



Program Name: First/Second Year Clinical Fellowship

Brief Program Overview/Description: This award is designed to support First Year and/or Second Year Clinical Fellows pursuing training in CF relevant subspecialties. The intent of this program is to encourage specialized training in the early career development stage and to prepare well-qualified candidates for careers related to CF.

Funding Amount: The maximum award amount ranges from \$62,000 for the First Year to \$69,500 for the Second Year. Indirect costs are not allowable.

Eligibility:

- Applicants may be either U.S. citizens, permanent residents, or non-U.S. citizens. International applicants must have the ability to obtain the appropriate visas, as applicable.
- Applicants must have completed at least three (3) years of training in an approved pediatric and/or internal medicine program by the time the fellowship begins. International applicants must be certified by the Educational Commission for Foreign Medical Graduates (ECFMG) and be able to fulfill the eligibility requirements of the Accreditation Council for Graduate Medical Education (ACGME) for entry into an accredited fellowship.
- The institutional status of a fellow must correlate with the CFF fellowship award to which the applicant is applying.

Key Dates:

Published	December 5, 2019
LOI Submission Deadline	NA
LOI Applicant Notified	NA
Full Application Deadline	February 14, 2020
Committee Review Date	May 2020
Notification to Applicants	Late-May 2020
Earliest Project Start Date	July 1, 2020

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I. About the Cystic Fibrosis Foundation

The mission of the Cystic Fibrosis Foundation (CFF) is to cure cystic fibrosis (CF) and to provide all people with the disease the opportunity to lead full, productive lives by funding research and drug development, promoting individualized treatment, and ensuring access to high-quality, specialized care.

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

CF Foundation Resources

The Cystic Fibrosis Foundation supports the development of a number of helpful tools and resources to assist the research community in accelerating the progress toward new scientific knowledge of and new therapies for cystic fibrosis. For more information on Tools and Resources for the CFF research community, please visit: <https://www.cff.org/Research/Researcher-Resources/Tools-and-Resources/>

CFF Patient Registry Data

The CF Foundation Patient Registry collects information on the health status of people with cystic fibrosis who receive care in CF Foundation-accredited care centers and agree to participate in the Registry. This information is used to create CF care guidelines, assist care teams providing care to individuals with CF, and guide quality improvement initiatives at care centers. Researchers also use the Patient Registry to study CF treatments and outcomes and to design CF clinical trials.

The Cystic Fibrosis Foundation Patient Registry is an invaluable tool for researchers who are interested in conducting studies about people with CF in the United States. About 50,000 individuals have been followed in the Registry, and many have been included for over 20 years. In addition, we recently linked the CF Foundation Patient Registry with the Pediatric Health Information System (PHIS) database. Investigators at PHIS sites can request to use these linked data. Instructions on how to request CFFPR data for your research project is included in the application instructions below.

CFF Biorepository

Cystic fibrosis biological samples are available to qualified researchers to help develop promising new studies that will support CF research and aid in drug development and drug discovery. Biorepository samples come in many different forms: blood, urine, stool, tissue, and other material. These samples are stored under appropriate conditions that ensure they are preserved for future analysis.

Since 2006, the Cystic Fibrosis Foundation has collected and stored samples from a variety of clinical trials. The CF Foundation has developed a database that combines information from these samples with data from CF clinical trials and the CF Foundation Patient Registry to create a unique and specific sample profile. Instructions on how to request CFF Biorepository samples for your research project is included in the application instructions below.

Community Voice

The CF Foundation is committed to ensuring that the CF community's voice is heard in all of our activities. In December 2014, the CF Foundation created Community Voice, formerly known as the CF Adult and Family Advisors group, to serve as a consultative body and partner to the Foundation on various activities. Research Voice, a sub-committee within Community Voice, consists of people with CF and their family members who undergo special training on the basics of clinical research to provide insight and feedback to the research community.

