**Award Type:** Harry Shwachman Cystic Fibrosis Clinical Investigator Award 2023

**Brief Program Overview/Description:** The Harry Shwachman CF Clinical Investigator Award is part of the Cystic Fibrosis Foundation's Physician Training Program and is meant to provide the opportunity for promising, clinically trained physicians with a commitment to research to develop into independent biomedical researchers who have active involvement in CF-related areas. The award is intended to help facilitate the transition from fellowship training to an academic career as an independent investigator. The award enables candidates to undertake three years of research, tailored to the individual's interests and needs, with a mentor(s) who is/are competent to provide appropriate research guidance and supervision.

**Funding Amount:** This award provides support for three years at a level of up to **$130,000 in direct costs** per year (indirect costs are not allowable). Funds may be used to support up to $100,000 in personnel costs, including awardee or other research staff working on the proposed project, and up to $30,000 per year may be requested for supplies, travel, minor equipment, etc. Support is based on a full-time, 12-month appointment.

**Eligibility:**

- Candidates 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.
- Junior faculty and senior fellows are eligible to apply
- In general, a successful candidate has: (i) previous relevant research training; (ii) expertise in a related research technique; and (iii) a presentation or publication record that demonstrates research competence and productivity during fellowship (and beyond, if applicable)
- *Additional eligibility requirements can be found in Section IV below.*

**Key Dates:**

| | |
|---|---|
| Published | ~~December 7, 2022~~ **January 31, 2023 Updated** |
| LOI Submission Deadline | N/A |
| LOI Applicant Notified | N/A |
| Full Application Deadline | February 16, 2023 |
| Committee Review Date | Late-April 2023 |
| Notification to Applicants | Late-May 2023 |
| Earliest Project Start Date | July 1, 2023 |

**Table of Contents:**

## 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 the disease 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. |
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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 (HSA), and the LeRoy Matthews Physician-Scientist Award (LMA) annually.

The PTP has budgeted funding for seven HSAs in 2022.

### Harry Shwachman CF Clinical Investigator Award Overview

The Harry Shwachman CF Clinical Investigator Award provides the opportunity for promising, clinically trained physicians with a commitment to research to develop into independent biomedical researchers who have active involvement in CF-related areas. The award is intended to help facilitate the transition from fellowship training to an academic career as an independent investigator.

Successful applicants are typically pre-NIH K-award and need strong mentorship to establish themselves as independent CF researchers. Most are utilizing the HSA to develop their research record and solidify data that will be used as preliminary data for a K-submission. More established junior investigators with limited experience in CF research and in need of mentorship as they develop in the CF research space may also apply.

The award enables candidates to undertake three years of research, tailored to the individual's interests and needs, with a mentor(s) who is/are competent to provide appropriate research guidance and supervision.

**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, awards are not transferable to another PI or institution without prior written approval from the Program Officer.

## III. Funding Amount

**Salary** and **research expenses** not to exceed $130,000 in direct costs per year (indirect costs are not allowable), for up to three (3) years. This includes up to $100,000 for stipend (salary and benefits) and up to $30,000 for allowable research-related expenses per year.

**Allowable costs include:**

- Salary and fringe benefits, not to exceed $100,000 total
- Consultant Costs
- Patient Research Costs
- Consumable research supplies
- Subcontractor
- Tuition costs up to $3,000 per year may be requested
- CF-relevant travel costs of up to $2,000 per person annually
- Minor equipment purchases under $5,000

All other costs are not allowable without prior written approval from the CFF Grants & Contracts and Administration (GCMA) Office.

**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 GCMA Office for more information on this program.

**Childcare Supplement**
Shwachman award recipients are eligible for the Childcare Supplement Program. This program offers up to $2,500 per year to offset eligible childcare expenses. Please refer to the Child Care RFA on http://awards.cff.org or contact your Program Officer for more information on this program.

