



For application technical support, please contact [ewarnke@cff.org](mailto:ewarnke@cff.org)

**Program Name:** 2023 Research Additional Mentoring Program (RAMP)

**Brief Program Overview/Description:** The Cystic Fibrosis Foundation (CFF) announces the CF Research Additional Mentoring Program (RAMP). The RAMP Award is designed to enable promising early-career physician scientists seeking additional research mentoring outside of their home academic institutions to enhance their clinical or translational research proficiency and support their development of the necessary clinical research capabilities to become independent investigators. The overarching purpose is to support local academic leaders in CF to strengthen CF clinical and research programs while leading or conducting single or multi-center clinical research studies. Research goals may also be translational but should have strong clinical relevance and incorporate human specimens and clinical data from people with CF donating such specimens.

**Funding Amount:** Individual Salary support requested may not exceed 20% of the NIH salary cap (currently \$212,100) and is limited to \$42,420 per year, for up to three years. In addition, the award will cover institutional fringe benefits for the salary, as well as travel for each year as outlined in Section III below.

**Eligibility:**

- U.S. citizens, U.S. permanent residents (must have obtained permanent residency prior to the time of application), and Canadian Citizens are welcome to apply.
- Applicants must be licensed physicians (MD/DO) affiliated with an accredited CF Program.
- *Additional eligibility requirements can be found in Section IV below.*

**Key Dates:**

|                            |                 |
|----------------------------|-----------------|
| Published                  | March 20, 2023  |
| Full Application Deadline  | May 23, 2023    |
| Committee Review Date      | July 2023       |
| Notification to Applicants | August 2023     |
| Project Start Date         | October 1, 2023 |

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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.

## II. Program and Award Overview

The Cystic Fibrosis Foundation (CFF) announces the Cystic Fibrosis Research Additional Mentoring Program (RAMP) Award. **The RAMP is designed to support promising early-career physician scientists in-need-of or seeking mentoring in CF research outside of their home institutions. The RAMP will pair early career investigators with more established CF researchers who will serve as mentors to enhance clinical or translational research proficiency and support academic research career goals.** The RAMP is specifically intended for investigators who will substantially benefit from additional CF research mentoring support outside of their home institution and is not intended to support existing distance mentoring activities. This program is suited for clinical investigators and certain translational researchers who rely heavily on human samples and clinical data from people with CF. Early career researchers in basic science or quality improvement science are less likely to benefit from the RAMP and should identify other more suitable programs. Those with strong local mentorship in place and those interested in developing larger, multi-center clinical research programs are encouraged to apply for the CFF/TDN Clinical Research Scholars Program (CRSP). Applicants must be affiliated with an accredited CF Program, and priority for the RAMP program will be given to applicants from smaller CF Care Centers that likely have fewer on-site mentoring resources.

### Program Structure:

Awards will provide early-career faculty the opportunity to undertake up to three years of support (up to 20% FTE per year) for their research training and mentoring. This dedicated time will be used for career development with a focus on the initiation and conduct of prospective clinical and translational investigations. Clinical investigations may be observational or interventional and should provide a strong basis for research mentoring and career development toward future funded research. Importantly, the RAMP award does not fund the research project itself, and strong candidates will apply with funding for a research project that will provide the framework for this mentoring and training program.

- **Year 1** – The first year of the program will consist of three main activities: remote mentoring meetings, engagement and service on one or more CF research network committees, and an annual in-person research career development retreat. For interactive, distance-training and mentoring, awardees will be organized into small groups and paired with a similar number of research mentors who represent accomplished CF investigators. Mentors will be identified by the CF Foundation. Group virtual meetings will occur monthly, and additional one-on-one meetings between awardees and one or more of the mentees will be encouraged as necessary. All awardees will be expected to join and serve as a member of a CF research committee based on their research interests and abilities (e.g. the TDN Protocol Review Committee, various grant review committees, Data and Safety Monitoring Committee, etc.). Work with mentors may include reviewing works in progress, identifying and conducting secondary data analyses, writing or revising an applicant's future research proposal, and navigating key academic career decisions.
- **Years 2 and 3** – The second and third years of the program will provide the opportunity to further develop skills through continued mentorship, though standing meetings may become less frequent. Future research goals, sustained grant support, and academic career development should be prioritized in later years. Applicants will be encouraged to continue to participate on CF research committees. Annual in-person mentoring, and career development meetings organized by the CF Foundation will occur each year, and RAMP awardees should plan to attend (travel expenses paid through this award).

