

Award Type: Medical Resident Research Award 2022/2023

Brief Program Overview/Description: This award is part of the Cystic Fibrosis Foundation's Physician Scientist Training Program and is designed to introduce residents to research through participation in a CF-relevant research project with the goal to develop and maintain interest in a career in CF research or as a CF care provider.

Funding Amount: The maximum award amount is \$10,000 per year for one year (Direct Costs Only). Indirect costs are not allowable.

Eligibility:

- Applicants may be either U.S. citizens, permanent residents, or non-U.S. citizens working in a U.S. based institution. International applicants must have the ability to obtain the appropriate visas, as applicable.
- Applicants must have completed medical school training and hold an M.D., D.O., or equivalent degree.
 International applicants must be certified by the Educational Commission for Foreign Medical Graduates (ECFMG).
- Applicants must be enrolled in an ACGME accredited residency program in the U.S. for the duration of the award.

Key Dates:

Published September 7, 2022

LOI Submission Deadline NA
LOI Applicant Notified NA

Full Application Deadline Rolling through November 15, 2023

Committee Review Date NA

Notification to Applicants 8 to 12 weeks post submission

Earliest Project Start Date

As determined by applicant but at least 2 months after

submission

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.

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 supporting applications for the Medical Resident Research Award, 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.

The Medical Resident Research Award was first offered in 2022.

Medical Resident Research Award Overview

The CF Foundation offers the Medical Resident Research Award to introduce residents to research through participation in a CF-relevant research project. The goal of this program is to expose residents to research in an effort to develop and maintain interest in a career in CF research or as a CF care provider.

Diversity, Equity, and Inclusion Training

Awardees are strongly encouraged to supplement their career development in CF relevant 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.

III. Funding Amount

The maximum award amount is \$10,000 per year for one year (Direct Costs Only); indirect costs are not allowable. Award payments will be made to the Awardee Institution. *Note: Salary support may be requested solely for the Resident Applicant.*

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 must have completed medical school training and hold an M.D., D.O., or equivalent degree.
 International applicants must be certified by the Educational Commission for Foreign Medical Graduates (ECFMG).
- Applicants must be enrolled in an ACGME accredited residency program in the U.S. for the duration of the award.
- Applicants must work with a faculty mentor (i.e., Institutional Mentor) on a research project related to cystic fibrosis.
- The project duration should be at least 10 weeks.
- Recipients of these traineeships may reapply for support in a subsequent year.
- Awards are not transferable.
- If institutional policies prevent residents from being the applicant, please contact the Grants and Contracts Office and Program Officer listed at the bottom of these guidelines.

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

- The mentor(s) must be able to provide the mentorship needed to guide the project if awarded.
- The mentor(s) must be at the institution where the applicant will be carrying out the work for the project.

VI. Goals of Research Currently of Interest to CFF

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 Focus Areas:

- Understand the biological mechanisms of, and advance new and improved treatments to address the many complications of CF, including:
 - Infections affecting people with CF;
 - Lung transplant and advanced lung disease;
 - o 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);
 - Mental health;
 - Sinus disease;
 - Sexual and reproductive health.
- 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.
- 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.

• 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.

Funding priority will be placed on those projects that will lead to a better understanding of disease mechanisms, pathophysiology, and prevention, and treatment strategies.

VII. Review and Award

Applications are accepted throughout the year but should be submitted at least two (2) months prior to the projected start date of the project. CF Foundation staff review applications and awards are made on the basis of individual and institutional merit and the relevance of the proposed project to CF research priorities. In general, applicants will be notified whether applications have been approved or declined by email within eight (8) to twelve (12) weeks from submitting the application.

If awarded, payments will be made to the Awardee Institution in two (2) equal installments in accordance with the Terms and Conditions of the Award. The final installment will be issued after submission and approval of a final progress report and expenditure report. The final progress report should include the results and/or achievements of the project. All reports are due within 90 days after completion of the project or the final payment will be subject to forfeiture.

VIII. Submission Information

Application Deadline: Rolling through November 15, 2023

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	Rolling through November 15, 2023
Review	_ N/A
Notification to Applicants	8 to 12 weeks post submission
Project Start Date	As determined by applicant

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 prior to submitting an application. *Please note:* Applicants should register using the "Domestic Institution" or "International Institution" options to ensure that your profile aligns properly with the institution where the project will be conducted.

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 "Medical Resident Research Award 2022/2023" 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.

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.