## IV. Eligibility

- Candidates 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.
- Junior faculty and senior fellows are eligible to apply. Applicants must hold faculty level positions. Fellows may submit applications; however, funding will only be considered if they will hold a faculty-level appointment at the time of the award.

- In general, a successful candidate has: (i) previous relevant research training; (ii) expertise in a related research technique; and (iii) presentation or publication record that demonstrates research competence and productivity during fellowship (and beyond, if applicable)
- Supplementation of salary from other sources is allowable
- A minimum of 70% of the applicant's time must be devoted to research. *Subspecialties that require a substantial commitment to clinical service (>30%) may be accommodated with a lower research commitment on a case-by-case basis at the discretion of the Program Officer (these include surgical and similar subspecialties)*

***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 applicant's training and research activities. Applicants are encouraged to have a either a CF Clinician or CF Researcher as part of their mentoring team.

Strong applications will describe how the selected mentor(s) will facilitate the applicant's development into an independent investigator within the CF research space. This may be demonstrated through mentor's past track record of trainees, clear descriptions of how a mentorship team will facilitate growth both within the applicant's institution and in their chosen research area, and letters of support that outline the planned relationship.

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

Proposed research must be relevant to the CFF's mission and to the health and well-being of CF patients. 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 not only on scientific merit but also on relevance to the CFF's 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.

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

CFF's Physician Training Programs (PTP) Committee will evaluate all applications. The PTP Committee recommendations are reviewed by the Board of Trustees. Funding of awards is based on the priority score awarded each application and the recommendations of the PTP. Relevance of the proposed study to issues in CF is also considered in determining awards. All research 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.

**In addition to scientific merit and relevance to the CFF mission, applications will be evaluated in the following areas:**

| Applicant | Mentor(s) | Environment | Training & Research Development Plan |
|---|---|---|---|
| • Commitment to, or intent to pursue, a research career related to CF<br>• Potential to develop an independent research career related to CF<br>• Research accomplishments, including publication/presentation record | • Established expertise in CF-related research or related research areas of high priority to CFF<br>• Commitment of the Mentor for the duration of the applicant's development and research plan<br>• Track record of the Mentor in training individuals for biomedical research<br>• Ability of the Mentor to support the applicant's career and training goals | • Quality (breadth and depth) of faculty in basic and/or clinical sciences related to CF at applicant institution<br>• Quality of institution's CF research and training programs<br>• Demonstrated interaction between basic and clinical investigators<br>• Institution's commitment and ability to provide opportunities and facilities necessary for research career development related to CF | • Feasibility and impact of the proposed plan<br>• Didactic course work required by the applicant (if indicated)<br>• Scientific and technical merit of the proposed research<br>• Ability of the proposed plan to develop research and analytical skills of the applicant needed for independence<br>• Relationship to applicant's career development<br>• 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
- Inadequate statement of hypothesis, experimental design, methods or analytical approaches
- Failure of the applicant to demonstrate awareness of and plans for coping with key problems and pitfalls associated with the proposed research
- Insufficient or improper controls, if applicable.
- Failure of the applicant to describe potential relevance of the proposed study to issues in CF
- Failure of the applicant to document the necessary skills or training to accomplish the goals of the proposal
- Failure of the applicant to meet all criteria described in the policy statement 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

## VIII. Submission Information

Application Deadline: Thursday, February 16, 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 _____ February 16, 2023
Review _____ Late-April 2023
Notification to Applicants _____ Late-May 2023
Earliest Start Date for Awarded Projects _____ July 1, 2023

## 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 "**Harry Shwachman CF Clinical Investigator Award 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 below Organizational Assurances and Certifications as cited on page 16.**

**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 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(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 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 four (4) Letters of Support/Reference are required as follows:

- **The Mentor(s) of the clinical fellowship training (or recent work as a junior investigator if the applicant is transitioning to CF post-fellowship)** – A Letter of Support from the fellowship Mentor(s) should clearly identify the merits of the applicant and must include a description of CF-specific and other training the applicant received while working under the Mentor's direction.
- **The Research Mentor(s) for this award –** The letter should clearly describe the role the research mentor will play in facilitating the applicant's growth in CF and/or other relevant areas. A clear commitment to the applicant and ensuring their development into an independent investigator in this research space is essential.
- **The CF Center Director(s) at the applicant (or nearby) institution**, if s/he is not the Mentor.
- **The Chair of the applicant's Department at the applicant institution** – The letter should clearly describe the institution's commitment to the professional growth of the applicant.

