Third Year Clinical Fellowship

POLICIES AND GUIDELINES

Published: November 1, 2018
Application Deadline: February 15, 2019

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 treatment.

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

II. **THIRD YEAR CLINICAL FELLOWSHIP AWARD OVERVIEW**
CFF invites applications for Third Year Clinical Fellowships from (pediatric and adult) physicians who have completed at least two years of CF-related fellowship training and seek support for additional clinical fellowship training. In most circumstances, this year of training will be devoted to clinical or basic research related to CF.

Major criteria considered in the selection process are the research potential of the applicant, the scientific merit of the proposed study, the research environment of the training program, and the fellow's long-term commitment to continued involvement with CF research and/or clinical care in an academic setting (see Section IV for details). Preference is given to applicants whose prior training was previously supported by CFF.

Applicants who plan to conduct clinical research should pay special attention to Section 'd' (Clinical Research only) of the Research Plan guidelines and to the completion of the Data Safety Monitoring Plan.

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 involves submitting a one-page description of the case, including clearly defined discussion points prior to the conference. Please check the NACFC website at www.nacfconference.org for further details and specific deadlines.

General Guidelines and 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.
- The applicant's institution must have Accreditation Council for Graduate Medical Education (ACGME) accredited training programs in the applicant's subspecialty.
- Applicants must have completed at least two years of clinical fellowship training by the anticipated start date of the award in order to be eligible.

Mentor and Applicant Institution Requirements:
- Training must take place in one of the CFF's accredited CF Care Centers or a Center-affiliated adult CF program.
- Each fellow must have a Mentor who will be responsible for the fellow's training and research activities.

Funding:
The maximum award amount is **US$100,000** in direct costs for one year (indirect costs are not allowable). This includes up to **US$80,000** for stipend (salary and benefits) and up to **US$20,000** for research expenses.

Allowable costs include:
- Salary and fringe benefits, not to exceed US$80,000 total
- Research supplies
- Minor equipment purchases under US$5,000
- CF-relevant travel costs of up to US$1,250 annually for the applicant

All other costs are non-allowable without prior written approval from the CFF Grants & Contracts Office.

In addition, CFF will underwrite the interest payments for educational loans for up to **US$7,000** per year of CFF fellowship. Please contact the CFF Grants & Contracts Office for more information on this program. In general, awardees will need to submit a request to the CFF Grants & Contracts Office for approval which includes a letter requesting payment of accumulated interest for the year in which the award is received, proof of interest accumulated during the fellowship period, and a signed W-9 or W-8BEN form no later than 90 days after the fellowship ends.

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 approval by CFF.

III. **GOALS OF RESEARCH CURRENTLY OF INTEREST TO CFF**
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
- Improving the detection and treatment of CF infections, especially from difficult to treat microorganisms (i.e. NTM, MRSA, Aspergillus)
- 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

o Effects of endocrine system dysfunction in CF, including Cystic Fibrosis Related Diabetes (CFRD)
o 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.

IV. REVIEW AND AWARD

CFF's Physician Training Programs (PTP) Committee will evaluate all applications. The PTP Committee recommendations are reviewed by the Board of Trustees. Funding of awards is based on the priority score awarded each application and the recommendations of the PTP. Relevance of the proposed study to issues in CF is also considered in determining awards. All research awards are subject to observance of the regulations and policies of CFF related to that category of research support and are contingent upon the availability of CFF funds.

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

Applicant	Mentor(s)	Environment	Training & Research Development Plan
• Commitment to, or intent to pursue, a research career related to CF • Potential to develop an independent research career related to CF • Research accomplishments	• Established expertise in CF-related research or related research areas of high priority to CFF • Commitment of the Mentor for the duration of the applicant's development and research plan • Track record of the Mentor in training individuals for biomedical research	• Quality (breadth and depth) of faculty in basic and/or clinical sciences related to CF at applicant institution • Quality of institution's CF research and training programs • Demonstrated interaction between basic and clinical investigators • Institution's commitment and ability to provide opportunities and facilities necessary for research career development related to CF	• Feasibility and impact of the proposed plan • Didactic course work required by the applicant (if indicated) • Scientific and technical merit of the proposed research • Ability of the proposed plan to develop research skill of the applicant needed for independence • Relationship to applicant's career development

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

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

- Insufficient information or documentation
- Inadequate statement of hypothesis, experimental design or methods
- Failure of the applicant to demonstrate awareness of and plans for coping with key problems and pitfalls associated with the proposed research
- Insufficient or improper controls, if applicable.
- Failure of the applicant to describe potential relevance of the proposed study to issues in CF
- Failure of the applicant to document the necessary skills or training to accomplish the goals of the proposal
- Failure of the applicant to meet all criteria described in the policy statement for a given award
- Failure of the applicant to describe career goals as they may be related to a long-term commitment to CF research

