

Program Name: EnVision CF: Emerging Leaders in CF Endocrinology III Program 2023

Brief Program Overview/Description: The CFF recognizes the growing demand for physicians trained to address the unique endocrine and reproductive health needs of CF patients and the corresponding need for clinical research in this domain. CFF releases this award to fund training for physicians interested in developing expertise in the endocrine and reproductive health care of patients with CF.

Funding Amount: Applicants may request up to \$54,000 per year, for three (3) years, plus an additional twelve percent (12%) of indirect costs.

Eligibility:

- Previous recipients of the EnVision award are not eligible to apply.
- 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.
- Applicants must be physicians trained in Internal Medicine or Pediatrics with a subspecialty certification in endocrinology or must be a physician trained in reproductive health.
- Fellows may submit applications; however, funding will only be considered if they will hold a faculty-level appointment at the time of the award.
- Preferred applicants will be assistant professors or instructors at an academic institution associated
 with a CFF-accredited CF Care Center or Affiliate program at the time of the award start date. Earlycareer associate professors with a strong track record of academic work in the field of CF who would
 benefit from senior mentorship will be considered.
- Applicants should be within six years of completion of post-graduate training at program onset.
 Faculty further out from fellowship who are committed to a career focus change to include CF endocrinology will also be considered.
- Additional eligibility requirements can be found in Section IV. below.

Key Dates:

Published December 19, 2022

Full Application Deadline February 15, 2023

Committee Review Date March 2023

Notification to Applicants April 2023

Project Start Date April 1, 2023 July 1, 2023

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^{*}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.

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I. About the Cystic Fibrosis Foundation

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 and clinical care in CF.

II. Program and Award Overview

The CFF recognizes the growing demand for physicians trained to address the unique endocrinologic needs of CF patients and the need for a greater endocrine focus in the clinical research enterprise. CFF releases this award to fund training for physicians interested in developing expertise in the endocrinologic care of patients with CF. CFF will award up to \$54,000 per year for three years for salary support (including fringe benefits), travel and registration for the awardee. Of the \$54,000, up to \$4,500 for travel and \$500 for NACFC conference registration may be requested each year for the awardee. Travel funds will cover the annual North American CF Conference (NACFC) each fall as well as travel to a program meeting each Spring. An additional 12% for indirect costs may be requested. This award is for 20% protected time for three years.

III. Funding Amounts

Applicants may request up to \$54,000 per year, for three (3) years, plus an additional twelve percent (12%) of indirect costs. The total funding request may include:

- Salary of 0.20 FTE using the federal salary cap (\$203,700 in 2022) plus fringe benefits for the applicant
- Travel of \$4,500 per year
- North American CF Conference Registration Fees of up to \$500 per year

IV. Eligibility

Applicants must be physicians trained in Internal Medicine or Pediatrics with a subspecialty certification in endocrinology or must be a physician trained in reproductive health. They must be an assistant professor or instructor at an academic institution associated with a CFF-accredited CF Care Center or Affiliate program and be within six years of completion of post-graduate training at program onset. Faculty further out from fellowship who are committed to a career focus change to include CF endocrinology will also be considered. Training and endocrinologic care of patients must be coordinated through a CFF-accredited Care Center or Affiliate program. Centers may submit a maximum of two applications, with only one each from a pediatric physician and an internal medicine physician from the same institution. Previous recipients of the EnVision award are not eligible to apply.

Summary of additional criteria:

- 1. Applicants must spend at least 10% of the time in CF clinical activities including CF endocrine or reproductive health clinic and other activities to increase their clinical understanding of this population (general CF clinic, CF inpatient rounds, and CF team conferences).
 - An additional 10% of time may be divided between CF clinical endocrinology care and CF scholarly activities.
- 2. Academic activities are expected. Examples include curriculum published on MedEdPORTAL, case reports, reviews, chapters, peer-reviewed publications, QI projects, individual clinical research

- projects, multicenter clinical projects, and bench research.
- 3. Applicants will be matched in clusters of 3-4 with a national expert mentor. It is not necessary for applicants to identify their own mentors.
- 4. The applicant must be available to travel to a kick-off meeting at NACFC in November 2023, and attend two face-to-face program meetings (NACFC and Spring Meeting) per program year.
 - North American CF Conference
 - o Phoenix, AZ November 1-4, 2023
 - o Boston, MA Sept 26-28, 2024
 - o Fall 2025 TBA
 - EnVision III Spring Meeting each year.
- 5. There will be a mandatory monthly webinar. Over the three-year period, each mentee will lead one webinar-- either a journal club or a case presentation. Journal clubs and case presentations will alternate monthly.
- 6. A letter of support from the CF Care Center Director AND a letter of support from the Chief of Endocrinology are required with the application.
 - The letter of support from the Division Chief must affirm the applicant's availability for the activities and meetings stated in this list. It must explicitly state the applicant's clinical responsibilities and guarantee the 20% protected time.
 - The letter of support from the CF Care Center Director or Affiliate Director must detail how the applicant will be integrated into the CF Care Center program.
- 7. Submission of annual progress reports as outlined in the award letter.

