



Pilot and Feasibility Awards – Fall 2019 Cycle

POLICIES AND GUIDELINES

Published: October 15, 2019

Application Deadline: December 5, 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 care.

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

II. PILOT AND FEASIBILITY AWARD OVERVIEW

Pilot and Feasibility Awards are intended to support projects that will develop and test new hypotheses and/or new methods (or those being applied to the problems of cystic fibrosis for the first time), and to support promising new investigators as they establish themselves in research areas relevant to cystic fibrosis. The intent of these awards is to enable investigators to collect sufficient data to compete successfully for support from the NIH or other funding agencies. Special consideration will be given to those projects that propose innovative and creative approaches to the problems of CF. Applications for continued funding of the same project, or for long-term support of an investigator, will not be considered.

General Guidelines and Eligibility:

- Funding of up to **US\$50,000** per year, plus twelve percent (12%) indirect costs may be requested.
- Awards may be approved for up to a two-year period. Funding for Year 2 is contingent upon submission and approval of a renewal progress report and the availability of funds.
- U.S. residents and applicants from outside the U.S. are welcome to apply.
- International applicants and institutions are required to submit additional information in accordance with USA Patriot Act and the U.S. Department of Treasury Anti-Terrorist Financing Guidelines (see section VI.10.L below).
- Applicants must be independent investigators.
 - Candidates who are clinical fellows should apply to the CFF Clinical Fellowship program for the appropriate year.
 - Candidates who are postdoctoral fellows should apply to the CFF Postdoctoral Research Fellowship program.
- Multiple CFF Pilot and Feasibility Awards held by a single investigator will not be permitted for this program when the total combined funding exceeds US\$56,000 per year. In such cases, the most recent application submitted will be considered administratively ineligible.

Pilot and Feasibility Award applications must focus on basic science research. Proposals that include methodologies requiring human subjects or sampling of materials from human subjects will be considered under this mechanism only if the sampling method constitutes minimal patient risk (e.g., venipuncture, nasal brushings) and the sample will be utilized in basic or laboratory research. Projects using previously obtained human samples or samples collected as part of routine clinical care may be allowed; however, this should be specified

clearly in the application. All other projects involving human subjects, including interventional studies, may not be reviewed nor funded through this award mechanism and should instead submit their proposals under the [Clinical Pilot and Feasibility Award](#) mechanism. Please refer to that program's Policies and Guidelines on the CFF website (www.cff.org).

III. RESEARCH AREAS OF INTEREST TO CFF

The landscape of CF has changed significantly over the past 30 years since the identification of the *CFTR* gene. In 2012, Kalydeco™ (VX-770), the first drug to target the basic *CFTR* defect, was approved for a small subset of people with CF and clearly demonstrated that *CFTR* modulating drugs can improve clinical parameters such as sweat chloride, lung function, and body weight. CFF realizes the remaining needs of the community and therefore continues 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 adaption to the CF lung remain relevant research endeavors, CFF will prioritize funding on those projects that will lead to a better understanding of disease mechanisms, pathophysiology, or the development of new prevention and treatment strategies.

Emerging areas of interest with 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
 - Fundamental studies that will enable gene editing/repair strategies to be used in therapeutic applications
 - Delivery methods for nucleic acids, 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, detection, pathogenesis, host-pathogen interactions, and treatment approaches for difficult to treat CF infections (i.e. NTM, MDR *Pseudomonas*, MRSA, *Aspergillus*, *Burkholderia*, *Stenotrophomonas*)
- 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) and CF bone disease

Note: Infection/microbiology-focused applications should utilize clinically relevant strains and specimens 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 generally receive lower relevance scores.

IV. REVIEW AND AWARD

All applications are evaluated by CFF's Research and Research Training (RRT) Committee, whose recommendations are reviewed by the Medical Advisory Council (MAC) and/or the Board of Trustees. Funding of awards is based on the priority score awarded to each application and the recommendations of the RRT Committee. Funding decisions are based on the relevance of the proposed study to the goals of the Foundation, alignment with specific research priorities, and enhancing the existing CFF project portfolio. All awards are subject to compliance with applicable regulations and CFF policies and are contingent upon the availability of CFF funds.

All applications will be reviewed and scored by the RRT Committee. 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 that have not been discussed (or triaged) in two review meetings will not be accepted for further consideration by CFF unless prior approval has been granted by the CFF Grants and Contracts Office. In order to resubmit unfunded applications during future application cycles, applicants must address reviewer critiques.