Opportunities to partner with the community occur throughout the stages of a research project. Recently, several CFF funded investigator-initiated clinical research projects have utilized community engagement through Community Voice to successfully execute and complete their projects. The CF Foundation strongly encourages you to engage people with cystic fibrosis throughout the stages of clinical research. Based on your goals and objectives, the CF Foundation will work with you to determine which mechanisms are most appropriate. To learn more about how community insights can help you optimize your research project, email CommunityVoice@cff.org.

National Resource Centers

Specialized procedures are often needed to measure the outcomes of cystic fibrosis clinical trials. These include both laboratory-based measurements, such as cytology and inflammatory markers, and interpretive outcomes, such as computed tomography and nasal potential difference. For more information about National Resource Centers, please visit: <https://www.cff.org/Research/Researcher-Resources/Therapeutics-Development-Network/Working-with-the-TDN/National-Resource-Centers/>

II. Program and Award Overview

Physician Training and Career Development Programs Overview

CF Foundation’s Physician Training & Career Development Programs (PTPs) aim to attract, develop, and retain exceptional clinicians and investigators into cystic fibrosis to address the evolving needs of the CF community. The PTPs ensure that there is physician workforce that meets the healthcare and research needs of the CF Community by requesting applications for the 1st/2nd Year Clinical Fellowship Award, the 3rd/4th Year Clinical Fellowship Award, the 5th Year Clinical Fellowship Award, the Harry Shwachman Clinical Investigator Award (HAS), and the LeRoy Matthews Physician-Scientist Award (LMA), annually.

The breakdown for 2019 funding is shown below.

PTP Award	Applications Received	Applications Funded
1st/2nd Year Clinical Fellowship Award	30	27
3rd/4th Year Clinical Fellowship Award	12	7
Harry Shwachman Clinical Investigator Award	7	5
LeRoy Matthews Physician-Scientist Award	3	3 [†]

† Leroy Matthew Physician-Scientist applications funded as Clinical Fellowship Awards.

First- and Second-Year Clinical Fellowship Award Overview

CFF invites applications for the First Year and/or Second Year Clinical Fellowship award from (pediatric and adult) physicians pursuing fellowship training in CF relevant subspecialties. The intent of this program is to encourage specialized training in the early career development stage and to prepare well-qualified candidates for careers related to CF.

Applications can be submitted for a first year only, a second year only, or a first and second year combined. If the applicant applies for a first and second-year combination, the second year of funding, if requested, is contingent upon submission and approval of a renewal progress report indicating the satisfactory performance for the portion of the first year that will have been completed at the time of submission.

CFF generally prefers that the first year of training provides intensive experience in patient management, diagnostic, and therapeutic procedures. The second-year clinical fellowship may include a research project for which additional funding is provided.

Note: CFF also offers third, fourth, and fifth year clinical fellowships which include funding for a research project (visit www.cff.org for more information on these funding opportunities).

All CFF-supported Clinical Fellows must submit a case study for presentation at the annual North American Cystic Fibrosis Conference (NACFC), at either the Pediatric Clinical Fellows session or the Adult Care Clinical Fellows session. This requirement is fulfilled by submitting a one-page description of the case, including clearly defined discussion points prior to the conference. It does not require acceptance for this requirement to be fulfilled. Please check the NACFC website at www.nacconference.org for further details and specific deadlines.

III. Funding Amount

The maximum award amount is as follows:

- **First-year clinical fellows: US\$62,000** in direct costs for one year (**indirect costs are not allowable**). This includes up to:
 - US\$60,000 for salary and benefits
 - US\$1,500 for travel to NACFC
 - US\$500 for registration fees for NACFC

- **Second-year clinical fellows: US\$69,500** in direct costs for one year (**indirect costs are not allowable**). This includes up to:
 - US\$65,000 for salary and benefits
 - US\$1,500 for travel to NACFC
 - US\$500 for registration fees for NACFC
 - US\$2,500 for research expenses (Research Plan required)

Student Loan Repayment Program

Physician Training Program Award recipients are eligible to apply for the CF Foundation's Student Loan Repayment Program. Please contact the CFF Grants & Contracts Office for more information on this program.