The applicant must explicitly agree to the following:

- 1. CF-CFRD/endo or CF reproductive health clinics, starting at half a day at least twice per month, and increasing as the practice builds; attending other clinical CF activities on non-clinic weekly half days. The candidate's current total number of expected half-day clinics per week and weeks on service per year (including non-CF) must be stated in the application so protected time can be estimated.
- 2. Attend the kick-off meeting plus two face-to-face meetings per year as detailed above.
- 3. Attendance at eight of the ten monthly webinars per year (2nd Friday, 7:00am pacific, 9:00am central, 10:00am eastern).
- 4. Lead at least one webinar over the three-year award period.
- 5. Monthly Zoom or conference calls with assigned national faculty mentor.
- 6. At least one abstract must be presented at NACFC, and one manuscript submitted over the three-year award period. These can be first author or collaborative submissions.

V. Mentorship Requirements

- The EnVision program will assign each mentee to a small team led by leaders in the field of CF endocrinology or reproductive health.
- Mentorship in the general field of CF is expected from the local CF Program or Affiliate Program Director.

The application should outline the plan for this local mentorship in the general care of CF patients. Plans for participation in local CF Center teaching activities, care conferences, quality improvement activities, and any other local mentoring activities should be described.

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

Not applicable to this RFA

VII. Review and Reward

The EnVision CF 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.

Selection criteria is based on the following:

- The applicant's interest in CF (preference will be given to those who can show a history previous engagement with CF patients and projects as evidence of interest)
- The commitment of the CF Center Director to integrate the applicant into the CF clinic/program
- The Division Chief's commitment to support and protect the time of the Emerging Leader in CF endocrinology
- Consideration will be given to distribution by adult/pediatric specialties, geographic distribution and need including the availability of CF endocrine support in the region, and area of academic interest across the spectrum of CF endocrine disease.

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 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: February 15, 2023, 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	February 15, 2023*
Review	_ March 2023
Notification to Applicants	_ April 2023
Project Start Date	July 1, 2023

^{*}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.

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 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 "EnVision CF: Emerging Leaders in CF Endocrinology III 2022 (Re-Launch)" 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 8.

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.

<u>Verification of Applicant Institution's Tax Status (upload as PDF documents):</u>

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 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, and collaborators. In order to add contacts external to the applicant institution, please select the appropriate "Add Consultants/Collaborators" button(s) and add the contacts in the table, then click "Save".

REFERENCES

This section will appear if you have selected "Yes" for the question on the **GENERAL** tab "**Are you a junior investigator?**" For this program, please select "Yes" even if you are not considered a junior investigator so that the **REFERENCES** tab will appear. References outlined below are required for this program:

- A letter of support from the CF Center Director (required)
 - The Emerging Leader is expected to spend at least 10% of time in CF clinical activities. The letter of support from the CF Center Director must document the structure of the CF endocrinology clinic (for example, embedded within the CF clinic or separate, but on the same floor), how CFRD education and carbohydrate counting instruction will be handled in clinic, and how the Emerging Leader will be integrated into the team on non-clinic days. Participation in local CF Center teaching activities, care conferences, quality improvement activities, and any other mentoring activities should be included.
- A letter of support from the Division Chief (required)
 - The Division Chief's letter must affirm a commitment to protect the applicant's time for program activities including monthly webinars, twice yearly national meetings, at least 10% time for clinical activities, and up to 10% time for scholarly activities (20% total). The candidate's current total number of expected half-day clinics per week and weeks on service per year (including non-CF) must be stated in the application so protected time can be estimated.
 - The program provides mentorship and protected time for scholarly activities, but not funding for those activities. Please describe the internal sources of funding for scholarly activities, if available.
- 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, then select the blue button to open a pop-up window in order to add the referees in the table. You must click "Invite" in order to trigger the e-mail to the referee. The referee(s) 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.

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 EnVision Awards are for a maximum of three years. The total budget requested cannot exceed \$54,000 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 \$4,500 total per person per year. Registration fees associated with conferences of \$500 per year 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
- Personal Statement
- 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.

PERSONAL STATEMENT

Provide a personal statement (not to exceed 2 pages) that addresses the applicant's interest in the topic and this project, the applicant's perception of his/her role in the project, and the applicant's career goals and commitment to a career in CF.

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 (If applicable)

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.

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 Face Page electronically using Adobe Sign. Once signed by the PI, the Face Page 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 programmatic question:

Whitney Brown, M.D. at awbrown@cff.org