Chief causes 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
- 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 of the criteria described in the policy statement for a given award

V. SUBMISSION INFORMATION & GENERAL TIMELINE

Applicants may only submit one (1) Pilot and Feasibility Award application in 2019

Application Deadline: Thursday, December 5, 2019 at 5:00 PM (ET)

Submit online through proposalCENTRAL: <https://proposalcentral.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 _____	December 5, 2019
Review by Research and Research Training Committee _____	March 2020
Notification to Applicants _____	April 2020
Earliest Start Date for Awarded Projects _____	May 1, 2020

VI. 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.*

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 Application (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 **“Pilot and Feasibility Award”** 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 next to the in-progress application.

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 the title of your project, indicate whether the Principal Investigator (PI) is an investigator new to CF, and whether this is a resubmission of an application that was reviewed previously (include date of previous submission in the corresponding field).
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
 - Biographical Sketches of Key Personnel
 - Results of Past and Current CFF/CFFT Support
 - Other Support
 - Facilities Available
 - Budget Detail
 - Budget Justification
 - Critique Response (if resubmission)
 - Research Plan
 - Names and Addresses of References for Junior Investigators (if applicable)
 - International Institution 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. 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 Reference for Junior Investigators*:** CFF defines “junior investigator” as any individual who has not received a CFF Research Grant or NIH equivalent (e.g. R01, R21, R23) as a Principal Investigator OR is within their first five (5) years of their first academic appointment at the level of Assistant Professor or equivalent. Letters of Reference for junior investigators must be submitted by the following individuals:
 - **The Chair of the Applicant’s Department at the Applicant Institution** – The letter of reference from the Department Chair should indicate the release of sufficient space and facilities for the work described, as well as guarantee the time commitment of the

investigator to the project. If the applicant is currently a fellow, the letter of reference should include confirmation of the pending faculty-level appointment.

- **At least two (2) other individuals** familiar with the applicant's scientific interests and abilities.

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.

Additionally, applicants must complete the “Names and Addresses of References for Junior Investigators” template and upload it in Section #10.

***Investigators who have received a prior CFF/CFFT Research Grant, Pilot and Feasibility Award or NIH equivalent, are not required to submit Letters of Reference; however, if new to CF research, Letters of Support and/or Collaboration should be provided (see Section H).**

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:

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.

Provide a statement of no more than 2,000 characters (including spaces) summarizing the relevance of the proposed research to the health and well-being of CF patients, for a scientific audience who may or may not have a background in the subspecialty of the proposed research.

- 8. Budget Summary:** Fill in the start and end date and applicable amounts for each year of support requested by completing the online fields (Period 1, 2). All Pilot & Feasibility Awards are for a maximum of two years. The total budget requested cannot exceed **US\$50,000** per year plus 12% indirect costs. ***Note: The Budget Detail and Budget Justification templates downloaded in Section #2 need to be completed and uploaded in Section #10 for each year of the award and for each subcontract (if applicable). The amounts included in the 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 K. 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, enter a description for the attachment in the corresponding field, choose the file to be uploaded, and click the **“Upload Attachment”** button to upload the file. Do this for each attachment.

A. BIOGRAPHICAL SKETCHES OF KEY PERSONNEL (template available online)

Complete and upload an NIH Biographical Sketch for all key project personnel, beginning with the Applicant/Principal Investigator. International applicants can upload a biosketch that is equivalent in content to the NIH template provided (CFF defines “key 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. RESULTS OF PAST AND CURRENT CFF/CFFT SUPPORT (template available online)

The Principal Investigator (PI) and any Co-Principal investigator(s), if applicable, 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 award from which they resulted for the past five (5) years. Please note that the following information must be included with each research project identified:

- CFF/CFFT Award Number
- 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 online)

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.

D. FACILITIES AVAILABLE (template available online)

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 (separate templates available online)

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 or period as well as start and end dates for the proposed budget period. If there are subcontracts, each subcontract requires a separate Budget Detail and Budget Justification. (Be sure the amounts entered in the Budget Detail match the amounts entered in the online budget summary in Section #8).

Budget Detail – Direct Costs

Salary & Benefits - List the names, positions, and percent effort of all professional and non-professional personnel involved in the project, whether or not salaries are requested. For each individual, be sure to complete all fields on the Budget Detail in full on the template provided. In accordance with National Institutes of Health (NIH) policy, salary requests may not use an institutional base salary in excess of the current federal salary cap of **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.

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 the project 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. Indirect costs are not allowable on equipment.

Subcontractors – Detailed budgets for each subcontract, including indirects, must be provided for each year of support (complete and upload a Budget Detail and Budget Justification template for each subcontract). For applications that include a subcontract with a third party, the applicant may request indirect costs on the first US\$25,000 of each subcontract per project period. Negotiations of subcontracts are between the

applicant institution and the subcontractor.

