Cystic Fibrosis Foundation

Pilot and Feasibility Awards

POLICIES AND GUIDELINES

February 6, 2017
I. PILOT AND FEASIBILITY AWARD OVERVIEW

Pilot and Feasibility Awards are offered 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 (CF). 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:

- Funding of up to US$50,000 per year, plus eight percent (8%) indirect costs may be requested.
- Awards may be approved for up to a 2-year period. Funding for year 2 is contingent upon submission and approval of a renewal progress report and the availability of funds.
- Applicants must be independent investigators.
- Applicants need not be U.S. citizens or hold a U.S. permanent visa to apply for this award.
- International applicants and institutions are required to submit additional information in accordance with U.S. anti-terrorist restrictions.

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 grant mechanism and should submit a Clinical Research Award Letter of Intent. Please refer to the Clinical Research Award Guidelines on www.cff.org.

Eligibility:

- United States residents and applicants from outside the United States are welcome to apply.
- Candidates who are clinical fellows should apply to the CFF Clinical Fellowship program for the appropriate year.

II. GOALS OF RESEARCH CURRENTLY OF INTEREST TO CFF

The majority of morbidity and mortality associated with CF today is due to lung disease. In CF, innate defenses are compromised and inhaled or aspirated pathogens are able to establish chronic infections. CF is unique in that only a small subset of pathogens have been linked to disease progression, and the infection remains, for the most part, compartmentalized. Unfortunately, the neutrophil dominant inflammatory response causes tissue destruction and compromised organ-level
function. Both the host and pathogen adapt as the initial insult evolves into an indolent, chronic infection punctuated by acute exacerbations.

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 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, CFF will prioritize funding of projects that are focused in areas of research that may lead to the development of new and innovative therapies. Investigators working in these areas are encouraged to submit an application for consideration.

Emerging areas of potential interest to the CF Foundation:

- Molecular characterization of CFTR mutations other than F508del
- Direct and indirect influences of CFTR modulation on the airway milieu in patients, animal models, and in vitro studies, including resident pathogens, inflammation, mucin structure (tethered and secreted), airway surface liquid (ASL), and mucociliary clearance
- Novel means for restoring CFTR function
  - Gene editing/repair strategies
  - Delivery methods for gene, RNA, and protein to the lung and other affected tissues
  - Cellular targets for CFTR correction
    - Lung progenitor cells, airway stem cell niche
- Mechanisms associated with mRNA stability and translational regulation, specifically related to nonsense mutations and means to overcome them
- Development and characterization of model systems, including patient derived samples (such as nasal and intestinal cells) and induced pluripotent stem cells (iPSC)
- Biological mechanisms involved in lung allograft dysfunction/rejection and transplant immunology
- Effect of CFTR activity on lung inflammation, inflammatory cell function, and bacterial killing and clearance
- Difficult to treat CF infections (i.e. NTM, MRSA, Aspergillus)

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

III. SUBMISSION INFORMATION & GENERAL TIMELINE

Note: Applicants may only submit one (1) Pilot and Feasibility Award application in 2017.

Application Deadline: Wednesday, April 19 or Wednesday, September 13, 2017 at 5:00 PM (EST).
Submit online through proposalCENTRAL: https://proposalcentral.altum.com/

Email a PDF copy of the signed Face Page to grants@cff.org by the same date (see section V.1 below). Late applications will not be accepted and the deadline will not be waived. The Foundation reviews applications electronically, and only the documents submitted online will be reviewed.

**General Timeline**

Application Deadline ____________________________ April 19 or September 13, 2017
Review by Research and Research Training Committee ________________ August or December 2017
Applicant Notified ________________________________ October 2017 or March 2018
Earliest Start Date ________________________________ November 1, 2017 or April 1, 2018

**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. 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.

*All applications will be reviewed and scored by the RRT Committee. Applications receiving low scores, and/or those deemed nonresponsive to the program announcement, may be triaged and withdrawn before the review meeting. Applicants will be notified if their application has been triaged without discussion. Applications that have not been discussed in two review meetings will not be accepted for further consideration by CFF.*

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. INSTRUCTIONS FOR COMPLETING SPECIFIC APPLICATION COMPONENTS

- Font: Times New Roman 12 or Arial 11 font
- Margins: Standard ½”

Note: When all the documents have been uploaded to proposalCENTRAL, the system will compile them into a single PDF file in the correct sequence.