Award Transfers:

Awards are made on the basis of individual and institutional merit; therefore, fellowships are not transferable to another trainee or institution without prior written approval from the CFF Grants and Contracts Office.

IV. Eligibility

- Applicants may be either U.S. citizens, permanent residents, or non-U.S. citizens. International applicants must have the ability to obtain the appropriate visas, as applicable.
- Applicants must have completed at least three (3) years of training in an approved pediatric and/or internal medicine program by the time the fellowship begins. International applicants must be certified by the Educational Commission for Foreign Medical Graduates (ECFMG) and be able to fulfill the eligibility requirements of the Accreditation Council for Graduate Medical Education (ACGME) for entry into an accredited fellowship.
- Training must take place in a CFF-accredited CF Center or a CF Center-affiliated adult CF program, and should provide a comprehensive educational curriculum in diagnostic and therapeutic procedures, comprehensive care, and clinical research. Types of fellowship training generally offered include

Pulmonary, Gastrointestinal and less commonly Endocrine, Infectious Disease and Organ Transplant. Other fellowship training programs can be accepted provided the applicant clearly outlines the relevance to the CFF mission.

- Adult caregivers in CF are encouraged to apply.
- The applicant's institution must have Accreditation Council for Graduate Medical Education (ACGME) accredited training programs in the applicants' subspecialty.
- Applicants must describe career goals related to a long-term commitment to CF research and care.
- The institutional status of a fellow must correlate with the CFF fellowship award to which the applicant is applying.

V. Mentorship Requirements

- Each fellow must have a Mentor who will be responsible for the fellow's training and research activities. If the CF Program Director is not the Mentor, then s/he must be listed as the Co-Mentor in the application.
- CFF will accept applications for up to two (2) fellowships per subspecialty, per fellowship year, per accredited CF Program (i.e. adult and pediatric).
- CFF will accept applications from applicants with different subspecialties (e.g. pulmonary, endocrine, gastrointestinal, transplant, infectious diseases, etc.) from the same accredited CF Program. However, in the event that more than two (2) applicants **from the same subspecialty** are qualified to apply for the award, the CF Program Director must determine which applicants should apply.

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 people with CF. Applicants are encouraged, but not required, to address an emerging area of potential interest stated below. All applications are reviewed and scored based on the individual, training program, scientific merit, and relevance to the CFF mission.

Research topics of high priority to the CF Foundation:

- Direct and indirect influences of CFTR modulation on the airway milieu, including resident pathogens, inflammation, mucin structure (tethered and secreted), airway surface liquid (ASL), and mucociliary clearance
- Understanding defects associated with CFTR mutations other than F508del (especially nonsense and other mutations not currently treated by CFTR modulators) and approaches for restoring CFTR function
- Biological mechanisms involved in lung allograft dysfunction/rejection and transplant immunology
- Improved understanding of acquisition, detection, pathogenesis, host-pathogen interactions, and treatment approaches for difficult to treat CF infections (i.e. NTM, MDR Pseudomonas, MRSA, Aspergillus, Achromobacter, Burkholderia, Stenotrophomonas)
- Approaches to understand and treat extra-pulmonary manifestations of CF including (but not limited to):
 - CF related GI issues and the impact of nutritional deficiencies
 - Effects of endocrine system dysfunction in CF, including Cystic Fibrosis Related Diabetes (CFRD) and CF bone disease
 - Mental health

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

VII. Review and Award

CFF's Professional Education Committee (PEC) will evaluate all applications on the training program content and applicant. Funding of awards is based on the priority score awarded to each application and

the recommendations of the PEC. All awards are subject to observance of the regulations and policies of CFF related to that category of research support and are contingent upon the availability of CFF funds.