Major Equipment - List all items of equipment greater than US\$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 and Contracts Office. Travel expenses may not exceed US\$1,250 per person per year. Registration fees associated with conferences are in addition to this allowance and 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 (under US\$5,000), computer charges, conference registration fees, etc. Tuition costs may be requested for personnel supported through this study but may not exceed **US\$10,000** per person per year.

Budget Detail – Indirect Costs

Indirect costs of up to twelve percent (12%) may be requested from CFF. Indirect costs may be requested for all expenses except for the following:

- Major equipment (items over US\$5,000 in value)
- Computer software
- Software licenses
- Tuition

Budget Justification

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

F. CRITIQUE RESPONSE (template available online, if applicable)

If the application is a resubmission of a previously declined application, please provide a point-by-point response to the prior reviews. There is no page limit to your responses, but please be concise and succinct.

G. RESEARCH PLAN (template available online)

- Page limit: **Six (6) single-sided pages**, not including the Literature Cited. Applications exceeding this page limit 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.

- 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.
 - 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.
 - If the application is a resubmission of an earlier one, revisions must be clearly indicated by a change in font, bolded or underlined. **CFF will not review resubmissions that have not been revised.**
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- 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:** 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 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:** 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 clinical samples are included in the research plan, provide details of the methods for patient selection. Discuss potential pitfalls 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. Since Pilot and Feasibility Awards are reviewed by CFF's Research and Research Training Committee, 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 cell 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. **Note: Interventional studies involving human subjects cannot be supported through this program and should instead apply as a [Clinical Pilot and Feasibility Award](#).**
 - e. **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 statement 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).

H. LETTER(S) OF SUPPORT FOR INVESTIGATORS NEW TO CF RESEARCH (upload as PDF documents, 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).

I. NAMES AND ADDRESSES OF REFERENCES FOR JUNIOR INVESTIGATORS (template available online)

List the names, titles, and contact information of the individuals who have been asked to submit Letters of Reference on the applicant's behalf. A PDF copy of the completed form should be uploaded. Though not required to submit Letters of Reference, Senior investigators should still check the box in the template that identifies them as Senior investigators and upload the form to proposalCENTRAL.

J. 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.

K. ORGANIZATION ASSURANCES & CERTIFICATIONS

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

L. INTERNATIONAL INSTITUTION FORM (template available online, 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 status documentation or equivalent, or a letter stating it is not available.
- A brief 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 who have provided these documents within the past three (3) years are not required to resubmit them. However, if any of the above documents have been updated since they were previously submitted, please upload any updated documents. The CFF Grants and Contracts Office will contact applicants if documents are outdated or missing.

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

M. APPENDICES (upload as PDF documents, if applicable)

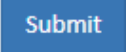
Appendices are restricted to the following three (3) categories:

- 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.

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. No hardcopy is required.

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 blue button with white lettering . 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 and Contracts at grants@cff.org or 301-841-2614

VII. ELECTRONIC APPLICATION CHECKLIST

Application Deadline: Thursday, December 5, 2019 at 5:00 PM (ET)

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

Face Page which includes:

- ☐ Signatures
- ☐ Principal Investigator (Co-PI's are not required to sign)
- ☐ The Official authorized to sign on behalf of the Awardee Institution
- ☐ 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
 - ☐ Recombinant or Synthetic Nucleic Acid Molecules/Biosafety Information
 - ☐ Research Involving Animals Approvals

Research Plan, Supporting Documents and Appendices:

- ☐ Abstracts ~ Summary of Relevance - (complete online)
- ☐ Biographical Sketches for Key Personnel - (upload)
- ☐ Results of Past and Current CFF/CFRT Support - (upload)
- ☐ Other Support (NIH Format) - (upload)
- ☐ Facilities Available - (upload)
- ☐ Budget Detail for each year - (upload)
- ☐ Budget Justification for each year - (upload)
- ☐ Critique Response - (upload, if applicable)
- ☐ Research Plan - (upload)
 - ☐ Hypothesis and Specific Aims
 - ☐ Background and Significance
 - ☐ Preliminary Results
 - ☐ Experimental Design and Methods
 - ☐ Consultants/Collaborative Arrangements
 - ☐ Literature Cited (not included in Research Plan page limitation)
- ☐ Letter(s) of Support for Investigators New to CF Research (upload, if applicable)
- ☐ Names and Addresses of References for Junior Investigators (upload, if applicable)
- ☐ Verification of Applicant Institution's Tax Status - (upload)
 - ☐ W-9 (US applicants) or W-8BEN-E (non-US 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
 - ☐ 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, 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
 - ☐ Signed Letters of Support and/or Collaboration