1. FACE PAGE
The Face Page is populated automatically with data entered in the online application (applicant’s name, institution, title of application, etc.). The Face Page can be downloaded after completing the application and clicking on the “Validate” button (Proposal Section 12). The Face Page must be signed by the Principal Investigator and Authorized Institutional Official. Co-Principal Investigators, if any, are not expected to sign the Face Page. However, signed letters of collaboration from Co-Principal Investigators should be provided in the Appendix. Scan and email the signed Face Page to grants@cff.org by the deadline. No hardcopy is required.

2. ABSTRACTS - SUMMARY OF RELEVANCE – KEYWORDS
Enter the abstracts and relevance information online (Proposal Section 7). A system-generated page will get attached to the application. There is no need to upload the same information on a separate document.

Lay Abstract
In the space provided online, 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. This statement will be used to inform the non-scientific departments of CFF and the general public of the nature of this work.

Scientific Abstract
In the space provided online, 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. 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 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.

**Keywords**
From the lists of options provided, select all applicable research topics, keywords, and relevant areas of CF research for the proposed project. A minimum of one option per category must be selected.

3. **LETTER(S) OF SUPPORT FOR INVESTIGATORS NEW TO CF RESEARCH**

**Not required for experienced CF investigators, e.g. recipients of CFF/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. 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. Upload a PDF of the signed, Letter(s) of Support as Appendices (Proposal Section 10).

4. **RESULTS OF PAST AND CURRENT CFF/CFFT SUPPORT (template available online)**
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 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

5. **CRITIQUE RESPONSE(S) (template available online, if applicable)**
If the application is a resubmission, 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.

6. **BUDGET DETAIL AND BUDGET JUSTIFICATION (separate templates available online)**
Complete the online budget summary in addition to a budget detail and budget justification (templates provided online in Proposal Section 2) for all years of support requested. Be sure the detailed budget matches the online budget summary.
• **Budget Detail – Direct Costs**

**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. For each individual, list dollar amounts separately for institutional base salary and fringe benefits. In accordance with National Institutes of Health (NIH) policy, the institutional base salary of an individual should not exceed the current federal salary cap of US$185,100. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all sponsors.

**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 patient care 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.

**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 “7. Facilities Available”, justify the duplication. Justify any item of equipment for which the need may not be obvious.

**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 travel. Please note: travel outside the North American continent for domestic applicants, including travel to Hawaii, Puerto Rico, and other U.S. territories, are not allowable expenses unless approved in advance by CFF. (Travel expenses are not to exceed US$1,250 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 publication costs, computer charges, equipment maintenance, etc. Tuition costs may be requested for personnel supported through this study, but may not exceed US$10,000 per person per year. Justify all items.

**Subcontracts** – The total cost of each subcontract (directs costs only) should be listed under “Other Expenses” and included in the applicant’s direct costs. Detailed budgets for each subcontract must be provided for each year of support. Negotiations of subcontracts are between the applicant institution and the subcontractor.
• **Budget Detail – Indirect Costs**
  Indirect costs of up to eight (8) percent 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

  For grant applications that include a subcontract with a third party, the Applicant may request indirect costs only on the first US$25,000 of each subcontract per year.

• **Budget Justification**
  Describe costs listed in the Budget Detail. Use major categories, such as Personnel, Consultant Costs, Equipment, etc.

7. **FACILITIES AVAILABLE (template available online)**
   Describe the facilities and equipment available at the applicant’s organization 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.

8. **BIOGRAPHICAL SKETCH (template available online)**
   Complete and upload an NIH Biographical Sketch for all key project personnel, beginning with the Principal Investigator. (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. A sample NIH Biographical Sketch is available for download on proposalCENTRAL.

9. **OTHER SUPPORT (template available online)**
   Complete and upload an “Other Support” form, for all key project personnel, beginning with the Principal Investigator. There is no page limitation.

10. **LETTERS OF REFERENCE FOR JUNIOR INVESTIGATORS**
    *Senior investigators are not required to submit Letters of Reference; however, Letters of Support and/or Collaboration should be provided and uploaded as Appendices as necessary* (in Proposal Section 10).
CFF defines “junior investigator” as any individual who as a PI has not received a CFF Research Grant or NIH equivalent (e.g. R01, R21, R23). Letters of Reference for junior investigators must be submitted by the following individuals:

- The Chair of the applicant’s department at the Grantee 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 other individuals familiar with the applicant's scientific interests and abilities.