Applications will be reviewed and scored by the Professional Education Committee (PEC). CFF may withdraw applications receiving low scores, and/or those deemed nonresponsive to the program announcement before the review meeting. In these cases, CFF will notify applicants if their application has been withdrawn without discussion.

Applications will be evaluated in the following areas:

Applicant	Mentor(s)	Environment	Training & Research Development Plan
<ul style="list-style-type: none"> • Commitment to, or intent to pursue, a career related to CF • Potential to develop a career related to CF • Quality of academic background and previous training 	<ul style="list-style-type: none"> • Established CF clinician/physician-scientist with experience in training fellows • Commitment of the primary Mentor for the duration of the applicant's training plan • Strong track record of successful trainees who continue in CF field 	<ul style="list-style-type: none"> • Quality of institution's CF research and training programs • Institution's commitment and ability to provide opportunities and facilities necessary for career development related to CF 	<ul style="list-style-type: none"> • Overall quality and organization of the training program • Didactic course work required by the applicant (if indicated) • Scientific and technical merit of the proposed research (if applicable)

CFF may withdraw applications receiving low scores, and/or those deemed nonresponsive to the program announcement before the review meeting. In these cases, CFF will notify applicants if their application has been withdrawn without discussion. Applicants must address reviewer critiques in order to resubmit their applications during future application cycles.

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

- Insufficient information or documentation
- Failure of the applicant to meet all criteria described in the policy and guidelines for a given award
- Failure of the applicant to describe career goals as they may be related to a long-term commitment to CF research, quality improvement, or care.

VIII. Submission Information

Application Deadline: Friday, February 14, 2020 at 5:00 PM (Eastern)

Submit online through proposalCENTRAL: <https://proposalcentral.com/>
 (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 proposalCENTRAL will be reviewed. Late applications will not be accepted, and the deadline will not be waived.

General Timeline:

Application Deadline _____	February 14, 2020
Review _____	May 2020
Notification to Applicants _____	Late-May 2020
Earliest Start Date for Awarded Projects _____	July 1, 2020

IX. Letter of Intent Guidelines

Not applicable to this RFA

X. Full Application Guidelines

Applications must be submitted online at proposalCENTRAL: <https://proposalcentral.com/>

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 proposalCENTRAL, the system will compile them into a single PDF file in the correct sequence as shown in Section XIII. ELECTRONIC APPLICATION CHECKLIST.*

Log-in at proposalCENTRAL: <https://proposalcentral.com/>

First-time applicants must register to create a username and password for proposalCENTRAL and will need to complete a profile online before applying. If you are registered and cannot remember your password, click on the **“Forgot Your Username/Password?”** link below the **“Application Login”** fields.

Award opportunities, including this Request for Applications (RFA), are listed on the opening screen, but you must be logged in first to see them.

Select the gray tab labeled **“Grant Opportunities”** found in the upper right-hand side of the page.

Click on the light blue **“Filter by Grant Maker”** button to the left and scroll down to locate **Cystic Fibrosis Foundation** in the list.

Locate the listing for the **“First/Second Year Clinical Fellowship”** program. Click on the **“Apply Now”** 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 before exiting in order to save their work. When logging in to continue, click on the blue tab, **“Proposals”**, and then the **“Edit”** button.

The following sections are listed in the navigation menu to the left of the application screen. Click on each section and follow the directions.

- 1. Title Page:** Select a project title from the choices available in the dropdown menu based on the fellowship year(s) for which you are applying. Answer the required questions about the number of years of residency completed, the type of fellowship, the subspecialty the applicant is interested in pursuing, if the applicant received a Student Traineeship previously, and whether the applicant’s institution has ACGME-accredited training programs in pulmonary or GI medicine. If the applicant is an international applicant, then answer whether s/he is certified by the Educational Commission for Foreign Medical Graduates (ECFMG).