***Note:** If a letter from any one referee listed above fulfills two of the required roles, additional letters from references 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 four (4) letters.*

**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

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. This award provides support for three years at a level of up to **$130,000 in direct costs** per year (indirect costs are not allowable). Funds may be used to support up to $100,000 in personnel costs, including awardee or other research staff working on the proposed project, and up to $30,000 per year may be requested for supplies, travel, minor equipment, etc.

**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 professional personnel. For each individual, list dollar amounts separately for institutional base salary and fringe benefits. At least 70% of the applicant's time must be devoted to research. Total personnel costs

(salary and benefits) requested through this program cannot exceed $100,000 per year. 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.

**Consultant Costs** – Give the name and institutional affiliation of any consultant who has agreed to serve in this capacity, including statisticians and physicians in connection with the project if they are not listed under personnel. In the budget justification, briefly describe services to be performed, the number of days, rate of compensation, per diem and any other associated costs.

**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 racts Office. **Travel expenses may not exceed $2,000 per person per year**. Registration fees associated with conferences are in addition to this allowance should be listed under "Other Expenses".

**Patient Research Costs** – Funds may be requested for patient research costs specifically related to the proposed research. The basis for estimating funds requested in this category must be justified and applicants must provide detailed information regarding the proposed costs (e.g., number of procedures, cost per procedure, ancillary costs). The scientific need for patient research costs will be considered in the review. Negotiation of these costs are between the applicant institution and the service provider.

If approved as part of the application, patient research costs are capped at the amount requested in the budget and under no circumstances is CFF responsible for any costs that are later determined non-covered by third party insurers. Applicants and applicant institutions acknowledge that CFF is solely a provider of funding for the research performed under an approved award and not a sponsor of the research as defined by the FDA (21 CFR §312.3(b)).

**Subcontractors Summary –** If applicable, detailed budgets and budget justifications for each subcontract, including indirects, must be provided for each year of support. Subcontractors are added in the prior section entitled **CONTACTS**. The lead/prime applicant (PI) and/or Grants Officer can initiate/complete the subcontract budget. After adding Subcontractor(s), in order to access the subcontract budget activity, please select the "**BUDGET**" tab of the application and click the "Open" button next to each listed subcontractor. After completing the subcontract budget activity, please select "**Pending PI Acceptance**", as well as "**Submit**" to ensure the subcontractor budget is included as part of the main application budget.

For applications that include a subcontract with a third party, the applicant may request indirect costs on the first $25,000 of each subcontract per project period. Negotiations of subcontracts are between the applicant institution and the subcontractor.

**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, tuition costs (not to exceed $3,000), publication costs, minor equipment items under $5,000, conference registration fees, etc.

**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
- Research Plan
- Data Safety Monitoring Plan (if applicable)
- Training Plan
- Critique Response (if resubmission)

**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**

Provide justifications for costs listed in the Budget tab. 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 tab.

**Research Plan**

- Key figures and legends must be included in the Research Plan and should be of sufficient quality and size to be evaluated by the reviewer. If uploaded as Appendices, they will NOT be reviewed.
- At the top of each page, type the Principal Investigator's name. Each page must be sequentially numbered at the bottom.
- Page limit: Ten (10) single-sided pages, not including the Literature Cited. Applications exceeding this page limit will not be reviewed. 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.

  If your application is a resubmission of an earlier one, **your revisions should be clearly indicated by a change in font, bolded or underlined**. CFF will not review resubmissions that have not been revised.

