



**Program Name:** CFF/NIH-Unfunded Award

**Brief Program Overview/Description:** In an effort to assure that all meritorious CF-related research is supported, CFF has developed the CFF/NIH-Unfunded Award mechanism to provide bridge funding. The objective of this Request for Applications (RFA) is to support excellent CF-related research projects that have been submitted to and approved by the NIH (or governmental funding agencies in other countries) but cannot be supported by available funds. In order to be eligible for this program, applications must fall within the upper 40th percentile (1%-40%).

**Funding Amount:** The maximum award amount is \$125,000 per year for up to two years (Direct Costs Only); indirect costs are not allowable. *Note: the level of funding will be determined by CFF following review by the designated medical/scientific advisors.*

**Eligibility:**

- The application must have been reviewed by an NIH study section and presented to an institute council within 12 months of applying for CFF support.
- Applications must have been submitted to NIH as an R01/R21 and fall within the upper 40th percentile. If an application has been submitted to NIH multiple times, the most recent submission must have been scored in the upper 40th percentile to be considered.
- Additional eligibility requirements are outlined below in Section IV.

**Key Dates:**

Published	February 19, 2020
LOI Submission Deadline	N/A
LOI Applicant Notified	N/A
Full Application Deadline	rolling
Committee Review Date	rolling
Notification to Applicants	12 to 16 weeks post submission
Project Start Date	As determined by applicant

**Table of Contents:**

- I. [About the Cystic Fibrosis Foundation](#)
- II. [Program and Award Overview](#)
- III. [Funding Amounts](#)
- IV. [Eligibility](#)
- V. Mentorship Requirements
- VI. [Goals of Research Currently of Interest to CFF/Priority Areas](#)
- VII. [Review and Award](#)
- VIII. [Submission Information](#)
- IX. Letter of Intent Guidelines
- X. [Full Application Guidelines](#)
- XI. Other Information
- XII. [Contact Information](#)
- XIII. [Electronic Application Checklist](#)

## I. About the Cystic Fibrosis Foundation

The mission of the Cystic Fibrosis Foundation is to cure cystic fibrosis and to provide all people with CF the opportunity to lead long, fulfilling lives by funding research and drug development, partnering with the CF community, and advancing high-quality, specialized care.

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

## II. Program and Award Overview

CFF has developed its research program to complement work at the National Institutes of Health (NIH). Support from CFF, through various mechanisms, is intended to provide support for the development of sufficient preliminary data to make CF-related applications highly competitive in the NIH review process. However, as a result of funding constraints on the NIH, coupled with the growing interest in CF research, occasions arise in which highly meritorious grants are submitted to the NIH but not funded. In an effort to assure that all meritorious CF-related research is supported, CFF has developed the CFF/NIH-Unfunded Award mechanism to provide bridge funding. The objective of this Request for Applications (RFA) is to support excellent CF-related research projects that have been submitted to and approved by the NIH (or governmental funding agencies in other countries) but cannot be supported by available funds. In order to be eligible for this program, applications must fall within the upper 40th percentile.

CFF does not intend to assume the role of the NIH or other governmental funding agencies, but instead wishes to ensure that the momentum in CF research is not irreversibly slowed due to budget constraints. The CFF/NIH-Unfunded Award offers a temporary mechanism for continuing highly meritorious projects until support can be obtained. The CFF will continue to vigorously encourage the NIH to assume support of meritorious CF-related projects.

## III. Funding Amount

The maximum award amount is \$125,000 per year for up to two years (Direct Costs Only); indirect costs are not allowable. *Note: the level of funding will be determined by CFF following review by the designated medical/scientific advisors.*

## IV. Eligibility

- The application must have been reviewed by an NIH study section and presented to an institute council within 12 months of applying for CFF support.
- Applications must have been submitted to NIH as an R01/R21 and fall within the upper 40th percentile. If an application has been submitted to NIH multiple times, the most recent submission must have been scored in the upper 40th percentile to be considered.
- For applications submitted to governmental funding agencies in other countries, in order to be considered for this program, the application must have been submitted in the previous 12 months to an NIH R01/R21 equivalent funding program, provide reviewer critiques, provide a report indicating the scores in the upper 40th percentile, and be able to resubmit to the funding agency for funding for this project.
- The original NIH application must be clearly relevant to advancing the CFF mission.
- The investigator should not be receiving other funding for this work. If other funding is obtained (through NIH or other funding bodies) for this work, the CFF award must be relinquished.
- If awarded, a revised application must be submitted to the funding agency within one (1) year of receiving the CFF award. Failure to do so will result in the loss of support. Documentation showing resubmission must be provided to CFF as part of the final scientific report.

