiated clinical research projects have utilized community engagement through Community Voice to successfully execute and complete their projects. The CF Foundation strongly encourages you to engage people with cystic fibrosis throughout the stages of clinical research. Based on your goals and objectives, the CF Foundation will work with you to determine which mechanisms are most appropriate. To learn more about how community insights can help you optimize your research project, email CommunityVoice@cff.org.

National Resource Centers

Specialized procedures are often needed to measure the outcomes of cystic fibrosis clinical trials. These include both laboratory-based measurements, such as cytology and inflammatory markers, and interpretive outcomes, such as computed tomography and nasal potential difference. For more information about National Resource Centers, please visit: <https://www.cff.org/national-resource-centers>

II. Program and Award Overview

Physician Training and Career Development Programs Overview

CF Foundation's Physician Training & Career Development Programs (PTPs) aim to attract, develop, and retain exceptional clinicians and investigators into cystic fibrosis to address the evolving needs of the CF community. The PTPs ensure that there is a physician workforce that meets the healthcare and research needs of the CF Community by requesting applications for the 1st/2nd Year Clinical Fellowship Award, the 3rd/4th Year Clinical Fellowship Award, the 5th Year Clinical Fellowship Award, the Harry Shwachman Clinical Investigator Award (HAS), and the LeRoy Matthews Physician-Scientist Award (LMA) annually.

In 2022, we aim to fund 30 meritorious 1st/2nd Year Clinical Fellowship Awards.

First- and Second-Year Clinical Fellowship Award Overview

CFF invites applications for the First and/or Second Year Clinical Fellowship award from all physicians pursuing fellowship training in CF relevant subspecialties (these include, but are not limited to, Endocrinology, Gastroenterology, Infectious Disease, Pulmonology, Pulmonary and Critical Care, Organ Transplant, Otolaryngology, Psychiatry, General Internal Medicine, Geriatric Care, and Adolescent Medicine). The intent of this program is to encourage specialized training in the early career development stage, provide exposure to CF research and patient care, and to prepare well-qualified candidates for careers related to CF. Applications are welcome from residents and fellows who have limited experience or exposure to CF, but are interested in learning more and gaining more exposure over the first few years of fellowship.

Applications can be submitted for a first and second year combined or second year only. If the applicant applies for a first and second-year combination, the second year of funding, if requested, is contingent upon submission and approval of a renewal progress report indicating the satisfactory performance for the portion of the first year that will have been completed at the time of submission.

CFF generally prefers that the first year of training provides intensive experience in patient management, diagnostic, and therapeutic procedures. The second-year clinical fellowship may include a research project for which additional funding is provided.

Note: CFF also offers third, fourth, and fifth year clinical fellowships which include funding for a research project (visit www.cff.org for more information on these funding opportunities).

All CFF-supported Clinical Fellows must submit one case study for presentation at the annual North American Cystic Fibrosis Conference (NACFC) during the award, at either the Pediatric Clinical Fellows session or the Adult Care Clinical Fellows session. Acceptance of the case study is not required. This requirement is fulfilled by submitting a one-page description of the case, including clearly defined discussion points prior to the conference. It does not require acceptance for this requirement to be fulfilled. Please check the NACFC website at www.nacfcconference.org for further details and specific deadlines. Should extenuating circumstances (e.g. continuing COVID-19 response) prevent submission of a case study to NACFC, submission and/or presentation of a CF-related case study to another conference or broad audience may be substituted at the discretion of the CFF Program Officer.

Diversity, Equity, and Inclusion Training

Awardees are strongly encouraged to supplement their career development in CF clinical care and research with appropriate DEI training. Many institutions have dedicated courses or certificate programs in this space that should be acknowledged in your Training Plan.

Award Transfers:

Awards are made on the basis of individual and institutional merit; therefore, fellowships are not transferable to another trainee or institution without prior written approval from the Program Officer.

