

Program Name: Program for Adult Care Excellence (PACE) 2022

Brief Program Overview/Description: As the average life expectancy of patients with CF continues to increase, CFF recognizes the growing demand for physicians trained to address the unique medical needs of adult patients with CF and the need for greater participation from adult care programs in the clinical research enterprise. CFF will recruit another cohort of caregivers to the Program for Adult Care Excellence (PACE) in order to expand the scope of adult care programs by increasing the number of adult caregivers. Accordingly, CFF has released this Request for Applications (RFA) for PACE training awards to physicians interested in developing expertise in the care of adult patients with CF.

Funding Amount: Applicants may request up to \$41,142 per year, for three (3) years, plus an additional twelve percent (12%) of indirect costs may be requested. The total funding request may include:

- Salary of .15 FTE using the federal salary cap (\$203,700 in 2022) plus fringe benefits for the applicant
- Travel of up to \$3,000

Eligibility:

- Previous PACE awardees are ineligible to apply.
- All applicants must be either a citizen of the United States or permanent resident (must have obtained permanent residency prior to the time of application).
- Applicants must be physicians trained in Internal Medicine, Internal Medicine/Pediatrics or Family Medicine.
- Additional eligibility requirements can be found in Section IV. below.

Key Dates:

Published June 1, 2022 Full Application Deadline July 19, 2022*

Committee Review Date mid September 2022
Notification to Applicants September 2022
Earliest Project Start Date November 1, 2022

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

^{*}We strongly encourage all applicants pre-register their profile, institution, contacts, and Title of their application at least two weeks prior to the application deadline. This will help to ensure the CFF Grants & Contracts Management and Administration (GCMA) Office is able to assist all applicant with any potential system-related queries prior to the Application Deadline.

I. About the Cystic Fibrosis Founadtion

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.

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

II. Program and Award Overview

As the average life expectancy of patients with CF continues to increase, CFF recognizes the growing demand for physicians trained to address the unique medical needs of adult patients with CF and the need for greater participation from adult care programs in the clinical research enterprise. CFF will recruit another cohort of caregivers to the Program for Adult Care Excellence (PACE) in order to expand the scope of adult care programs by increasing the number of adult caregivers. Accordingly, CFF has released this Request for Applications (RFA) for PACE training awards to physicians interested in developing expertise in the care of adult patients with CF.

III. Funding Amounts

Applicants may request up to \$41,142 per year, for three (3) years, plus an additional twelve percent (12%) of indirect costs may be requested. The total funding request may include:

- Salary of .15 FTE using the federal salary cap (\$203,700 in 2022) plus fringe benefits for the applicant
- Travel of up to \$3,000

IV. Eligibility

- Previous PACE awardees are ineligible to apply.
- All applicants must be either a citizen of the United States or permanent resident (must have obtained permanent residency prior to the time of application).
- Applicants must be physicians trained in Internal Medicine, Internal Medicine/Pediatrics or Family Medicine.
- Applicants whose primary focus is on inpatient care (e.g. a hospitalist) will also be considered and are encouraged to apply. The sponsoring institution must have a CFF-accredited CF Care Center or affiliate program, and the CF Care Center or affiliate must have an existing adult program or meet the requirements for an adult program (at least 20 CF patients 18 years of age or older).
- A letter of support from the CF Care Center Director or Affiliate Director must be included in the application to confirm that the applicant will work in the Adult CF Clinic.

V. Mentorship Requirements

- The mentor of this award should be a CF Center or Affiliate Director outlining the plan for mentoring the applicant in the care of adult CF patients (not exceeding two pages).
- Participation in local CF Center teaching activities, care conferences, quality improvement activities, attendance at the annual North American CF Conference and any other mentoring activities should be included.

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

Not applicable to this RFA

VII. Review and Reward

The PACE Application Review Committee will evaluate all applications and make recommendations to CFF and the Board of Trustees for final approval and funding. CFF considers the availability of funds, the

priority score awarded to each application, and the committee recommendations when determining awards.

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

- Insufficient information or documentation
- Inadequate or absent documentation of the necessary skills, training and/or commitment to protected time
- Failure to meet all of the criteria described in this policies and guidelines statement
- Failure to describe career goals related to a long-term commitment to CF care/research

VIII. Submission Information

Applications deadline: July 19, 2022 by 5:00 PM (Eastern)

Submit online through 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 only documents submitted online at https://awards.cff.org will be reviewed.