## V. Mentorship Requirements

*Not applicable to this RFA*

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

Kalydeco™ (VX-770), the first drug to target the basic CFTR defect, demonstrated that CFTR modulating drugs improve clinical parameters such as sweat chloride, lung function, and body weight. CFF will continue to support efforts that improve our understanding of basic CFTR defects as well as mechanisms by which CFTR modulators improve patient outcomes. While CFTR biogenesis, trafficking, structure/function, airway defense, and microbial adaptation to the CF lung remain relevant, CFF will prioritize funding of projects that are focused in areas of research that may lead to the development of new and innovative therapies. Microbiology-focused applications should utilize clinically relevant strains and samples or should address host responses to the organism as part of the application. Those applications that do not have a clear translational component or path to therapeutic development will receive a lower relevance score. Investigators working in the following areas are particularly encouraged to submit an application for consideration.

### Research areas with a high priority to the CF Foundation:

- Molecular characterization of CFTR mutations other than F508del
- Direct and indirect influences of CFTR modulation on the airway milieu, including resident pathogens, inflammation and inflammatory cell function, mucin structure (tethered and secreted), airway surface liquid (ASL), and mucociliary clearance (MCC)
- Novel means for restoring CFTR function
  - Gene editing/repair strategies
  - Delivery methods for DNA, RNA, and protein to the lung and other affected tissues
  - Cellular targets for CFTR correction
  - Airway progenitor cells, airway stem cell niche
- Mechanisms associated with nonsense mutations and means to overcome them, specifically mRNA stability and translational regulation
- Biological mechanisms involved in lung allograft dysfunction, rejection and transplant immunology
- Improved understanding of acquisition, pathogenesis, host-pathogen interactions, and treatment approaches for difficult to treat CF infections (i.e. NTM, MDR Pseudomonas, MRSA, Aspergillus)
- Approaches to understand and treat CF related GI complications and the impact of nutritional deficiencies
- Effects of endocrine system dysfunction in CF, including Cystic Fibrosis Related Diabetes (CFRD)

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

## VII. Review and Award

Since applications to this program have already been reviewed and scored by an NIH (or other governmental agency) study section, CFF medical/scientific advisors will focus on the following points:

- Relevance of the proposed study to issues in CF
- Adequacy of the budget
- Potential for future support by the NIH (or other governmental funding agencies)

All awards are subject to observance of CFF policies and Terms and Conditions in addition to applicable Federal regulations or equivalent regulations in the Awardee Institution's country, based on the type of research involved. All awards and ongoing support are also contingent upon the availability of CFF funds.

Applications may be resubmitted through this mechanism after they have gone through another round of review by NIH (or other governmental agency), and still have a priority score in the upper 40th percentile.

## VIII. Submission Information

**Application Deadline (rolling): through Monday, November 2, 2020 at 5:00 PM (EST)**

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.

### General Timeline:

Application Deadline _____	rolling
Review _____	rolling
Notification to Applicants _____	12 to 16 weeks post submission
Project Start Date _____	As determined by applicant

## 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 **“CFF/NIH-Unfunded Award (Rolling Deadline)”** 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:** Enter a project title for the CFF application. Answer the required questions about the title of the NIH (or relevant governmental agency) unfunded application, the NIH unfunded application number (or relevant governmental agency's application number), whether the applicant is a new investigator to CF research, and about the applicant's prior application and award history with CFF.
- 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:
  - Results of Past and Current CFF/CFFT Support
  - Budget Detail
  - Budget Justification
  - Response to NIH Summary Statement
  - Revised Research Plan
  - Other Support
  - International Institutional Form (if applicable)
- 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. Key Personnel:** In the table online, provide contact information for key personnel included in the application, other than the PI/Applicant. To add a new contact, enter the e-mail address of the person in the available field. Click the "Add contact" icon. Complete the contact form that pops up and click "Save". *Note: if the person is already registered in proposalCENTRAL, some information will be pre-loaded into the contact form.* To edit the person's contact information, click the "Edit" icon in the Actions column to the far right. To delete a person from the table, click the "Delete" icon. *Note: Changes made to the person's contact information will apply to this proposal only. Permanent changes must be made in the person's Professional Profile by the person.*
- 7. Abstracts/Relevance:** 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 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.***

- 8. 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 budget requested cannot exceed \$125,000 per year.  
*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 J. ORGANIZATION ASSURANCES & CERTIFICATIONS in these guidelines for details.
- 10. Revised 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. Budget Detail and Budget Justification (separate templates available for download)**

Fill out the Budget Detail and Budget Justification templates for each and 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**

**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 \$197,300. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all funding agencies and foundations.