Names and Addresses of References (template available online, if applicable)
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.

Invite Referees to Submit Letters of Reference through proposalCENTRAL (instructions available online)
Letters of Reference must be submitted electronically ONLY. To “invite” Referees, go to the “Letters of Reference” section of the online application (Proposal Section 6), 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.

11. RESEARCH PLAN (template available online)
- Key figures and legends must be included in the Research Plan. If uploaded as Appendices, they will NOT be reviewed.
- At the top of each page, type the PI's name. Each page must be sequentially numbered at the bottom.
- Page limit: Six (6) 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.
• If your application is a resubmission of an earlier one, your revisions should be clearly indicated by a change in font, or bolded or underlined. CFF will not review resubmissions that have not been revised.

**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 particular those 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.

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

**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 studies are involved, provide details of the methods for patient selection and care. Discuss potential difficulties and/or limitations of the proposed procedures and alternative approaches to achieve aims. 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) 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 instead should be submitted via a Clinical Research Award Letter of Intent.**

**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 grant 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.
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).

12. VERIFICATION OF APPLICANT INSTITUTION’S TAX STATUS (upload as PDF documents)
CFF’s 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, on file. CFF’s Grants and Contracts Office will not issue Award Letters to Grantees 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 Form 147C, or other 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.

13. INTERNATIONAL INSTITUTION FORM (template available online, if applicable)
Applicants whose grantee 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 your organization’s most recent Mission Statement.
- A copy of your organization’s Tax Exemption Letter, if organization is not-for-profit.
- A description of other sources of support, such as official grants, private endowments, and commercial activities, received by your organization.
- A copy of your organization’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 organizations must submit a complete list of key employees, members of the governing board, and/or other senior management.

* English translations must be provided for any documents that are written in the applicant’s or grantee’s institution’s native language, including material provided in support of the Research Plan.

14. ORGANIZATION ASSURANCES & CERTIFICATIONS

Research Involving Human Subjects: The IRB application must be submitted to your institution before the CFF application deadline. CFF policy pertaining to the protection of individuals as
research subjects requires that the applicant 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 Department of Health and Human Services policies. This certification should accompany the application and must be received prior to activation of any grant. If the IRB approval is pending, give the date when it is expected. The approved certification should be submitted as soon as it is available.

**Research Involving Recombinant DNA:** All research involving recombinant deoxyribonucleic acid (DNA) techniques and human gene transfer supported by CFF must meet the requirements contained in the document *NIH Guidelines for Research Involving Recombinant DNA Molecules* (updated April 2016). This publication and announcements of modifications and changes to the NIH Guidelines are available from the Office of Biotechnology Activities, 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. The purpose of the *NIH Guidelines* is to specify practices for the construction and handling of: (i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids; (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or (iii) molecules that result from the replication of those described in (i) or (ii) above.

Many types of studies involving recombinant DNA are exempt from the NIH Guidelines while others are prohibited. The applicant organization is required to establish and implement policies that provide for the safe conduct of the research in full conformity with the NIH Guidelines. This responsibility includes establishing an Institutional Biosafety Committee to review all recombinant DNA research to be conducted at or sponsored by the applicant organization, and to approve those projects it finds are in conformity with the Guidelines.

CFF policy pertaining to recombinant DNA research requires that the applicant institution certify in writing that an institutional committee has reviewed and approved the procedures involving recombinant DNA in accordance with the NIH Guidelines. Applicants that do not have institutional committee approval must submit a recombinant DNA application to the applicant institution before the CFF application deadline. Certifications need not accompany the application, but all required certifications should be available upon request by CFF.

**Research Involving Animals:** Grant applications submitted to CFF involving the use of animals must meet the guidelines of the National Institutes of Health, U.S. Public Health Service, which require that all proposed studies be reviewed and approved by an Institutional Animal Care and Use Committee (IACUC). In addition, CFF grantee 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. Applicants that do not have institutional committee approval must submit an IACUC application to the applicant institution before the CFF application deadline. Certifications need not accompany the application. Applicants must be able to provide copies of all required certifications upon request by CFF.

15. APPENDICES (upload as PDF documents, if applicable)
Appendices are restricted to the following three (3) categories:

- Certification of IRB approval, or statement indicating a pending approval and anticipated date. Other applicable organization assurances documents such as IACUC and IBC Approval Letters.
- Up to three (3) reprints of the applicant’s work relating to the general area of research in the grant 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. The letter from the collaborator/consultant should be explicit as to how the proposed work is relevant to CF and how he/she will assist the investigator new to CF research.