V. SUBMISSION INFORMATION & GENERAL TIMELINE

Application Deadline: Friday, February 15, 2019 at 5:00 PM (ET)

Submit online through proposalCENTRAL: https://proposalcentral.altum.com/
(Refer to Section VI 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 15, 2019**
Review by Physician Training Program Committee	April 2019
Notification to Applicants	Late-May 2019
Earliest Start Date for Awarded Projects	July 1, 2019

VI. FULL APPLICATION GUIDELINES

Applications must be submitted online at proposalCENTRAL: https://proposalcentral.altum.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.*

Log-in at proposalCENTRAL: https://proposalcentral.altum.com/

First-time applicants must register to create a user name 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 **"Third 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 gray navigation box to the left of the application screen. Click on each section and follow the directions.

1. **Title Page:** Enter the title of your project and answer the required questions about type of fellowship, discipline being pursued, and previous awards.

2. **Download Templates & Instructions:** Download the available templates applicable to the project, fill them out and upload them when completed in Section #10. 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, Research Plan, Data Safety Monitoring Plan (if applicable), Mentor's List of Previous Fellows, Training Plan, Names and Addresses of References, and Appendices.

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. Check the "**Auto Notify**" box and then "**Save**".

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:
   - **The Mentor(s) for this award** – A Letter of Support from the fellowship Mentor(s) should clearly identify the merits of the applicant and must include a description of CF-specific and other training the applicant received while working under the Mentor's direction. The letter should detail how the Mentor(s) will provide the applicant the tools and resources necessary for her/him to undertake their proposed research project and develop into a CF-focused independent investigator.
   - **The applicant's Division or Section Chief**, if s/he is not the CF Center Director, should detail career and faculty development plans and opportunities, as well as institutional resources available and relevant to the applicant.
   - **The CF Center Director(s) at the applicant (or nearby) institution**, if s/he is not the Mentor.
   - **The Mentor(s) of the previous years of the clinical fellowship training** should address what the applicant has achieved in his/her prior fellowship training.
   Note: If a letter from any one referee listed above fulfills two or more of the required roles, additional letters from references who can speak to the applicant's scientific and clinical abilities, interests, and potential to become an independent investigator must be provided to meet the minimum requirement of five (5) letters.
   - **Additional referees** – At least one (1) other individual who is familiar with the applicant's scientific interests and abilities should attest to the applicant's academic qualifications, motivation, research potential and commitment to CF research and care.

   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. **Abstracts/Relevance/Keywords:** In the space provided online for abstracts, provide a statement of no more than 250 words (up to 2,000 characters max, 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:** Provide a statement of no more than 250 words (up to 2,000 characters max, 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. 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 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.

    - **Keywords:** From the lists of options provided in this section, select all applicable research type, research topics, and keywords for the proposed project. A minimum of one (1) option must be selected per category. Click each keyword you want to select, then the arrow tab, until you have all applicable keywords selected on the list to the right.

8. **Budget Summary:** Fill in the start and end date and applicable amounts for the support requested by completing the online fields for Period 1. The total requested stipend (salary and benefits) must not exceed US$80,000. The total budget requested cannot exceed US$100,000.
    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 #10. The amounts included in this uploaded Budget Detail must match the amounts entered in the Budget Summary online.

9. **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.

10. **Research 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)**
   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 #8).

- **Budget Detail – Direct Costs Only**
  Personnel - List the names and positions of all professional and non-professional personnel involved in the project, whether or not salaries are requested. Indicate the percent effort on the project for professional personnel. Personnel costs (salary and benefits) may only be requested for the applicant through this program and cannot exceed **US$80,000 per year.** In accordance with National Institutes of Health (NIH) policy, salary requests may not use an institutional base salary in excess of the current federal salary cap of US$189,600. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all funding agencies and foundations.

  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.

  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 **US$1,250 per year**. Registration fees associated with conferences should be listed under "Other Expenses."

  Other Expenses - Itemize other expenses by major categories, such as duplication costs, publication costs, minor equipment items under US$5,000, conference registration fees, 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. **Research Plan (template available for download)**
- Key figures and legends must be included in the Research Plan and should be of sufficient quality and size to be evaluated by the reviewer. If uploaded as Appendices, they will NOT be reviewed.

- At the top of each page, type the Principal Investigator's name. Each page must be sequentially numbered at the bottom.
- *Page limit:* Seven (7) 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.