### **Program Learning Objectives:**

- Provide research mentorship to enable rigorous CF clinical and translational science by applicants seeking additional mentoring resources beyond their home institution.
- Through training and committee participation, increase appreciation for regulatory aspects of clinical trials conduct and drug development.
- Increase proficiency in developing formal clinical or translational research protocols that consider the current state of science in CF.
- Support growth in research study design, including analytical and statistical requirements.
- Increase awareness and opportunity for secondary data analysis or utilization of human biospecimens held in the CFF repositories.
- Improve quality of research proposals in order to increase the rate of success in obtaining funding.
- Provide applicants with the opportunity to serve on relevant CF research committees as both service and educational activities.
- Provide outside experienced mentorship to assist in making key academic career decisions.

### **Requirements:**

- Awardees are expected to submit informal progress reports to their Mentors throughout the project period. Reports are required monthly during Year 1 and at a mutually agreed upon frequency for years 2 and 3.
- Awardees are expected to attend monthly group mentoring sessions by videoconference and will present at these sessions on a rotating basis (i.e. 3-4 times each year).
- Duration and Effort – this is a non-renewable award for up to three years of salary support. Support is divided into three distinct years that relate to the individual's progress in becoming an independent investigator. Awardees are required to devote at least 20% effort to research, and, if possible, to the Research Additional Mentoring Program (RAMP) throughout the entire project period<sup>1</sup>. This award does not serve to fund the research project itself, but rather protect the awardee's time for career development in clinical and translational research. If receiving this RAMP award will put the applicant's current effort over 100%, a statement on how the effort will be adjusted to ensure appropriate involvement in the program is required.
- Minimum Requirements - Awardees must agree to inform the 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 and Terms and Conditions of Award.

### **III. Funding Amount**

- Individual Salary support requested may not exceed 20% of the NIH salary cap (currently \$212,100) and is limited to \$42,420 per year, for up to three years. In addition, the award will cover institutional fringe benefits for the salary.
- If an applicant is a recipient of another career development award that protects at least 70% of their effort for research AND they are unable to commit an additional 20% effort to research for this award, the equivalent amount to 20% of the applicant's calculated base salary may be requested for salary to support staff relevant to the work proposed to this program (e.g. biostatistical support for the clinical study proposed).
  - Minimal Level of Effort required for the PI is 5%.
  - The remaining percentage of the PI's calculated base salary may be distributed among appropriate support staff. The total salary support may not exceed 20% of the PI's salary or \$42,420.
  - Fringe may be applied separately in addition to these cost limitations.

- Travel Support may be requested for each year as follows (registration costs associated with the below meetings are part of the funding allotments, but should be listed under “Other Expenses” in the Budget Detail template):
  - **Year 1** (*up to \$12,500 may be requested*)
    - 2023 NACFC meeting, November 1-4, 2023 Phoenix, AZ
    - 2024 CFF Career Development Retreat- date and location TBD
    - 2024 NACFC meeting – September 26-28, 2024 Boston, MA
    - Additional CF or scientific meeting directly supportive of the research project
  - **Year 2** (*up to \$2,500 may be requested*)
    - 2025 CFF Career Development Retreat- date and location TBD
  - **Year 3** (*up to \$5,000 may be requested*)
    - 2025 NACFC meeting – October 23-25, 2025 Seattle, WA
    - 2026 CFF Career Development Retreat- date and location TBD

***Due to restrictions on travel resulting from the COVID-19 pandemic, awardees may reallocate these expenses to relevant training costs upon approval by the CF Foundation Program Officer.***

**Allowable costs include:**

- Salaries and fringe benefits
- Travel
- Other Expenses – registration fees associated with required travel