**Consultant Costs** - Give the name and institutional affiliation of any consultant who has agreed to serve in this capacity, including statisticians and physicians in connection with acquiring patient samples if they are not listed under personnel. In the budget justification, briefly describe services to be performed, the number of days, rate of compensation, per diem and any other associated costs.

**Subcontractors** - The total cost of each subcontract (directs costs only) should be listed under “Other Expenses” and included in the applicant’s direct costs. Separate Budget Details and Justifications must be provided for each subcontract, for each year of support (complete and upload a Budget Detail and Budget Justification template for each subcontract). Negotiations of subcontracts are between the applicant institution and the subcontractor.

**Major Equipment** – List all items of equipment greater than \$5,000 requested and the cost of each item. If funds are requested to purchase equipment that is equivalent to items listed under “Facilities Available,” justify the duplication. Justify any item of equipment for which the need may not be obvious.

**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 may not exceed \$1,500 per person, per year. Registration fees associated with conferences should be listed under “Other Expenses.”

**Other Expenses** - Itemize other expenses by major categories, such as subcontracts, duplication costs, publication costs, computer charges, conference registration fees, etc. Tuition costs may be requested for personnel supported through this study but may not exceed \$10,000 per person per year.

**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.

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

**Indirect costs are not allowable.**

#### **Budget Justification**

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

### **B. Copy of NIH (or other governmental funding agency) unfunded application (upload as PDF document)**

A PDF copy of the entire unfunded grant application should be uploaded to proposalCENTRAL (in Section #10) of the online application. When uploading the file:

- Select “Copy of NIH/Other-Unfunded Application” as Attachment Type from the available drop-down menu.
- Describe attachments as “NIH/Other-Unfunded Application” in the corresponding field.

### **C. Copy of NIH Summary Statement (or equivalent) (upload as PDF document)**

A PDF copy of the entire NIH Summary Statement associated with the unfunded grant application must be uploaded to proposalCENTRAL (in Section #10) of the online application. Applications that were submitted to governmental funding agencies in other countries should submit the reviewer critiques provided by the funding agency. When uploading the file:

- Select “Copy of NIH Summary Statement (or equivalent)” as Attachment type from the available drop-down menu.
- Describe attachment as “NIH Summary Statement” in the corresponding field.

#### D. Responses to NIH Summary Statement (template available for download)

Please provide a point-by-point response to the critiques noted in the NIH Summary Statement (or reviewer critiques provided by the funding agency) and specific plans to address identified weaknesses. There is no page limit to the responses; however, be as concise and succinct as possible.

#### E. Revised 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(s). If uploaded as Appendices, they will NOT be reviewed.
- Type the PI's name in the space available in the header of the document. The template available will track page numbers at the bottom.
- Page limit: Ten (10) 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.

The Revised Research plan should not be a copy of the submitted NIH (or other governmental funding agency in another country) unfunded application. Instead, **this section should highlight the scope of work and experiments that will be completed using the funds from CFF if the award is funded.** This section should specifically address weaknesses noted in the NIH Summary Statement (or reviewer critiques provided by the funding agency) as well as the reduced CFF budget. The Revised Research Plan must also include a clear strategy for resubmission of the original application to the funding agency. The plan may include the following components:

- 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.
- 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.
- Preliminary Results:** If applicable, provide a detailed discussion of any preliminary results.
- Experimental Design and Methods:** Discuss 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 the 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. Applications that include methodologies requiring sampling of materials from human subjects will only be considered under this mechanism if the sampling method constitutes minimal patient risk (e.g., venipuncture, nasal brushing) and patient samples or data are anonymous. Describe the level of risk and measures taken to assure patient anonymity to the PI and other professional personnel, unless the PI or other professional personnel are care providers.
- Consultant Arrangements:** If the proposed project includes consultant arrangements and/or collaboration with other individuals outside the applicant's group, describe the working

relationships and support this description by letter(s) of intent signed by collaborating individual(s). If clinical material required by this award is to be furnished by other individuals, include a letter from these individuals agreeing to their participation and precautions taken to ensure anonymity of patients.

- f. **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).

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

Complete and upload the Other Support form for all key project personnel, beginning with the Applicant/Principal Investigator. There is no page limitation. Information on other support assists CFF in the identification and resolution of potential sources of overlap. Scientific and budgetary overlap should be minimized. Commitment of an individual's effort greater than 100 percent, is not permitted.