III. Funding Amount

The maximum award amount is as follows:

- **First-year clinical fellows: \$62,000** in direct costs for one year (**indirect costs are not allowable**). This includes up to:
 - \$60,000 for salary and benefits
 - \$1,500 for travel to NACFC
 - \$500 for registration fees for NACFC

- **Second-year clinical fellows: \$69,500** in direct costs for one year (**indirect costs are not allowable**). This includes up to:
 - \$65,000 for salary and benefits
 - \$1,500 for travel to NACFC
 - \$500 for registration fees for NACFC
 - \$2,500 for research expenses (Research Plan required)

Student Loan Repayment Program

Physician Training Program Award recipients are eligible to apply for the CF Foundation's Student Loan Repayment Program. This program offers up to \$14,000 per year to offset student loan debt existing

during the award period. Please refer to <https://www.cff.org/student-loan-repayment-program> or contact the CFF Grants & Contracts Management and Administration (GCMA) Office for more information on this program.

IV. Eligibility

- Applicants may be either U.S. citizens, permanent residents, or non-U.S. citizens. International applicants must have the ability to obtain the appropriate visas, as applicable.
- Applicants should have completed at least three (3) years of training in an approved pediatric and/or internal medicine program by the time the fellowship begins. Some exceptions may be made for subspecialties that do not require prior training. International applicants must be certified by the Educational Commission for Foreign Medical Graduates (ECFMG) and be able to fulfill the eligibility requirements of the Accreditation Council for Graduate Medical Education (ACGME) for entry into an accredited fellowship.
- Training must take place in a CFF-accredited CF Center or a CF Center-affiliated adult CF program, and should provide a comprehensive educational curriculum in diagnostic and therapeutic procedures, comprehensive care, and clinical research. Types of fellowship training encouraged to apply include Pulmonary, Gastrointestinal, Endocrine, Infectious Disease, and Organ Transplant. Other fellowship training programs are accepted provided the applicant clearly outlines the relevance to the CFF mission.
- Adult caregivers/participants in internist programs in CF are strongly encouraged to apply.
- The applicant's institution must have Accreditation Council for Graduate Medical Education (ACGME) accredited training programs in the applicants' subspecialty.
- 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 to which the applicant is applying.

Note: Awardees are required to inform CFF annually for a period of five years subsequent to completion of the award about academic status, publications, and research grants or contracts received. In addition, all awardees and institutions must comply with CFF award policies.

V. Mentorship Requirements

- Each fellow must have a Mentor who will be responsible for the fellow's training and research activities. If the CF Program Director is not the Mentor, then they must be listed as the Co-Mentor in the application.
- CFF will accept applications for up to two (2) fellowships per subspecialty, per fellowship year, per accredited CF Program (i.e. adult and pediatric).
- CFF will accept applications from applicants with different subspecialties (e.g. pulmonary, endocrine, gastrointestinal, transplant, infectious diseases, etc.) from the same accredited CF Program. However, in the event that more than two (2) applicants **from the same subspecialty** are qualified to apply for the award, the CF Program Director must determine which applicants should apply.

VI. Goals of Research Currently of Interest to CFF/Priority Areas

Although research is not required for First and/or Second Year Clinical Fellowship award applications, the applicant is strongly encouraged to submit a plan for review.

Proposed research must be relevant to the CFF's mission and to the health and well-being of people with CF. Applicants are encouraged, but not required, to address a research priority outlined below, and in further detail on <https://www.cff.org/key-research-priorities-applicants>. All applications are reviewed and scored based on the individual, training program, scientific merit, and relevance to the CFF mission.

Research Priorities:

- Treat the underlying cause of CF for all people with the disease and drive progress toward a cure. In particular, research related to **evaluating genetic-based therapies** that may have clinical impact for people with CF, developing therapies that address the **underlying cause of CF for individuals with nonsense and rare mutations**, and **improving and better understanding cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapies**.
- Understand the biological mechanisms of, and advance new and improved treatments to address the many complications of CF, including:
 - Mental health;
 - Infections affecting people with CF;
 - Inflammation, impaired airway hydration, and mucus clearance;
 - Serious complications of CF outside the lungs, such as GI complications (including in the liver, the pancreas, and the impact of nutritional deficiencies), endocrine system dysfunction (including CF related diabetes and CF bone disease);
 - Sinus disease;
 - Lung transplant and advanced lung disease;
 - Sexual and reproductive health – applicants with an existing hypothesis and interest in research in this space are encouraged to connect with the Sexual Health, Reproduction, and Gender Research (SHARING) Working Group for additional mentoring: Raksha Jain is the working group chair (Raksha.Jain@UTSouthwestern.edu), and Traci Kazmerski is the co-chair (Traci.Kazmerski@chp.edu).
- Characterize the best CF care and treatment regimens to provide optimal, individualized care as the CF treatment landscape evolves.
- Improve understanding of system-level and societal barriers to optimal CF care and explore opportunities to minimize their effects, including racial disparities and socioeconomic barriers to equitable care.
- Ensure that the CF care model adapts to meet the future needs of people with CF across their lifespan. This includes considerations for the aging CF population and the increasing utilization of remote care.

VII. Review and Award

CFF's Professional Education Committee (PEC) will evaluate all applications based on the training program content and applicant. Funding of awards is based on the priority score provided to each application and the recommendations of the PEC. All awards 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:

Applicant	Mentor(s)	Environment	Training & Research Development Plan
<ul style="list-style-type: none"> • Potential to develop a career related to CF • Commitment to, or intent to pursue, a career including care of those with CF • Quality of academic background and previous training 	<ul style="list-style-type: none"> • Established CF clinician/physician-scientist with experience in training fellows • Commitment of the primary Mentor for the duration of the applicant's training plan • Strong track record of successful trainees who continue in CF field 	<ul style="list-style-type: none"> • Quality of institution's CF research and training programs • Institution's commitment and ability to provide opportunities and facilities necessary for career development related to CF 	<ul style="list-style-type: none"> • Overall quality and organization of the training program • Didactic course work required by the applicant (if indicated) • Scientific and technical merit of the proposed research (if applicable) • Commitment to diversity and inclusion (e.g. implicit bias training).

CFF may withdraw applications receiving low scores, and/or those deemed nonresponsive to the program announcement before the review meeting. In these cases, CFF will notify applicants if their application has been withdrawn without discussion. Applicants must address reviewer critiques in order to resubmit their applications during future application cycles.

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

- Insufficient information or documentation
- Failure of the applicant to meet all criteria described in the policy and guidelines for a given award
- Failure of the applicant to describe career goals as they may be related to a long-term commitment to CF research, quality improvement, or care.

VIII. Submission Information

Application Deadline: Wednesday, March 1, 2023 at 5:00 PM (Eastern)

Applications must be submitted online at <https://awards.cff.org>

(Refer to Section X of these guidelines for specific submission instructions)

An application will be considered incomplete if it fails to comply with the instructions, or if the submitted material is insufficient to permit adequate review. CFF reviews applications electronically, and documents should be submitted online at <http://awards.cff.org> for review.

General Timeline:

Application Deadline _____ March 1, 2023
 Review _____ late-May 2023
 Notification to Applicants _____ June 2023
 Earliest Start Date for Awarded Projects _____ July 1, 2023

The CF Foundation will host a webinar to walk through what makes a good application with a live question and answer session at 11:00 am ET January 10, 2023. Register Here:
https://cff.zoom.us/webinar/register/WN_CFbnMwnaRtKiRdf7cRV8eA

IX. Letter of Intent Guidelines

Not applicable to this RFA

X. Full Application Guidelines

Applications must be submitted online at <https://awards.cff.org>

Documents should be typed using:

- Font: Times New Roman 12 or Arial 11
- Margins: No less than a half inch on each side

Note: When all the documents have been uploaded to awards.cff.org, the system will compile them into a single PDF file. You may preview this file by selecting “Application Full Print”, as well as exporting the compiled PDF file.

To login, please visit: <https://awards.cff.org>

*For all first-time applicants in the new Grants Management System, we ask that you pre-register to create a username and password for “<http://awards.cff.org>” and complete a profile well before the date you plan to submit an application. We also request that as you begin your application, you enter the title of your project, if available. If you are registered and cannot remember your password, click on the “**Forgot Password?**” link below the “**Login**” fields.*

Once logged in, the award opportunities, including this Request for Applications (RFA), will be listed in the **Funding Opportunities** tab on the opening screen.