- 2. Download Templates & Instructions:** Download the available templates applicable to the project, fill them out and upload them when completed in Section #9. Templates available include:
 - Applicant Instructions for Letters of Reference (for reference only)
 - Biographical Sketches for Key Personnel
 - Mentor’s Results of Past and Current CFF/CFFT Support
 - Other Support
 - Facilities Available
 - Budget Detail
 - Budget Justification
 - Second Year Research Plan (if applicable)
 - Mentor’s List of Previous Fellows
 - Personal Statement (Previous Training and Future Plans)
 - Training Plan
 - Names and Addresses of References

- 3. Enable Other User to Access this Proposal:** Complete this section online if you wish to designate access to another individual, such as an assistant who has registered on proposalCENTRAL. Enter the email address of the individual and in the “Permissions” column, use the pulldown menu to select the type of access you wish to give. Please note that only delegates who are granted “Administrator” rights can submit applications on behalf of the applicant. Click on “Accept Changes”.

- 4. Applicant/PI:** 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, click the “Edit Professional Profile” button and follow the instructions. If a profile was not completed, enter the required information and click “Save”.

- 5. Institution & Contacts:** If a profile was completed upon registration, the Principal Investigator’s (PI) institution will be preloaded as Lead Institution. If a profile was not completed, enter the required information and click “Save”. Be sure to use the full legal name of the institution.

- 6. Letters of Support/Reference:** Letters of Support and Reference are weighted heavily in the review. At least five (5) Letters of Support/Reference are required as follows:
 - **Mentor:** Please describe the types of CF learning experiences to which the applicant will be exposed. If the application includes a research project, please describe in detail on how you will provide the fellow with the tools and resources necessary for her/him to develop into a CF-focused independent investigator.
 - **CF Program Director(s):** The CF Program Director(s) at the applicant/nearby institution if s/he is not a Mentor, should be listed as Co-Mentor. Please describe the types of CF learning experiences, tools and resources to support the fellow.
 - **Division or Program Chief (if you are not the Program Director):** Please describe career and faculty development plans and opportunities, as well as institutional resources available and relevant to the applicant.
Note: If a letter from any one referee listed above fulfills two or more of the required roles, additional letters from referees who can speak to the applicant’s scientific and clinical abilities, interests, and potential to become an independent investigator must be provided to meet the minimum requirement of five (5) letters.
 - **Additional Referees:** At least two (2) other individuals who were closely associated with the applicant during his/her medical training.

Invite Referees to Submit Letters of Reference through proposalCENTRAL

Letters of Reference must be submitted electronically ONLY. To “invite” Referees, go to the “Letters of Reference” section of the online application, and enter the email addresses of the individuals you have asked to submit letters. This will generate automated emails (with instructions) sent to each Referee through the proposalCENTRAL website. 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 proposalCENTRAL 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.

Note: Detailed Instructions on how to invite referees to submit the Letters of Support/Reference are also available in a downloadable document found in Section #2. Letters uploaded to proposalCENTRAL 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.

- 7. Budget Summary:** Fill in the start and end date and applicable amounts for the support requested by completing the applicable online fields (Period 1 and/or Period 2). The total requested salary and benefits must not exceed US\$60,000 for first-year fellows and US\$65,000 for second-year fellows. The total budget requested cannot exceed US\$62,000 for first-year fellows and US\$69,500 for second-year fellows.

Note: The Budget Detail and Budget Justification templates downloaded in Section #2 must also be completed for each year of support requested and uploaded in Section #9. The amounts included in this uploaded Budget Detail must match the amounts entered in the Budget Summary

- 8. Organization Assurances:** Select the type of assurances that are applicable to the project and provide all required information (i.e. IRB, IACUC, and/or IBC/rDNA approval letter and status at the time of submitting the application). Refer to Section L. ORGANIZATION ASSURANCES & CERTIFICATIONS in these guidelines for details.
- 9. Training Plan & Supporting Documents:** In this section, upload the completed templates downloaded in Section #2 above in PDF format. Fill out the fields describing the attachment, select the attachment type from the pulldown menu, choose the file to be uploaded, and click the “Upload Attachment” button to upload the file. Do this for each attachment.