No other types of Appendices will be reviewed.

VI. ELECTRONIC SUBMISSION GUIDELINES

Application Deadline: Wednesday, April 19 or Wednesday, September 13, 2017 at 5:00 PM (EST).

Online registration required, and all applications must be submitted online to proposalCENTRAL at: https://proposalcentral.altum.com.

Late applications will not be accepted and the deadline will not be waived. A PDF copy of the signed Face Page should be emailed to grants@cff.org by the same date. Please do not mail any hardcopy to CFF.

The opening screen, after logging in to proposalCENTRAL, includes multiple grant opportunities organized by Grant Maker and Program. Click on the gray tab labeled “Grant Opportunities” found in the upper right hand side of the page. Then click on the light blue “Filter by Grant Maker” button to the left and scroll down to the Cystic Fibrosis Foundation and click on the “Apply Now” button that appears on the far right in the “Apply” column for the program for which you are applying.

Instructions and templates are provided for review/download in related sections of the application. If you need technical support, please use the contact information that is provided on each screen.
Applicants may stop at any point, each time remembering to click the SAVE button before exiting, and continue/revise until clicking the SUBMIT button. When logging in to continue, click on the blue tab, “Manage Proposals,” and then the “Edit” button.

Access may be designated to another registered individual, such as an assistant, do so in Section 3, “Enable Other Users to Access This Proposal.” Enter the full name and email address and then, in the “Permissions” column, use the drop down menu to select the type of access you wish to give.

An application will be considered incomplete if it fails to comply with 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.

Upon validating your application, follow the prompts to print the system-generated face page. Please click on the SUBMIT key to complete the application process. Sign, scan and email the Face Page to grants@cff.org by the deadline date.

An email confirming successful upload will be sent from proposalCENTRAL, not CFF. This email will be the only acknowledgment that the application was successfully uploaded. If this acknowledgement is not received, please contact proposalCENTRAL to make sure the application is properly submitted.

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: Wednesday, April 19 or Wednesday, September 13, 2017 at 5:00 PM (EST).

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

A PDF copy of the signed Face Page should be emailed to CFF (grants@cff.org) by the same date. The complete application must be submitted online, and no other documents will be reviewed.
Face Page which includes:

- Signatures
  - Principal Investigator (Co-PI’s are not required to sign)
  - The Official authorized to sign on behalf of the Grantee Institution
- Applicant/PI information (online)
- Complete Institution and PI Contact information, including correct mailing address (online)
- Organization Assurances (check those that apply online)
  - Human Subjects Certification - Minimal patient risk only
  - Recombinant DNA Biosafety information
  - Research Involving Animals information

Research Plan, Supporting Documents and Appendix:

- Abstracts ~ Summary of Relevance ~ Keywords (online)
- Letter(s) of Support for Investigators New to CF Research (upload as Appendices)
- Results of Past and Current CFF/CFFT Support (upload)
- Critique Response(s) (upload, if applicable)
- Budget Detail for each year (upload)
- Budget Justification for each year (upload)
- Facilities Available (upload)
- Biographical sketches for all key personnel (NIH Format) (upload)
- Other Support for all key personnel (NIH Format) (upload)
- Letters of Reference (for junior investigators)
  - Names and Addresses of References must be provided (upload)
  - Letters are electronically submitted by each Referee through the proposalCENTRAL website
- 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)
- Verification of Applicant Institution’s Tax Status (upload as PDF documents)
  - W-9 (US applicants) or W-8BEN-E (non-US applicants)
  - 501(c)3, IRS Form 147C or equivalent tax status letter
- International Institution Form (non-US based entities only - upload if applicable)
  - Organization’s most recent Mission Statement
  - Organization’s Tax Exemption Letter, if organization is not-for-profit
  - Description of other sources of support
  - Organization’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 organizations must submit a complete list of key employees, members of the governing board, and/or other senior management

☐ Appendices (upload if applicable)
  ☐ Certification of IRB approval, or statement indicating a pending approval and anticipated date. Other applicable organization assurances documents such as IACUC and IBC Approval Letters
  ☐ Up to three copies of the applicant’s work relating to the general area of research in the proposal
  ☐ Letters of Support and/or Collaboration