Please note: Only select the "**Sign & Submit to AIO**" button after the application has been fully completed. This will trigger validation on all required fields and send the application to your Authorized Institutional Official "AIO" for review and signature through Adobe Sign.

GENERAL

Enter the title of your project, enter the project start and end dates, 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 10.

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 preloaded 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.

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

The CFF Grants and Contracts Office must have a copy of the applicant institution's current W-9 and 501(c)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 Grants and Contracts Office.

Applicants who have provided these documents within the past three (3) years are not required to resubmit them. However, if any of the above documents have been updated since they were previously submitted, please upload any updated documents. The CFF Grants and Contracts Office will contact applicants if documents are outdated or missing.

*Applicants must provide English translations for all non-English documents, including material provided in support of the Research Plan.

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.

See a How-To Guide Here: https://www.cff.org/sites/default/files/2022-01/Grants-Management-System-How-To-Guide-for-Active-and-Activated-Awards.pdf

REFERENCES

Letters of Support and Reference are weighted heavily in the review. At least two (2) Letters of Support/Reference are required as follows:

- Mentor (REQUIRED): A letter of support from the resident's Institutional mentor in support of their
 project and stating the applicant's educational experience, academic abilities, and research potential is
 required. The letter should also indicate the resident's research and/or clinical interest in CF and also
 any training or exposure the resident will receive during the traineeship period. If the mentor does not
 have prior publications or funding in CF, the letter should state how the trainee will receive CF-relevant
 training during the award period.
- Division/ Program Chief or Resident Program Director (REQUIRED): Please describe career and faculty
 development plans and opportunities, as well as institutional resources available and relevant to the
 applicant.

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 https://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.

*Senior investigators, or those who have received a prior CFF/CFFT Research Grant or NIH equivalent, are not required to submit Letters of Reference; however, if they are new to CF research, Letters of Support and/or Collaboration should be provided and uploaded as Appendices.

ABSTRACTS/RELEVANCE

Not Applicable to this RFA. Please enter **N/A** in these sections.

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 one (1) year. The maximum award amount is \$10,000. Indirect costs are not allowable.

The following budget categories are offered under this program:

Salaries & Benefits - List the names and positions of all professional and non-professional personnel involved in the project, whether or not salaries are requested. Indicate the percent effort on the project for all personnel. *Note: Salary support may be requested solely for the Resident Applicant*. 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 Grants and Contracts Office. **Travel expenses may not exceed \$1,250 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 not be requested.

Budget Detail – Indirect Costs

Indirect costs are not allowable

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 Sketch for Key Personnel
- Mentor's Results of Past and Current CFF/CFFT Support
- Budget Justification
- Research Plan
- Training Plan
- Personal Statement

Biographical Sketches for Key Personnel

Complete and upload an NIH Biographical Sketch for the applicant and primary mentor. International applicants can upload a biosketch that is equivalent in content to the NIH template provided. 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

Budget Justification

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

Research Plan - *Limit five (5) pages*

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
- 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 https://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.
- **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.

- 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 patient eligibility criteria, recruitment, and activities conducted during study visits. 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).

Training Plan

Provide a brief summary of the applicant's previous research and/or clinical 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 residency 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. This should also include a description of the applicants 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.

Personal Statement – *Limit two (2) pages*

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

Letters of Support

Letters of Support should be uploaded by the applicant from the following individuals:

- **CF Program Director(s):** If the proposed project includes recruitment of CF patients, the application must also include a letter from the CF Center Director where the study will be undertaken. This letter should indicate the ability of the CF Center to recruit the subjects for the study and also the willingness of the CF Center to participate in the study. If the Mentor is the CF Center Director, this information could be included in the Institutional Mentor's Letter. For international applications, this letter should come from the CF physician who will be responsible for recruiting subjects for the study.
- Additional Referees: Up to two (2) other individuals who were closely associated with the applicant during his/her medical training.

Appendices (upload as PDF documents) – *Limit five (5) uploads*

- Certification of organization assurances (i.e. IRB, IACUC and IBC approvals), if applicable.
- Any other materials pertinent to the proposal, not already described in these guidelines, that the institutional mentor may find relevant to the project, or that speaks to the applicant's capabilities and skills to carry it out.

*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 Grants and Contracts 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 Grants and Contracts 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 Grants and Contracts 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 Grants and Contracts contact Aimee Lee Russell arussell@cff.org or 301-841-2614

For scientific questions:

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

XIII. Electronic Application Checklist

Application Deadline: Rolling through November 15, 2022

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

e)
t the ilities
t