Below are instructions specific to each template as well as additional information regarding other application components.

A. Biographical Sketches for Key Personnel (template available for download)

Complete and upload an NIH Biographical Sketch for all key project personnel, beginning with the Applicant/Principal Investigator (fellow) and the Mentor(s). (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.

B. Mentor’s Results of Past and Current CFF/CFFT Support (template available for download)

Mentors are requested to identify the results of past and current CFF/CFFT support (e.g., subsequent funding from other sources, journal articles, and invited presentations) and the

CFF/CFFT grant/award from which they resulted for the past three to five years. Please note that the following information must be included with each research project identified:

- CFF/CFFT Account #
- Principal Investigator (PI)
- CFF/CFFT Project Title
- Applicant's Title on Project
- Project Start/End Dates
- Total CFF/CFFT Award Amount
- Results of Support

C. Other Support (template available for download)

Complete and upload an "Other Support" form for all key project personnel, beginning with the Applicant/Principal Investigator (fellow) and the Mentor(s). There is no page limitation.

D. Facilities Available (template available for download)

Not applicable to applicants applying only for the first year of the fellowship. Describe the facilities and equipment available at the applicant's institution that will be used for this project, such as laboratory, clinical, animal, computer, office, etc. Provide any additional information about the environment, including any support services available that will be utilized. Describe their pertinent capabilities, proximity and anticipated extent of use. If facilities or equipment at a consultant's or collaborative site will be used, they should be identified and clearly described. There is no page limit. Use continuation pages, if necessary.

E. Budget Detail and Budget Justification (templates available for download)

Fill out the Budget Detail and Budget Justification templates for all years of support requested. In the space provided on the templates, indicate the year as well as start and end dates for the proposed budget period. (Be sure the amounts entered in the Budget Detail(s) match the amounts in the online budget summary in Section #7).

Budget Detail – Direct Costs Only

Salary & 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 US\$192,300. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all funding agencies and foundations.

Travel - Describe the purpose of any CF-relevant travel. Please note: expenses for travel outside the North American continent, including travel to Hawaii, Puerto Rico, and other U.S. territories are not allowable expenses without prior written approval from the CFF Grants & Contracts Office. Travel expenses are limited to the applicant and may not exceed \$1,500 per year. Registration fees associated with conferences should be listed under "Other Expenses."

Consumable Supplies - Itemize supplies e.g. glassware, chemicals, animals, in separate categories and give the estimated cost of each category. If animals are involved, state the number, unit purchase cost, and unit care cost.

Other Expenses - Itemize other expenses by major categories, such as duplication costs, publication costs, minor equipment items under \$5,000, conference registration fees (up to \$500), etc.

Budget Detail – Indirect Costs

Indirect costs are not allowable.

Budget Justification

Describe costs listed in the Budget Detail. Use major categories, such as Personnel, Supplies, etc. Justify all items.

F. Second Year Research Plan (template available for download, if applicable)

If research funding is requested, a research plan must be uploaded. Please follow the instructions below.