**G. Letter(s) of Support for Investigators New to CF Research (upload documents as Appendices, if applicable)**

*Note: Not required for experienced CF investigators, e.g. recipients of CFF/past CFFT funding, investigators with recent publications in the field.*

Investigators new to CF research are strongly encouraged to consult or collaborate with an established CF investigator/clinician either at their own institution or another. An investigator is considered new to CF if they have not previously (1) published in CF or (2) received extramural funding for a CF-focused research project. A letter of support from the collaborator/consultant should be included with the application, explicitly describing how the proposed work is relevant to CF and how the collaborator/consultant will assist the investigator (such as providing scientific expertise or CF-relevant samples and reagents). Upload a PDF of the signed letter(s) of support as appendices to proposalCENTRAL (in Section #10).

**H. 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.
- 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.

**I. 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](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.

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

Applicants whose institution is not a United States based entity must complete the International Institution Form. **Upload a PDF version of the completed and signed form, together with the following documents\*:**

- A copy of the institution's most recent Mission Statement.
- A copy of the institution's Tax Exemption Letter, if institution is nonprofit.
- A description of other sources of support, such as official awards, private endowments, and commercial activities, received by the institution.
- A copy of the institution's Standard Operating Procedure(s) or relevant policy to ensure that funds provided are neither distributed to terrorists or their support networks, nor are funds used for activities that support terrorism or terrorist organizations.
- For-profit institutions must submit a complete list of key employees, members of the governing board, and/or other senior management.

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

**K. APPENDICES (upload materials as PDF documents)**

Appendices are restricted to the following four (4) 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.
- **Signed Letters of Support and/or Collaboration:** A Letter of Collaboration from Co-PIs, if any, should be uploaded and included in the application. Investigators new to CF research are strongly encouraged to consult/collaborate with an established CF investigator/clinician either at their own institution or another and required to submit a Letter of Support. The letter of support from the collaborator/consultant should be explicit as to how the proposed work is relevant to CF and how s/he will assist the investigator new to CF research.
- Additional NIH (or equivalent) Biographical Sketches, that are not already included in the original application, should be completed/uploaded for any new key personnel named in the CFF application. *Note: CFF defines “key personnel” as any individual with an advanced degree that will plan an instrumental role in the accomplishment of the research project.*

**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.

**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.  CFF will not receive your application unless the “Submit” button is clicked.

**15. 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](mailto: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](mailto:grants@cff.org) or 301-841-2614

### XIII. Electronic Application Checklist

**Application Deadline (rolling): through Monday, November 2, 2020 at 5:00 PM (EST)**

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
- Key Personnel (online)

#### Research Plan & Supporting Documents:

- Results of Past and Current CFF/CFFT Support - (upload)
- Budget Detail for each year of support requested - (upload)
- Budget Justification for each year of support requested - (upload)
- Copy of NIH-Unfunded (or other governmental funding agency) Application - (upload)
- Copy of NIH Summary Statement (or equivalent) - (upload)
- Responses to NIH Summary Statement (or reviewer critiques provided by the funding agency) - (upload)
- Revised 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)
- Other Support – (upload)
- Verification of Applicant Institution's Tax Status - (upload)
  - W-9 (U.S. applicants) or W-8BEN-E (non-U.S. applicants)
  - Federal (IRS) tax status letter (U.S.-based applicants) or equivalent tax status letter, or letter indicating it is not available (non-U.S.-based applicants)
- International Institution Form (non-U.S.-based entities only) - (upload, if applicable)
  - Institution's most recent Mission Statement
  - Applicant institution's tax status documentation or equivalent, or a letter stating it is not available
  - Description of other sources of support, such as official awards, private endowments, and commercial activities, received by institution
  - Institution's Standard Operating Procedure(s) or relevant policy to ensure that funds provided are neither distributed to terrorists or their support networks nor used for activities that support terrorism or terrorist organizations
  - For-profit institutions must submit a complete list of key employees, members of the governing board, and/or other senior management
- Appendices (upload as PDF documents, if applicable)
  - Certification of organization assurances (i.e. IRB, IACUC and IBC approvals), if available at the time of application.

- Up to three (3) reprints of the applicant's work relating to the general area of research in the proposal
- Signed Letter(s) of Support and/or Collaboration. Note: Letter of Support is required for Investigators New to CF Research - (upload)
- Additional NIH (or equivalent) Biographical Sketches not already included in the original unfunded application - (upload)