**Indirect Costs are not allowable**

**IV. Eligibility**

- Applicants at US academic institutions must be U.S. citizens or permanent residents (must have obtained permanent residency prior to the time of application). Canadian citizens or permanent residents are also welcome to apply.
- Environment – applications are encouraged from academic institutions with:
  - An existing CF clinical program.
  - Strong research environment (CF or otherwise) that will support the career and scientific goals of the applicant.
  - A commitment from senior faculty at the applicant’s home institution with the capability to provide guidance and mentorship to applicants in the development of independent careers as cystic fibrosis researchers and clinicians.
- Applicants may only apply to either the 2023 RAMP or 2023 Clinical Research Scholars Program (CRSP). If you have already submitted an application to CRSP, CFF reserves the right to administratively withdraw your application.
- Applicants eligible for the program must have completed subspecialty training (as an MD or DO) and have an academic faculty appointment at their home institution at the time of application. Priority will be given to early career faculty who are within 7 to 10 years of completing their subspecialty training. In some cases, consideration will be given to mid-career faculty who are making a transition in their career/research focus and for which this program would provide the training necessary to lead clinical research studies.
- Prospective applicants will need to demonstrate sufficient commitment to and experience in CF clinical or translational research to support the rationale for participating in this program at this time in their career. This program is not suitable to support strictly basic science (i.e. laboratory only) research. Ideal candidates will be funded to lead an ongoing or upcoming clinical research study (or critical translational or data analyses aims) that can be directly applied to program objectives and mentoring opportunity.

- Applicants with significant local research mentorship in place or those interested in developing and leading larger multi-center clinical research programs should consider the CFF/TDN Clinical Research Scholars Program (CRSP).
- Applicants with existing career development awards should assess the compatibility of this program with the stipulations of those awards (e.g. K-awards, others) and reach out to the Program Officer ([eyu@cff.org](mailto:eyu@cff.org)) with questions.
- Prospective applicants will be required to outline key mentorship needs in support of their growing research skills and goals. Ideally, this will incorporate both local mentors and additional training and mentoring that may be provided as a RAMP awardee.

## V. Mentorship Requirements

- Mentor – each applicant must identify a primary Academic Mentor from their home institution who is committed to their academic and research career success. Local mentors are not expected to be experts capable of providing all mentoring needs but must demonstrate commitment to the research and career goals of the applicant. Local mentors need not be CF-focused researchers.
- Applicants with significant clinical or teaching requirements should provide letters of support from their Division or Department, as appropriate, to ensure that the funding from this award will allow greater protected time to focus on research career development and sustained research activities.

## 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:

- Understand the biological mechanisms of, and advance new and improved treatments to address the many complications of CF, including:
  - Infections affecting people with CF;
  - Lung transplant and advanced lung disease;
  - Inflammation, impaired airway hydration, and mucus clearance;
  - Serious complications of CF outside the lungs, such as GI complications (including in the liver, the pancreas, and the impact of nutritional deficiencies), endocrine system dysfunction (including CF related diabetes and CF bone disease);
  - Mental health;
  - Sinus disease;
  - Sexual and reproductive health.
- Characterize the best CF care and treatment regimens to provide optimal, individualized care as the CF treatment landscape evolves.
- Improve understanding of system-level and societal barriers to optimal CF care and explore opportunities to minimize their effects, including racial disparities and socioeconomic barriers to equitable care.
- Treat the underlying cause of CF for all people with the disease and drive progress toward a cure. In particular, research related to **evaluating genetic-based therapies** that may have clinical impact for people with CF, developing therapies that address the **underlying cause of CF for individuals with nonsense and rare mutations**, and **improving and better understanding cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapies**.

## VII. Review and Award

The RAMP Application Review Committee will evaluate all application 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 each application, and the committee recommendations when determining awards. The below review criteria are utilized for the CRSP proposal:

### RAMP Proposal Review Criteria

- The Applicant
  - Competence in clinical activities related to the needs of people with CF
  - Commitment to research related to CF and a career with substantial effort committed to clinical or translational research (e.g. ≥30% of professional effort).
  - Clear rationale to seek and benefit from additional research mentoring outside of one’s home academic institution
- The Environment
  - Need for remote mentorship in CF due to limited access to CF-focused investigators at the applicant’s home institution. This may be due to small size of the affiliated CF Care Center (and therefore fewer faculty with CF research experience), or due to a lack of expertise on-site in the applicant’s research area of interest or subspecialty in CF
  - Institution’s commitment and ability to provide the opportunities necessary for the clinical and research career development related to CF
  - Institution’s commitment to the applicant’s overall academic career development
- Applicant Project Proposal
  - Feasibility and value of the proposed plan, including separate awarded funding to conduct the scientific work
  - Clinical/translational research merit of the proposed research and an ability to use this to facilitate the training and mentoring goals of this program
  - Ability of the proposed plan to develop the applicant into a research investigator
  - Relationship to the applicant’s career development

### Payments

Payments for successful proposals are made quarterly in arrears to the Awardee Institution and not to the individual Awardee. Payments are subject to various contingencies, such as a Signed Assurances, Progress Report and Financial Reporting.

