Infection Research Initiative Planning Grant

POLICIES AND GUIDELINES

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Application Deadline: September 27, 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 grants and awards are offered to support meritorious research in CF.

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

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

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

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

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

https://www.cff.org/Research/Researcher-Resources/Tools-and-Resources/CFFT-Biorepository/

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

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

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

II. INFECTION RESEARCH INITIATIVE

The mission of the Infection Research Initiative is to improve detection, diagnosis, treatment, and outcomes of infections for people with CF, and builds on the broad infection research portfolio already funded by the CF Foundation. The initiative focuses on all aspects of CF-related infection and can be described by the six Areas of Research Focus.

Infection Research Initiative Areas of Research Focus
- Improving Detection and Diagnosis
- Understanding CF Microorganisms
- Developing New Treatments
- Optimizing Current Treatments
- Evaluating Long-term Antimicrobial Use
- The Future of CF Infection

For more information on the Infection Research Initiative and the Areas of Research Focus, please visit https://www.cff.org/Research/Research-Into-the-Disease/Research-into-CF-Complications/Infections/.

Currently, researchers in academia and industry can request funding for infection research through numerous CF Foundation funding mechanisms. However, the Infection Research Initiative Award is targeted for proposals seeking to address key scientific questions that have been identified as priorities by the Infection Research Steering Committee. All other funding mechanisms will remain available to academic and industry researchers for broader infection-related research and therapeutic development. Applications received through other mechanisms will be assessed for alignment with the Areas of Research Focus and may also be considered part of the Initiative. To learn more about CF Foundation funding mechanisms, please visit https://www.cff.org/Research/Researcher-Resources/Awards-and-Grants/.

2019 Infection Research Initiative Research Priorities
In April 2019, the Infection Research Initiative Steering Committee met to review and evaluate the current CF Foundation research portfolio to identify gaps in knowledge and to recommend further research that is needed to address key questions to improve infection outcomes in people with CF. As a product of the first steering committee meeting, the CF Foundation announces the 2019 Infection Research Initiative Research Priorities and Request for Applications to support research that addresses these priorities.

Applications are *required* to address one or more of the following 2019 Research Priorities:

Improving Detection and Diagnosis
- Novel pathogen detection methods that enable pathogen detection in patients unable to expectorate.
- Standardization of fungi detection and diagnosis of fungal infection, specifically Aspergillus.

Understanding CF Microorganisms
- Characterization of exacerbation phenotypes and understanding the microbial mechanisms driving exacerbations
- Understanding host-pathogen, host-environment-pathogen and pathogen-pathogen interactions that impact lung disease progression
- Optimization of research techniques and methods to better define the biogeography of airway microbial communities, including lung sampling, specimen preparation, and data interpretation

Developing New Treatments
- Development and evaluation of novel model systems to study chronic CF lung infections.
- Research to develop alternatives to conventional antibiotics including bacteriophage therapy, antibiotic adjuvants, and others.

Optimizing Current Treatments
- Pharmacokinetic, pharmacodynamic studies and/or drug-drug interaction studies in CF population of FDA-approved antimicrobials/antivirals including interactions with CFTR modulators and other standard therapies

Evaluating Long-Term Antimicrobial Use
- Data mining or epidemiological approaches to identifying emerging risks and benefits of antimicrobial use
- Understanding mechanisms for toxicities associated with antimicrobial use and identification of prevention or treatment strategies

The Future of CF Infection
- Research to understand the effects of highly effective modulator therapy (HEMT) on established lung infections, risk for future infection, and how to use culture and antibiotics in the post HEMT era.

III. INFECTION RESEARCH INITIATIVE PLANNING GRANT (IRIPG) OVERVIEW

Infection Research Initiative Planning Grants are offered to provide support for the initial development of a research project that addresses a 2019 Research Priority for the Infection Research Initiative and has the potential to make an important contribution to the CF Foundation's Infection Research Initiative mission. Research projects *must address* one or more of the identified research priorities within the six Areas of Research Focus. The planning grant can support activities required to develop a strategy to address a research priority or to develop full application for a large, multi-center clinical research study, including, but not limited to, meeting/workshop support, establishment of the research team, development of study design, finalization of protocol, collection of feasibility data or feedback obtained through surveys or focus groups with people with CF and their families, or others in the research community.

General Guidelines:
- Applicants may request funding of up to $75,000 per year, plus twelve (12) percent indirect costs.
- Awards may be approved for up to a one (1) year period
- International applicants and institutions are required to submit additional information in accordance with U.S. anti-terrorism restrictions.
- Applications *must* address one or more of the identified 2019 Research Priorities within the six Areas of Research Focus to be considered responsive to the Infection Research Initiative RFA.

Eligibility:
- United States residents and applicants from outside the United States are welcome to apply.
- Applicants must be independent investigators.
  - Must be a M.D., D.O., Ph.D. or dual M.D./D.O., Ph.D.
  - To bring new technologies and expertise to the CF field, investigators without experience in CF research are encouraged to apply

- Industry-sponsored research projects are not eligible to apply through this program and instead should consider applying to the [Therapeutics Development Awards](#) program. For additional information, please contact [afield@cff.org](#).