  ***Note**: If applicants plan to conduct clinical research during their fellowship training, special attention should be given to Section 'd' of the Research Plan (Experimental Design and Methods for Clinical Research only) and, for studies that place human subjects at more than minimal risk, to the completion of the Data Safety Monitoring Plan (DSMP).*

**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, in particular in those areas listed as areas of special interest to CFF. 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. Preliminary Results:** If applicable, provide a detailed discussion of any preliminary results.

**d. Experimental Design and Methods:**

**For applicants proposing to carry out Basic Research through this support mechanism:**
Provide a detailed discussion of the experimental design and methods to be used to accomplish the specific aims. Describe the protocols, including methods for new techniques, and explain potential advantages over existing methodologies. Discuss the data expected to be obtained and the means by which data will be analyzed and interpreted. If human subjects 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. Point out any procedures, situations or materials that may be hazardous to personnel or patients and the precautions to be exercised.

**For applicants proposing to carry out Clinical Research through this support mechanism:**
Provide a detailed discussion of the experimental design and procedures to be used to accomplish specific aims. Please discuss: study hypothesis; primary and secondary outcome measures; study sample-inclusion and exclusion criteria; sample size estimates*; subject enrollment including age range; puberty status; gender distribution; randomization scheme if applicable; description of experimental procedures and schedule including a study time-line; drugs and dosage; measures of compliance; follow-up schedule including a study time-line for full project up to three years; efficacy and safety evaluation, data monitoring and quality control; and a description of your proposed data

analysis and statistical procedures for your hypothesis testing. Although no page limit is specified for this section, make every attempt to be concise and succinct.

***For sample size estimates,** please provide all estimates of means, standard deviations, rates or proportions used to calculate each of your sample size or power estimates. Please include in the statistical section whether you will use a one or two-tailed test, the power selected for such a test (if making a sample size calculation), and the reference for your sample size or power calculation. In instances of pilot studies where some of these parameters are unknown, we will accept your best estimates of the unknown parameters if preliminary data are not available, and if your calculation is a preliminary estimate before formal sample size can be calculated for a larger study. Please identify if you are making estimates from data or from personal estimates. This section must document access to adequate numbers of subjects.

Discuss the potential difficulties and limitations of the proposed procedures and alternative strategies for achieving the aims. If the Mentor(s) is not a CF Center Director or Co-Director, a letter of support from the Center Director is required.

e. **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).

**Data Safety Monitoring Plan (if applicable)**

***For clinical research projects only**

In compliance with Federal regulations, applicants whose proposed study places human subjects at more than minimal risk must submit a general description of the Data Safety Monitoring Plan (DSMP). A DSMP helps to ensure subject safety, as well the validity and integrity of the data. Furthermore, a DSMP allows for the monitoring of study data to assess whether or not an early termination is necessary for safety or efficacy reasons.

The extent of monitoring required for a study is dependent on the level of risk involved for the subjects, as well as the size and complexity of the study. Large, multi-center CFF-funded interventional clinical trials must utilize a Data Safety and Monitoring Board (DSMB). In addition, CFF may require that investigators utilize the CFF DSMB for any other interventional CF clinical trial that meets one or more of the following criteria:

- Multi-center;
- Randomized;
- Conducted in an emergency setting;
- Use high-risk interventions, such as gene therapy or gene transfer; or
- Include particularly vulnerable study populations, such as pediatric patients.

***Note:*** *On the available template, please check whether a DSMP is required and upload the template regardless of the response.*

**Address the following areas in the DSMP:**

**Assessment of Risk** – Describe the level of risk the proposed research presents to subject participants and provide a detailed justification for the level of risk. Discuss who will monitor the study.