## VIII. Submission Information

**Application Deadline: May 23, 2023 at 5:00 PM EST**

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

(Refer to Section IX and 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:**

|                            |       |                 |
|----------------------------|-------|-----------------|
| *Full Application Deadline | _____ | May 23, 2023    |
| Review by Committee        | _____ | July 2023       |
| Notification to Applicants | _____ | August 2023     |
| Award Start Date           | _____ | October 1, 2023 |

## IX. Letter of Intent Guidelines

*Not applicable to this RFA*

## X. Full Application Guidelines

**Full Application Deadline: Tuesday, May 23, 2023 at 5:00 PM (EST)**

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 (GMS), 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. **Please note:** Applicants should register using the “Domestic Institution” or “International Institution” options to ensure that your profile aligns properly with the institution where the project will be conducted.

We also request that as you begin your application, you enter the title of your project, if available. If you are registered and cannot remember your password, click on the “**Forgot Password?**” link below the “**Login**” fields.

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

Locate the listing for the “**2023 Research Additional Mentoring Program (RAMP)**” program. Click on the “Apply” button in the column on the far right to open the application form.

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

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

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

## GENERAL

Enter the title of your project, enter the project start and end dates, select the number of periods being requested, and complete any additional questions. Also, please complete the organizational assurances indications (i.e. IRB, IACUC, and/or IBC/rDNA approval letter and status at the time of submitting the application) in this section.

**\*Please ensure that you review and comply with the Organizational Assurances and Certifications as cited below.**

## 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-XXXXXXX).** 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.
- 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):

Applicants whose institution is not a United States based-entity are required to provide additional information and complete a CFF International Institution Form. The completion of this form also includes submission of additional documentation.

## CONTACTS

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

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

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



## REFERENCES

Letters of Support and Reference are weighted heavily in the review. At least three (3) letters are required. Letters must be submitted by the following individuals:

- **Academic/Local Mentor(s) for this applicant**
- **The Chair of the applicant's department at the applicant institution.**  
Letters from the Academic Mentor and the Department Chair should clearly describe the Institution's commitment to the professional growth of the applicant. The Chair's letter must affirm a commitment to protect the applicant's time for program activities, including travel to meetings required for this award.
- **CF Center Director**  
The CF Center Director at the applicant institution (or nearby) institution (if the same person as the Academic Mentor, there is no need to submit duplicates).
- **At least one (1) other individual familiar with the applicant's scientific interests and abilities**  
These individuals must be familiar with the applicant's CF-related research and care; consider including previous preceptors and mentors. The letter of recommendation should attest to the applicant's academic qualifications, motivation, research potential and commitment to CF related research and care.

**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) that will be sent to each Referee. **The applicant will not be alerted when a reference is completed or declined; 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. All RAMP awards are for a maximum of three (3) years.

### **The following budget categories are offered under this program:**

**Salaries & Benefits** - List the names and positions of all professional and non-professional personnel involved in the project, whether or not salaries are requested. Indicate the percent effort on the project for all personnel. 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 \$212,100. Individual Salary support requested may not exceed 20% of the NIH salary cap and is limited to \$42,420 per year, for up to three years. In addition, the award will cover institutional fringe benefits for the salary. 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** – Funds may be requested for award-related travel costs. Awardees are required to attend a CFF Career Development Retreat, and the annual North American CF Conference (NACFC) (see Section III. above for the schedule of required meetings). Registration fees associated with conferences should be listed under “Other Expenses” and are counted as part of the per year travel support allotment.

**Other Expenses** – Itemize meeting/conference registration fees related to above required meetings.

### **Budget Detail – Indirect Costs**

Indirect costs are not allowable.