- Key figures and legends must be included in the Research Plan. If uploaded as Appendices, they will NOT be reviewed.
 - At the top of each page, type the Applicant's name. Each page must be sequentially numbered at the bottom.
 - Page limit: Five (5) single-sided pages, not including the Literature Cited. Applications exceeding this page limit will not be reviewed. A template is available for download on proposalCENTRAL. 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. **Scientific Abstract:** Provide a statement of no more than 250 words explaining the subject of the research proposal and its relationship to CF. This will be used to inform the scientific community.
 - b. **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.
 - c. **Background and Significance:** Briefly describe the background. Critically evaluate existing knowledge and specifically identify the gaps that the project is intended to fill. Concisely state the importance and rationale of this research by relating the specific aims to longer-term objectives. This section should also show the potential importance of the proposed work to CF. In addition, describe the relationship of the proposed work to your long-term career goals. Preference will be given to applicants who express an interest in a long-term career in CF-related research.
 - d. **Experimental Design and Methods:** Provide a concise discussion of the experimental design and methods to be used to accomplish the specific aims. Discuss the data expected to be obtained and the means by which data will be analyzed and interpreted. If clinical studies are involved, provide details of the methods for patient selection and care. Discuss potential difficulties and/or limitations of the proposed procedures and alternative approaches to achieve aims.
 - e. **Literature Cited:** References should be numbered in the sequence that they appear in the text and listed at the end of the Research Plan. Each citation must include the names of authors, the name of the journal or book, volume number, page number and year of publication (titles are optional).

G. Mentor’s List of Previous Fellows (template available for download)

The current Mentor(s) must provide a list of all previous fellows under his/her supervisions over the past 10 years, including the fellows’ source(s) of support.

H. Personal Statement – Previous Training and Future Plans (template available for download)

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

I. Training Plan (template available for download)

The applicant, in conjunction with the Mentor(s) and fellowship program director, should provide a brief summary of the applicant’s previous research and/or clinical fellowship training, including the reasons for entering the fields related to CF research and care. In addition, the applicant and Mentor(s) should develop a training plan that outlines skills and techniques that will be learned during this fellowship period as well as CF-specific training that will be available to the applicant, including participation in supplemental course work and special seminars. Further, this section should clearly indicate plans for introducing the applicant to CF research. This should include training on study planning and design, statistical methods, data management, etc. This should also include a description of the applicants anticipated CF research. This plan should address the applicant’s long-term career goals and include training and professional development activities that will facilitate the applicant’s transition to the next phase of their career. Do not exceed five (5) pages.

J. Names and Addresses of References (template available for download)

List the names, titles, and contact information of the individuals who have been asked to submit Letters of Support/Reference on the applicant’s behalf via Section #6 in proposalCENTRAL. A PDF copy of the completed form should be uploaded.

K. Verification of Applicant Institution’s Tax Status (upload as PDF documents)

The CFF Grants and Contracts Office must have a copy of the applicant institution’s current W-9 and 501(c)3 letter, or other documentation verifying its Federal tax status and will not issue Award Letters to Awardees if these documents are not received and on file.

- Applicants from for-profit organizations must submit a copy of the applicant institution’s W-9 and IRS documentation verifying the organization’s Federal tax status. Awards are not issued prior to having these documents on file with the CFF Grants and Contracts Office.

L. Organization Assurances & Certifications (if applicable and available, upload as PDF document under Appendices)

CFF requires, as applicable, that all U.S.-based awardees obtain Institutional Review Board (IRB) approvals for human subject research, Institutional Animal Care and Use Committee (IACUC) approval for animal research, and Institutional Biosafety Committee (IBC) approval for recombinant DNA research (see additional information regarding these approvals below). Copies of these approvals, if available at the time the application is submitted, must be uploaded with the application as appendices. CFF will not release payments to awardee institutions until these documents are received and on file with the CFF Grants and Contracts Office.

Awardees based outside of the U.S. must comply with the applicable equivalent regulations in their respective countries and provide copies of approvals as soon as they are available. CFF will not release payments until these documents are received and on file with the CFF Grants and Contracts Office.

Research Involving Human Subjects: CFF policy pertaining to the protection of individuals as research subjects requires that for each proposal awarded, the awardee institution certify in writing that an Institutional Review Board (IRB) has reviewed and approved the procedures for the use of human subjects, or human organs, tissues and body fluids, in the proposed research, in accordance with the Department of Health and Human Services policies found at <https://www.hhs.gov/ohrp/regulations-and-policy/index.html>. In the event the IRB has determined a study is exempt, documentation demonstrating the exempt status must also be submitted to the CFF Grants and Contracts Office.