Locate the listing for the “**First-Second Year Clinical Fellowship 2023**” program. Click on the “Apply” button in the column on the far right to open the application form.

Applicants may stop at any point but must click the “**Save**” button at the bottom of each page *before exiting* in order to save their progress. When you wish to return to your draft application, please do not go through the “Funding Opportunities” tab. Instead, go to the “My Applications” tab in the right corner of the main page. When you are in the “My Applications” tab you will be able to find all your draft applications by clicking on the “Draft Applications” module.

Upon beginning the application, you will need to select the appropriate role (PI or Mentor) for who will be starting the application. Mentors will see and have access to the same application as PIs/fellows. However, the mentor does not have the option to submit an application. *Only the PI will have the permissions to submit the application to the AIO.*

The following sections are displayed as tabs across the application screen. Click on each section and follow the directions. Click “**Save**” as you complete each section.

GENERAL

Enter the title of your project, enter the project start and end dates, select the number of periods being requested, and complete any additional questions. Also, please complete the organizational assurances

indications (i.e. IRB, IACUC, and/or IBC/rDNA approval letter and status at the time of submitting the application) in this section.

***Please ensure that you review and comply with the Organizational Assurances and Certifications as cited on page 14.**

CONTACT PROFILE

If a profile was completed upon registration, the fields in this section will already be populated with the information entered in your Professional Profile. If you need to make any changes, you may update your profile in this section.

Once updated you must **“Save and Validate”** prior to returning to continue your submission

INSTITUTION

If a profile was completed upon registration, the applicant’s/principal investigator’s institution will be pre-loaded as the Lead Institution. Domestic applicants must verify their institution by entering the Employer Identification Number (EIN) or Tax Identification Number (TIN) to search the system for the correct institution. You may find your EIN by referencing the Institutional W-9 or equivalent documentation. If the EIN/TIN is not located in our system, you have the option to add the legal institution. Please also confirm if the project site is the same as the legal institution.

Note: When choosing an institution, please select the institution where the applicant will plan to complete their fellowship. Do not choose the Institution where the applicant is completing their residency unless they are the same.

Verification of Applicant Institution’s Tax Status (upload as PDF documents):

The CFF GCMA Office must have a copy of the applicant institution’s current W-9 and 501©3 letter, or other documentation verifying its Federal tax status and will not issue Award Letters to Awardees if these documents are not received and on file.

- Applicants from for-profit organizations must submit a copy of the applicant institution’s W-9 and IRS documentation verifying the organization’s Federal tax status. Awards are not issued prior to having these documents on file with the CFF GCMA Office.
- Non-U.S. applicants must provide a copy of the W-8BEN-E form (required). In addition, a tax equivalency letter should be uploaded, if available. If a tax equivalency letter is not available, applicants must upload a letter stating this documentation is not available.

International Applicants (if applicable):

Not Applicable

CONTACTS

Please note: The INSTITUTION tab must be completed prior to adding internal contacts to ensure that the contacts are properly associated with the applicant institution.

Complete the required contact fields by searching by name for existing contacts at your institution for each role. If the desired institutional contact is not available in the system, you may select **“Add Internal Contact”** to create a basic contact profile in order to add the individual to your application.

Additional contacts not associated with the applicant institution may also be added. These contacts are considered additional contributors involved in the proposed research plan. These may include consultants, collaborators, or subcontractors (if applicable). In order to add contacts external to the applicant

institution, please select the appropriate “Add Subcontractors” or “Add Consultants/Collaborators” button(s) and add the contacts in the table, then click “Save”.