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

a. **Hypothesis and Specific Aims:** State concisely and realistically the intent of the proposed research and the hypothesis to be tested. The specific aims should be relevant to the mission of the Cystic Fibrosis Foundation. Do not exceed one page.

b. **Background and Significance:** Briefly describe the background. Critically evaluate existing knowledge and specifically identify the gaps that the project is intended to fill. Concisely state the importance and rationale of this research by relating the specific aims to longer-term objectives. This section should also show the potential importance of the proposed work to CF, in particular in those areas listed as areas of special interest to CFF. In addition, describe the relationship of the proposed work to your long-term career goals. Preference will be given to applicants who express an interest in a long-term career in CF-related research.

c. **Preliminary Results:** If applicable, provide a detailed discussion of any preliminary results.

d. **Experimental Design and Methods:**
   For applicants proposing to carry out Basic Research through this support mechanism:
   Provide a detailed discussion of the experimental design and methods to be used to accomplish the specific aims**.** Describe the protocols, including methods for new techniques, and explain potential advantages over existing methodologies. Discuss the data expected to be obtained and the means by which data will be analyzed and interpreted. If human subjects are involved, provide details of the methods for patient selection and care. Discuss potential difficulties and/or limitations of the proposed procedures and alternative approaches to achieve aims. Point out any procedures, situations or materials that may be hazardous to personnel or patients and the precautions to be exercised.

For applicants proposing to carry out Clinical Research through this support mechanism:

Provide a detailed discussion of the experimental design and procedures to be used to accomplish specific aims. Please discuss: study hypothesis; primary and secondary outcome measures; study sample-inclusion and exclusion criteria; sample size estimates*; subject enrollment including age range; puberty status; gender distribution; randomization scheme if applicable; description of experimental procedures and schedule including a study time-line; drugs and dosage; measures of compliance; follow-up schedule including a study time-line for full project up to three years; efficacy and safety evaluation, data monitoring and quality control; and a description of your proposed data analysis and statistical procedures for your hypothesis testing. Although no page limit is specified for this section, make every attempt to be concise and succinct.

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

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

e. **Literature Cited:** References should be numbered in the sequence that they appear in the text and listed at the end of the Research Plan. Each citation must include the names of authors, the name of the journal or book, volume number, page number and year of publication (titles are optional).

G. **Data Safety Monitoring Plan (template available for download, if applicable)**
*For clinical research projects only

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

The extent of monitoring required for a study is dependent on the level of risk involved for the subjects, as well as the size and complexity of the study. Large, multi-center CFF-funded interventional clinical trials must utilize the CFF Data Safety and Monitoring Board

(DSMB). In addition, CFF may require that investigators utilize the CFF DSMB for any other interventional CF clinical trial that meets one or more of the following criteria:

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

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

Address the following areas in the DSMP:

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

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

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

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

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

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

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

H. 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.

I. Training Plan (template available for download)
The applicant, in conjunction with the Mentor(s), 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 should be included. Further, this section should clearly indicate plans for introducing the applicant to research study planning and design, statistical methods, data management, etc. 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 2016). 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 http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines.

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 (template available online, 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.

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

12. **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 #10. Co-Principal Investigators, if any, are not expected to sign the Face Page. CFF will not submit applications for committee review if it does not have the Face Page on file signed by the Principal Investigator and Authorized Institutional Official.

13. **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.

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

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.

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 & Contracts at grants@cff.org or 301-841-2614

VII. ELECTRONIC APPLICATION CHECKLIST

Application Deadline: Friday, February 15, 2018 at 5:00 PM (ET)

Applications must be submitted at proposalCENTRAL: https://proposalcentral.altum.com/

Face Page which includes:
☐ Signatures
  ○ Principal Investigator (Co-PI's are not required to sign)
  ○ Authorized Institutional Official
☐ Applicant/PI information (online)
☐ Complete Institution and PI Contact Information, including correct mailing address (online)
☐ Organization Assurances (check those that apply online/complete the required information)
  ○ Human Subjects Certification
  ○ Research Involving Recombinant or Synthetic Nucleic Acid Molecules information
  ○ Research Involving Animals Information

Research Plan & Supporting Documents:
☐ Abstracts ~ Summary of Relevance ~ Keywords - (complete online)
☐ 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)
☐ Budget Detail - (upload)
☐ Budget Justification - (upload)
☐ Research Plan - (upload)
  ○ Hypothesis and Specific Aims
  ○ Background and Significance
  ○ Preliminary Results
  ○ Experimental Design and Methods
  ○ Literature Cited (not included in Research Plan page limitation)
☐ Data Safety Monitoring Plan (for clinical research projects only – upload, if applicable)
☐ Mentor's List of Previous Fellows - (upload)
☐ 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