General Timeline:

| Application Deadline | July 19, 2022* |
|--|--------------------|
| Review | mid September 2022 |
| Notification to Applicants | September 2022 |
| Earliest Start Date for Awarded Projects | November 1, 2022 |

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
- Each section should be numbered individually

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: http://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

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application. *Please note:* Applicants should register their profile 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 "**Program for Adult Care Excellence (PACE) 2022**" 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.

GENERAL

Enter the Project Start Date, and complete any additional questions. Also, please complete the organizational assurances indications (i.e. IRB approval letter and status at the time of submitting the application) in this section.

*Please ensure that you review and comply with the below Organizational Assurances and Certifications as cited at the end of this section on page 7.

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. Please be sure to use the dash formatting when entering your EIN/TIN (XX-XXXXXX). If the EIN/TIN is not located, you may 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 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.

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 optional contacts not associated with the applicant institution may also be added. These contacts would be considered as additional contributors involved in the proposed research plan. These may include consultants, collaborators, or subcontractors. If the desired external contact is not available in the system, you may select "Add External Contact" to create a basic contact profile in order to add the individual to your application.

REFERENCES

A letter of support from the CF Care Center Director, the Adult Program Director or Affiliate Director must be included in the application to confirm that the applicant will work in the Adult CF Clinic.

- A letter of support from the CF Center, Adult CF Program or Affiliate Diractor (required)
 - The letter of support from the CF Care Center, Adult CF Program or Affiliate Director must be included to confirm that the applicant will work in the Adult CF Clinic.
- Other letters of reference (optional, but recommended)
 - Up to two letters of reference from individuals who are familiar with the applicant's prior work record, interests, and abilities related to CF.

Letters of Reference must be submitted prior to submission of the application. To invite Referees, go to the "REFERENCES" tab of the online application, and first search for the referee using the lookup field. If the referee is not located in the system you may select "Add Referee" to create a basic contact profile in order to add the individual to the application. Once added, this will generate automated emails (with instructions) sent to each Referee. 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.

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. All PACE Awards are for a maximum of three years. The total budget requested cannot exceed \$41,142 per year for salaries & benefits, and travel expenses. An additional twelve percent (12%) of indirect costs may be requested.

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 travel being requested. Please note: 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 \$3,000 per person per year. Registration fees associated with conferences are considered as part of this allowance and must be listed under the "Other Expenses" category. Applicants are encouraged to attend the North American CF Conference each year to present their work.

Other Expenses – Other Expenses are limited to registration fees associated with conference attendance.

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:

- Budget Justification
- Biographical Sketches for Key Personnel
- Other Support
- Previous Training and Future Plans
- Proposed Mentoring Plan

BUDGET JUSTIFICATION

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

BIOGRAPHICAL SKETCH(ES) OF KEY PERSONNEL

CFF defines "Key Project Personnel" as any individual with an advanced degree who will play an instrumental role in the research project. An NIH Biographical Sketch form should be completed for each key project personnel and uploaded as PDF. The maximum length for each biosketch is five (5) pages.

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.

PREVIOUS TRAINING AND FUTURE PLANS

Provide a brief description (not exceeding one page) of previous clinical training and scholarly training, especially in CF, and a summary of future career plans. This section should note previous and anticipated clinical activities in general and particularly those related to CF such as special training or clinics.

PROPOSED MENTORING PLAN

This section should be completed in conjunction with the CF Center, Adult CF Program or Affiliate Director. It should outline the plan for mentoring the applicant in the care of adult CF patients (not exceeding two pages). Participation in local CF Center teaching activities, care conferences, quality improvement activities, attendance at the annual North American CF Conference and any other mentoring activities should be included.

APPENDICES (IF APPLICABLE)

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

- 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 may be uploaded in PDF format.

*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.

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.

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 Erik Warnke ewarnke@cff.org and grants@cff.org or 301-841-2614 Secondary CFF GCMA Office contact Edwin Gregorian at egregorian@cff.org or 301-841-2614

For scientific questions:

Bruce Marshall, M.D., bmarshall@cff.org and Alyssa Maher, amaher@cff.org