See a How-To Guide Here: <https://www.cff.org/sites/default/files/2021-10/GMS-Guide-Applicants.pdf>

REFERENCES

Letters of Support and Reference are weighted heavily in the review. At least five (5) Letters of Support/Reference are required as follows:

- **Mentor:** Please describe the types of CF learning experiences to which the applicant will be exposed. If the application includes a research project, please describe in detail on how you will provide the fellow with the tools and resources necessary for her/him to develop into a CF-focused independent investigator.
- **CF Program Director(s):** The CF Program Director(s) at the applicant/nearby institution if s/he is not a Mentor, should be listed as Co-Mentor. Please describe the types of CF learning experiences, tools and resources to support the fellow.
- **Division or Program Chief (if you are not the Program Director):** Please describe career and faculty development plans and opportunities, as well as institutional resources available and relevant to the applicant.
Note: If a letter from any one referee listed above fulfills two or more of the required roles, additional letters from referees who can speak to the applicant’s scientific and clinical abilities, interests, and potential to become an independent investigator must be provided to meet the minimum requirement of five (5) letters.
- **Additional Referees:** At least two (2) other individuals who were closely associated with the applicant during his/her medical training.

Letters of Reference must be submitted prior to submission of the application. To invite Referees, go to the “REFERENCES” tab of the online application, then select the blue button to open a pop-up window in order to add the referees in the table. Once you click “Save” and close the pop-up window, the referees will be sent an e-mail asking them to Accept or Decline the invitation to submit a letter of reference and will be provided instructions to submit the letter. **The applicant will be alerted if a referee Declines the invitation; please make sure to check this tab regularly to see the status of the references.** 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 <http://awards.cff.org> 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.

ABSTRACTS/RELEVANCE (Required for 2nd year Fellowships with Research Plan)

In the space provided online for each abstract, provide a statement of no more than 2,000 characters (including spaces) explaining the subject of the research proposal and its relationship to CF. Two different abstracts are required, as follows:

- **Lay Abstract:** This statement will be used to inform the non-scientific departments of CFF and the general public of the nature of this work. Applicants should not include any confidential or proprietary information, including intellectual property, in the lay abstract.
- **Scientific Abstract:** This statement will be used to inform the scientific community.
- **Summary of Relevance to CFF mission:** All applications are reviewed and scored not only on scientific merit but also on relevance to CFF’s mission:

The mission of the Cystic Fibrosis Foundation is to cure cystic fibrosis and to provide all people with CF the opportunity to lead long, fulfilling lives by funding research and drug development, partnering with the CF community, and advancing high-quality, specialized care.

Provide a statement of no more than 3,000 characters (including spaces) summarizing the relevance of the proposed research to the health and well-being of CF patients, for a scientific audience who may or may not have a background in the subspecialty of the proposed research.

BUDGET

Select the “**Edit Budget**” button under Application Budget, to enter and begin completion of the application’s budget detail for each year of funding being requested. Awards funded through this RFA are for a maximum of two (2) years. The maximum award amount ranges from \$62,000 for the First Year to \$69,500 for the Second Year. Indirect costs are not allowable.

Salaries & Benefits - List the names, positions, and percent effort of all professional and non-professional personnel involved in the project, whether or not salaries are requested. For each individual, be sure to complete all fields on the Budget Detail in full on the template provided. In accordance with National Institutes of Health (NIH) policy, salary requests may not use an institutional base salary in excess of the current federal salary cap of **\$203,700**. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all funding agencies and foundations.

Travel - Describe the purpose of any CF-relevant travel. Please note: expenses for travel outside the North American Continent, including travel to Hawaii, Puerto Rico, and other U.S. territories are not allowable expenses without prior written approval from the CFF GCMA Office. **Travel expenses may not exceed \$1,500 per person per year**. Registration fees associated with conferences are in addition to this allowance should be listed under “Other Expenses”.

Consumable Supplies - 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.

Other Expenses - Itemize other expenses by major categories, such as duplication costs, publication costs, minor equipment (under \$5,000), computer charges, conference registration fees, etc. Tuition costs may be requested for personnel supported through this study but may not exceed **\$10,000** per person per year.

FULL APPLICATION UPLOADS

Download the available templates applicable to the project, upload the completed templates to the corresponding attachment types within this section. Templates available for download include:

- Biographical Sketches for Key Personnel
- Mentor’s Results of Past and Current CFF/CFFT Support
- Other Support
- Facilities Available
- Budget Justification
- Second Year Research Plan (if applicable)
- Mentor’s List of Previous Fellows
- Personal Statement (Previous Training and Future Plans)
- Training Plan

Biographical Sketches for Key Personnel

Complete and upload an NIH Biographical Sketch for all key project personnel, beginning with the Applicant/Principal Investigator. International applicants can upload a biosketch that is equivalent in content to the NIH template provided. (CFF defines “key 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.