## FULL APPLICATION UPLOADS

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

- Research Plan
- Budget Justification
- Biographical Sketches of Key Personnel
- Other Support
- CF-Related Activities of the Academic Mentor and Applicant Institution
- Previous Training and Future Plans
- Future Career Goals
- International Institution Form (if applicable)

### **Research Plan (template available for download)**

- Key figures and legends must be included in the Research Plan. If uploaded as Appendices, they will NOT be reviewed.
- At the top of each page, type the applicant’s/PI’s name. Each page must be sequentially numbered at the bottom.
- Page limit: Five (5) single-sided pages, not including the Literature Cited. Applications exceeding this page limit will not be reviewed. Include sufficient information to permit effective review without reference to previous applications. Information should be presented in a clear and concise manner, while being specific and informative.
  - a) **Hypothesis and Specific Aims:** State concisely and realistically the intent of the proposed research and the hypothesis to be tested. The specific aims should be relevant to the mission of

the Cystic Fibrosis Foundation. Do not exceed one page.

- b) **Background and Significance:** Briefly describe the background of the present proposal. Critically evaluate existing knowledge and specifically identify the gaps that the project is intended to fill. Concisely state the importance and rationale of this research by relating the specific aims to longer-term objectives. This section should also show the potential importance of the proposed work to CF. In addition, the applicant should describe the relationship of the proposed work to his/her long-term career goals. Description of how the RAMP participation builds off of on-going research efforts is encouraged. Note: This award does not include support for research costs.
- c) **Preliminary Results:** If applicable, provide a detailed discussion of any preliminary results.
- d) **Experimental Design and Methods:** As described in the introduction, the optimal applicant will be one who has an ongoing or upcoming clinical or translational research study or trial that can be directly applied to program objectives. Provide a detailed discussion of the ongoing or proposed study 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. If applicable, discuss the data expected to be obtained and the means by which data will be analyzed and interpreted. Provide details of the methods for patient selection and care, as applicable. Discuss potential difficulties and/or limitations of the proposed procedures and alternative approaches to achieve aims. As applicable, please specify facets of the project that are clearly defined and those that need further development.
- e) **Benefit of this training award toward successful completion of the planned research:** As noted above, it is important to explain how this unique support and training opportunity will directly advance the research project of the applicant. This is separate from considerations of career development in CF. Please address this consideration either as a separate section or as part of sections above when discussing the experimental hypothesis, specific aims, design and methods. Note that the protected effort provided by the RAMP award is not intended to provide enough time to complete a research project but rather is designed to allow protected effort for *additional* training and program participation to enhance the project and career success of the scholar. For example, the RAMP award may critically support a research project by helping the investigator to: refine a study hypothesis, identify appropriate outcome measures, better understand and defend study inclusion and exclusion criteria, refine sample randomization scheme, study time-line, or procedures, improve measures of compliance, ascertainment of response variables, data collection and monitoring, and/or refine data analysis and statistical procedures for your hypothesis testing.
- f) **Literature Cited** (not included in the five (5) page limit): 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)

### **Budget Justification**

Describe costs listed in the Budget Detail. Use major categories, such as Salary & Benefits, Consultant Costs, Major Equipment, etc. Justify all items and make sure amounts and figures listed in the narrative are consistent with those listed in the Budget Detail. For Salary and Benefits, if choosing to allocate 20% of the applicant's salary to support staff relevant to the work proposed to this program, clearly explain why this is being requested.

### **Biographical Sketches of Key Personnel (template available for download)**

Complete and upload an NIH Biographical Sketch for all key project personnel, beginning with the applicant/PI (CFF defines "key project 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.

**Other Support (template available for download)**

Complete and upload an “Other Support” form, for all key project personnel, beginning with the applicant/PI. There is no page limitation.

**CF-Related Activities of the Academic Mentor and Applicant Institution (template available for download)**

Describe fully the CF related clinical and research activities of the applicant institution. The Academic Mentor and the applicant institution should also include a list of their previous trainees (past 10 years) and the current affiliations of these trainees.

**Previous Training and Future Plans (template available for download)**

Prepare a brief summary of the applicant’s previous research and/or clinical fellowship training, including the reasons for entering fields related to CF research and care. In conjunction with the Academic Mentor, a future training plan should be completed in and should outline the general plan for training the applicant in CF-related research. Participation in supplemental course work and special seminars should be included. Further, this section should clearly indicate plans for introducing the applicant to leading multi-center clinical research. Do not exceed two (2) pages.

**Future Career Goals (template available for download)**

Prepare a brief summary of the applicant’s intended future career goals. This section should specifically describe how this training award will help the applicant meet their career goal of becoming an independent investigator with a focus in CF translational or clinical research. Do not exceed one (1) page.