**Level of Risk**

- Minimal Risk
    - Study poses no more risk than expected in daily life (blood draw, physical exam, etc.)
    - Observational studies

    - Survey or questionnaire studies
- Low Risk
    - Post-marketing study Phase IV drug or device, as defined by FDA
- Moderate Risk
    - Substantial risk (>5%) of a Serious Adverse Event (SAE) originating from the underlying condition of the enrolled subject
    - Phase I or II study with available safety data in humans
- High Risk
    - Involves an intervention or invasive procedure with substantial risk
    - Involves the use of a new chemical or drug for which there is little or no toxicology data in humans
    - A gene therapy study or research involving recombinant DNA molecules (gene transfer)
    - Involves vulnerable populations (pediatric, pregnant, etc.)

**Anticipated Adverse Events and Grading Scale** – Describe anticipated adverse events (AEs), including expected frequency and the grading scale to be used. Discuss plans for addressing AEs.

**Reporting of AEs** – Detail the plan for reporting AEs, including who shall be notified in the event an AE should occur.

**Safety Monitoring Plan –** Describe all tests, evaluations, and exclusion criteria that will be implemented to ensure and monitor the safety of human subjects. Discuss plans for stopping the study if necessary.

**Safety Reviews –** Describe the process for monitoring and reviewing subject safety data, including the frequency of such reviews. Include details as to who will perform the monitoring and plans for reporting. If this information is not available at the time of submission of the application, note that CFF will not release awarded payments until it is provided.

**Registrations for Investigator-Initiated Clinical Trials:**

- **Clinicaltrials.gov (United States):** Applicants are required to register all non-exempt human subject studies in the ClinicalTrials.gov database to ensure information is freely available on CFF-funded trials within the community. The registration should be no later than twenty-one (21) days after the first subject is enrolled. CFF requires copies of documentation confirming this registration, when applicable.

**CFF Patient Registry Data Request (if applicable)**
Researchers who wish to request Registry data for their proposed research study must complete and submit the "Application for CFFPR Data and Confidentiality Agreement"
application to datarequests@cff.org prior to submitting their full application to CFF. The formal application for CFF Patient Registry Data Requests can be found at https://www.cff.org/researchers/patient-registry-data-requests

Note: The application must be submitted using the online system available from the link above and the email from the system indicating receipt of the application must be uploaded to the submission. Funding is contingent upon approval to access registry data.

**CFF Biorepository Clinical Specimen Confirmation Letter (if applicable)**
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.

To request clinical samples to use in the proposed study, download and complete the template from https://www.cff.org/researchers/cf-foundation-biorepository Applicants should supply a letter from the clinical research program manager confirming samples are available for their use with their application, but such a letter is required before funding will be approved. For more information, contact JP Clancy, MD, senior vice president of clinical research at the CF Foundation, at jpclancy@cff.org.

Note: If available at the time of application, applicants must upload the confirmation letter provided by the CFF Clinical Research Program Manager to the application. Funding is contingent upon approval and availability to access clinical specimens.

**Training Plan**
The applicant, in conjunction with the Mentor(s) and division chief/department chair, 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 award 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 developing the applicant's successful career in 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.

Specifically, training plans are meant to clearly outline how mentorship, coursework, and other training undertaken during this award will facilitate accomplishment of the research goals, or career advancement. It should be clear to reviewers how gaps in prior education or training will be filled to ensure this project can be completed adequately and awardees are appropriately placed to accomplish the next step of their long-term career plan at the end of this award. Do not exceed five (5) pages.

**Critique Response**
If the application is a resubmission, please provide a point-by-point response to the prior reviews. There is no page limit to your responses, but please be concise and succinct.

**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: Thursday, February 16, 2023 at 5:00 PM (Eastern)

Submit online through: http://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

**Research Plan & 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)
- ☐ Research Plan - (upload, if applicable)
  - ☐ Hypothesis and Specific Aims
  - ☐ Background and Significance
  - ☐ Preliminary Results
  - ☐ Experimental Design and Methods
  - ☐ Literature Cited (not included in Research Plan page limitation)
- ☐ Data Safety Monitoring Plan
- ☐ Mentor's List of Previous Fellows - (upload)
- ☐ Training Plan - (upload)
- ☐ Critique Response – (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