Mentor’s Results of Past and Current CFF/CFFT Support

Mentors 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

Other Support

Complete and upload the Other Support form for all key project personnel, beginning with the Applicant/Principal Investigator. There is no page limitation. Information on other support assists CFF in the identification and resolution of potential sources of overlap. Scientific and budgetary overlap should be minimized. Commitment of an individual’s effort greater than 100 percent, is not permitted.

Facilities Available

Describe the facilities and equipment available at the applicant’s institution that will be used for this project, such as laboratory, clinical, animal, computer, office, etc. Provide any additional information about the environment, including any support services available that will be utilized. Describe their pertinent capabilities, proximity and anticipated extent of use. If facilities or equipment at a consultant’s or collaborative site will be used, they should be identified and clearly described. There is no page limit. Use continuation pages, if necessary.

Budget Justification

Describe costs listed in the Budget Detail. Use major categories, such as Salary & Benefits, etc. Justify all items and make sure amounts and figures listed in the narrative are consistent with those listed in the Budget Detail.

Second Year Research Plan (if applicable)

If applying without the research component, please upload a blank page stating “Not Applicable” or “Research is not proposed in this fellowship”.

If there is a possible research plan developed at the time of application, the applicant is encouraged to submit it for review. This gives an opportunity for constructive feedback and refinement that serves to further develop grant-writing skills.

First and Second Year Fellowship awardees may submit a research plan in their renewal report for approval by the Program Officer if they wish to request the additional research costs.

If research funding is requested, a research plan must be uploaded. Please follow the instructions below.

- Key figures and legends must be included in the Research Plan. If uploaded as Appendices, they will NOT be reviewed.
- At the top of each page, type the Applicant's name. Each page must be sequentially numbered at the bottom.
- Page limit: Five (5) single-sided pages, not including the Literature Cited. Applications exceeding this page limit will not be reviewed. A template is available for download on awards.cff.org. 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.
- a. **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 page.* This Aims page serves as the foundation for a research grant. The NIH provides useful suggestions for what to consider as you draft this page here: <https://www.niaid.nih.gov/grants-contracts/draft-specific-aims>. The hypothesis should be clear and testable, and any aims should produce data that will support or refute the hypothesis.
- b. **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.
- c. **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.
- d. **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).

Mentor's List of Previous Fellows

The current Mentor(s) must provide a list of all previous fellows under his/her supervisions over the past 10 years, including the fellows' source(s) of support.

Personal Statement – Previous Training and Future Plans

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

Training Plan

The applicant, in conjunction with the Mentor(s) and fellowship program director, 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 Mentor(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. Further, this section should clearly indicate plans for introducing the applicant to CF research. This should include training on study planning and design, statistical methods, data management, etc. If appropriate, applicants should provide a description of their anticipated CF research. 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. A description of any planned DEI training that will take place during the award should be included. *Do not exceed five (5) pages.*

**Successful Training Plans are traditionally clearly co-authored by the fellowship program and applicant with the program structure and applicant's career goals in mind. They should detail both fixed program training and timelines, along with didactics, additional clinical work, workshops, mentorships, or other training the applicant will undergo to both 1) further their development as CF providers and researchers, and 2) achieve their long-term career goals. This may include training or work in programs that is not CF-specific, e.g. mentorship with an expert in social determinants of health, work towards an MPH, or additional biostatistics training.*

Appendices (upload as PDF documents)

- Certification of organization assurances (i.e. IRB, IACUC and IBC approvals), if applicable.
- Up to three (3) reprints of the applicant's work relating to the general area of research in the proposal

***Organization Assurances & Certifications**

CFF requires, as applicable, that all U.S.-based awardees obtain Institutional Review Board (IRB) approvals for human subject research, Institutional Biosafety Committee (IBC) approval for recombinant or synthetic nucleic acid research, and Institutional Animal Care and Use Committee (IACUC) approval for animal research, (see additional information regarding these approvals below). Copies of these approvals, if available at the time the application is submitted, must be uploaded with the application as appendices. CFF will not release payments to awardee institutions until these documents are received and on file with the CFF GCMA Office.