**International Institution Form (template available for download, if applicable)**

Applicants whose institution is not a United States based-entity must complete the CFF International Institution Form. The completion of this form also includes submission of the following documentation:

- Institution’s mission statement
- If the Institution is a nonprofit organization, provide government-issued documentation of the Institution’s nonprofit status, if available, as well as governing documents (such as a Charter, Statute, or By-Laws) detailing the funding and expenditures related to activities outlined in the Mission Statement of the Institution compared to activities outside of the mission of the Institution
- If the Institution is a for-profit organization, provide a complete list of key employees, members of the governing board, and/or other senior management as well as any governing documents (such as an Articles of Association or Organization) detailing the funding and expenditures of the Institution
- A complete and accurate Form W-8 signed by the institutional official within the last three years. While CFF issues grant funding to 501(c)(3) and nonprofit institutions, CFF also issues contract award funding to other kinds of institutions.
- A description of external sources of support, including the names of individuals and organizations providing the Institution with major donations, official awards, private endowments, and/or commercial activities
- Standard Operating Procedure(s) or relevant policy to ensure that all awarded funds, including but not limited to CFF funds, are used in compliance with all applicable U.S. anti-terrorist financing, privacy and asset control statutes, regulations and executive orders, resulting in the Institution neither distributing awarded funds to terrorists nor supporting their networks, organizations, or activities (*If your institution does not have a relevant policy, please provide a statement signed by an institutional official indicating that all award funds, including but not limited to CFF funds, will be used in compliance with applicable U.S. anti-terrorist financing, privacy and asset control statutes, regulations and executive orders, resulting in funds never being used to support terrorist networks, organizations and/or activities. In the alternative, if the institution does not have this policy, CFF can provide an Anti-Terrorism Certification Form to be signed by the institutional official).*

Applicants who have provided these documents within the past one (1) year is not required to resubmit them. However, if any of the above documents have been updated since they were previously submitted, please upload any updated documents. The CF Foundation GCMA Office will contact applicants if documents are outdated or missing.

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

#### **Appendices (upload materials as PDF documents)**

Appendices are restricted to the following three (3) categories:

- Proposed Protocol (if applicable)
- Up to three (3) reprints of the applicant's work relating to the general area of research in the proposal
- Other materials pertinent to the proposal, not already described

**\*No other types of Appendices will be reviewed**

#### **\*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](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**

**The CFF GCMA Office Hours of Support: Monday through Friday, 9:00AM – 5:00PM EST**

**For technical support and program/content information:**

Primary CFF GCMA contact Erik Warnke at [ewarnke@cff.org](mailto:ewarnke@cff.org) or 301-841-2614

**For scientific questions:**

Elizabeth Yu, Ph.D. at [eyu@cff.org](mailto:eyu@cff.org)

### XIII. Electronic Application Checklist

**Full Application Deadline: Tuesday, May 23, 2023 at 5:00 PM (EST)**

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

#### **FULL APPLICATION**

##### **Face Page (upload) which includes:**

- Signatures
- Principal Investigator (Co-PI's are not required to sign)
- The Official authorized to sign on behalf of the Applicant Institution
- Applicant/PI information (online)
- Complete Institution and PI Contact information, including correct mailing address (online)

##### **Research Plan & Supporting Documents**

- Research Plan (upload)
  - Hypothesis and Specific Aims
  - Background and Significance
  - Preliminary Results
  - Experimental Design and Methods
  - Benefit of this training award toward successful completion of the planned research and career goals
  - Literature Cited (not included in Research Plan page limitation)
- Budget Detail individually for each year requested
- Budget Justification individually for each year requested (upload)
- NIH Biographical Sketch of Key Personnel (upload)
- Other Support for all key personnel (upload)
- CF-Related Activities of the Mentor and Applicant Institution (upload)
- Previous Training and Future Plans (upload)
- Future Career Goals (upload)
- Verification of the Applicant Institution's Tax Status (upload)
- W-9 (US applicants) or W-8BEN-E (non-US applicants)
- 501(c)3, IRS Form 147C or equivalent tax status letter
- International Institution Form (if applicable)
- Appendices (upload as PDF documents, if applicable)
  - Proposed Protocol
  - Up to three (3) reprints of the applicant's work relating to the general area of research in the proposal
  - Other materials pertinent to the proposal, not already described