Research Involving Recombinant or Synthetic Nucleic Acid Molecules: All research involving recombinant or synthetic nucleic acid and human gene transfer studies supported by CFF must meet the requirements contained in the document NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (updated April 2019). This publication and announcements of modifications and changes to the NIH Guidelines are available from the Office of Science and Policy, National Institutes of Health, 6705 Rockledge Drive, Ste 750, MSC 7985, Bethesda, MD, 20892-7985 or online at https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf.

Research Involving Animals: Applications submitted to CFF involving the use of animals must meet the guidelines of the National Institutes of Health found at <https://grants.nih.gov/grants/olaw/olaw.htm>, which require that all proposed studies be reviewed and approved by an Institutional Animal Care and Use Committee (IACUC). In addition, CFF awardee institutions and laboratories must be accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC) and/or have other verifiable assurances that the institution and laboratory meet appropriate standards.

M. Appendices (upload materials as PDF documents, 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.

10. PI Data Sheet: Fill in the required fields, save and exit.

11. Print Face Pages: Follow the prompts on the screen to generate and print a Face Page. The Face Page will be populated automatically with data entered in the online application (applicant's name, institution, title of application, etc.). The Face Page must be signed by the Principal Investigator and Authorized Institutional Official and uploaded in Section #9. Co-Principal Investigators, if any, are not expected to sign the Face Page.

12. Validate: Upon completing the application, click on the "Validate" button on the main screen. Attend to any omissions/errors as prompted onscreen, and then click "Validate" again.

13. Submit: Click on the gray button with blue lettering.  CFF will not receive your application unless the "Submit" button is clicked.

14. Confirmation: Applicants will receive an e-mail confirmation from proposalCENTRAL (not from CFF) that the Application was successfully submitted. This e-mail will be your only acknowledgement. If you do not receive this confirmation, please contact proposalCENTRAL immediately to ensure that your submission was submitted and processed.

XI. Other Information

Not applicable to this RFA

XII. Contact Information

For technical support with the online application:

proposalCENTRAL at pcsupport@altum.com or
800-875-2562 on weekdays, 8:00 a.m. to 5:00 p.m. (Eastern)

For program/content information:

CFF Grants and Contracts at grants@cff.org or 301-841-2614

XIII. Electronic Application Checklist

Application Deadline: Friday, February 14, 2020 at 5:00 PM (Eastern)

Submit online through proposalCENTRAL: <https://proposalcentral.com/>

Face Page which includes:

- Signatures
 - Applicant
 - The Official authorized to sign on behalf of the Applicant Institution
- Applicant information (online)
- Complete Institution and Applicant Contact Information, including correct mailing address (online)
- Organization Assurances (check those that apply online/complete the required information)
- Human Subjects Certification
- Research Involving Recombinant or Synthetic Nucleic Acid Molecules information
- Research Involving Animals Information

Training Program & Supporting Documents:

- Biographical Sketches for Key Personnel - (upload)
- Mentor's Results of Past and Current CFF/CFFT Support - (upload)
- Other Support (NIH Format) - (upload)
- Facilities Available - (upload, if applicable)
- Budget - (upload)
- Budget Justification - (upload)
- Second Year Research Plan - (upload, if applicable)
 - Scientific Abstract
 - Hypothesis and Specific Aims
 - Background and Significance
 - Experimental Design and Methods
 - Literature Cited (not included in Research Plan page limitation)
- Mentor's List of Previous Fellows - (upload)
- Personal Statement (Previous Training and Future Plans)
- Training Plan - (upload)
- Names and Addresses of References - (upload)
- Verification of Applicant Institution's Tax Status - (upload)
 - W-9
 - Federal (IRS) tax status letter
- Appendices (upload, if applicable)
 - Certification of organization assurances (i.e. IRB, IACUC and IBC approvals), if applicable.
 - Up to three (3) reprints of the applicant's work relating to the general area of research in the proposal