Awardees based outside of the U.S. must comply with the applicable equivalent regulations in their respective countries and provide copies of approvals as soon as they are available. CFF will not release payments until these documents are received and on file with the CFF GCMA Office.

Research Involving Human Subjects: CFF policy pertaining to the protection of individuals as research subjects requires that for each proposal awarded, the awardee 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 the Department of Health and Human Services policies found at <https://www.hhs.gov/ohrp/regulations-and-policy/index.html>. In the event the IRB has determined a study is exempt, documentation demonstrating the exempt status must also be submitted to the CFF GCMA Office.

Research Involving Recombinant or Synthetic Nucleic Acid Molecules: All research involving recombinant or synthetic nucleic acid and human gene transfer studies supported by CFF must meet the requirements contained in the document *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (updated April 2019)*. This publication and announcements of modifications and changes to the NIH Guidelines are available from the Office of Science and Policy, National Institutes of Health, 6705 Rockledge Drive, Ste 750, MSC 7985, Bethesda, MD, 20892-7985 or online at https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf.

Research Involving Animals: Applications submitted to CFF involving the use of animals must meet the guidelines of the National Institutes of Health found at <https://grants.nih.gov/grants/olaw/olaw.htm>, which require that all proposed studies be reviewed and approved by an Institutional Animal Care and Use Committee (IACUC). In addition, CFF awardee 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.

Validation and Submission

Prior to selecting “**Sign & Submit to AIO**”, please complete a thorough review of the entire application. The “**Sign & Submit to AIO**” button will trigger validation on all required fields and identify any upload errors or incomplete fields. Upon selecting Sign & Submit to AIO, the ability to edit the application will be locked pending review and approval by your AIO.

After selecting **Sign & Submit to AIO**, the applicant will receive an email asking them to sign the application FacePage electronically using Adobe Sign. Once signed by the PI, the FacePage will then be routed to the AIO contact that is listed on the application for review and signature.

To ensure the application is fully signed and submitted ahead of the Application Deadline for this program, please be sure to complete the application, and begin the Sign & Submit to AIO process in advance of the 5:00 PM EST deadline. The status of your application will display “Submitted” once fully signed, to indicate that your application has been received by CFF.

XI. Other Information

Not applicable to this RFA

XII. Contact Information

For technical support and program/content information:

Primary CFF GCMA Office contact Angela Minucci at aminucci@cff.org or 301-841-2614

For scientific questions:

Elizabeth Yu, Ph.D. at eyu@cff.org

XIII. Electronic Application Checklist

Application Deadline: Wednesday, March 1, 2023 at 5:00 PM (Eastern)

Submit online through: <https://awards.cff.org>

Face Page which includes:

- Signatures
 - Applicant
 - The Official authorized to sign on behalf of the Applicant Institution
- Applicant information (online)
- Complete Institution and Applicant Contact Information, including correct mailing address (online)
- Organization Assurances (check those that apply online/complete the required information)
- Human Subjects Certification
- Research Involving Recombinant or Synthetic Nucleic Acid Molecules information
- Research Involving Animals Information

Training Program & Supporting Documents:

- Biographical Sketches for Key Personnel - (upload)
- Mentor's Results of Past and Current CFF/CFFT Support - (upload)
- Other Support (NIH Format) - (upload)
- Facilities Available - (upload, if applicable)
- Budget Justification - (upload)
- Second Year Research Plan - (upload, if applicable)
 - Scientific Abstract
 - Hypothesis and Specific Aims
 - Background and Significance
 - Experimental Design and Methods
 - Literature Cited (not included in Research Plan page limitation)
- Mentor's List of Previous Fellows - (upload)
- Personal Statement (Previous Training and Future Plans)
- Training Plan - (upload)
- Appendices (upload, if applicable)
 - Certification of organization assurances (i.e. IRB, IACUC and IBC approvals), if applicable.
 - Up to three (3) reprints of the applicant's work relating to the general area of research in the proposal