Budget Guidelines:

For the Infection Research Initiative Planning Grant, direct costs may be requested for:

- Salary
- Consultant costs
- Support for multidisciplinary collaborations, including travel

Direct costs must not be requested for:

- Tuition
- Equipment
- Supplies
- Patient Research Costs

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

- Computer software
- Software licenses

Applicants may request indirect costs on the first $25,000 of each subcontract for the project period.

IV. REVIEW AND AWARD

Applications to the Infection Research Initiative Planning Grants RFA are reviewed by an established ad-hoc review committee comprising of basic and clinical researchers, biostatistical reviewers, and community representative reviewers (people with CF and families). Funding of awards is based on priority score, responsiveness to the RFA, and the recommendations of the review committee. All awards are subject to applicable regulations and CFF policies and are contingent upon the availability of CFF funds.

Applications will be evaluated on the proposal's relevance to the identified research priorities and overall goals of the Infection Research Initiative. Applications will also be evaluated on their likelihood of success. Applicants should adequately describe the tasks that will be executed during the planning period. Applicants proposing clinical research projects are required to consult with a biostatistician prior to submitting their proposals and required to include a biostatistician with a minimum of 5% effort for their project.

Community representative reviewers evaluate applications on its relevance to the CF Foundation's mission and the project's potential to impact those living with CF. Community representative reviewers do not review an application for scientific merit. Reviews from the community representative reviewers are used to inform funding decisions.

Funding of awards is approved by the CFF Board of Directors and is based on the availability of funds, priority score assigned to each application, and recommendations of the ad hoc committee, community representative reviewers, and CFF Program Officers. All awards are subject to compliance with applicable regulations and CFF policies.

Chief reasons for assigning low priority scores to applications during review include the following:
- Unresponsiveness to the RFA
- Insufficient information or documentation
- Inadequate statement of hypothesis
- 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 the criteria described in these guidelines
- Failure of the applicant to demonstrate adequate level of statistical support and appropriate plan for data analysis

CFF may redirect applications to other funding mechanisms or withdraw applications receiving low scores, and/or those deemed nonresponsive to the program announcement before the peer review meeting. In these cases, CFF will notify applicants if their application has been redirected or withdrawn without discussion. Applications withdrawn and that have not been discussed in two review meetings will not be accepted for further consideration by CFF.   Applicants may revise and resubmit their applications one time; however, further resubmissions are granted on a case by case basis. Applicants must address reviewer critiques in order to resubmit their applications during future application cycles.

V. SUBMISSION INFORMATION & GENERAL TIMELINE

Submit online submission at proposalCENTRAL: http://proposalcentral.com/
(Refer to Section VI of these guidelines for specific submission instructions)

General Timeline:
Full Application Deadline _____September 27, 2019
Review by Ad hoc Committee _____November 2019
Notification to Applicants _____mid-December 2019
Earliest Start Date for Awarded Projects _____February 1, 2020

VI. APPLICATION GUIDELINES

Full Application Deadline: Friday, September 27, 2019 at 5:00 PM (EST)

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

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.

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 VIII. ELECTRONIC APPLICATION CHECKLIST.*

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

First-time applicants must register to create a user name and password for proposalCENTRAL and will need to complete a profile online before applying. If you are already registered and cannot remember your password, click on the **"Forgot Your Username/Password?"** link below the **"Application Login"** fields. *Note: Use the Customer Service link on the top right of each screen as needed.*

Grant and award opportunities, including this, 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 **"Infection Research Initiative Planning Grant"** 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 the title of your project, indicate whether if you are a new CF investigator, please indicate **YES/NO** if you will be requesting access to the Patient Registry Data or Biorepository Clinical Specimens as outlined in Sections 10. I. and J. respectively, and also select from one of the six Areas of Research Focus and sub-category Priority Areas.

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
   - Research Plan
   - Planning Period Statement of Work (SOW)
   - Budget Detail
   - Budget Justification
   - Biographical Sketches of Key Personnel,
   - Other Support
   - Facilities Available
   - Results of Past and Current CFF/CFFT Support
   - Names and Addresses of References for Junior Investigators (if applicable)
   - [CFF Patient Registry Data Request Application](#)
   - 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 the 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/CFFT Research Grant or NIH equivalent (e.g. R01, R21, R23) as a Principal Investigator OR is within their first five 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 other individuals** familiar with the applicant's scientific interests and abilities.

Enter the email addresses of the individuals who will be asked to submit Letters of Reference for the applicant. Automated emails (with instructions) will be sent to each Referee through the proposalCENTRAL website. **The letters must be uploaded by the referees prior to submitting the application, <u>preferably one (1) week before the application deadline.</u>** Additionally, applicants must complete the "Names and Addresses of References for Junior Investigators" template and upload it in Section #10.

Note: Detailed Instructions on how to invite referees to submit the letters of reference are also available in a downloadable document found in Section #2. Letters uploaded to proposalCENTRAL should not be password protected or otherwise encrypted. Such encryption will cause errors in assembling a single-print PDF of the application. The applicant should inform the individuals writing letters to not include password protection on their documents.

*Senior investigators, or those who have received a prior CFF/CFFT Research Grant or NIH equivalent, are not required to submit Letters of Reference; however, if they are new to CF research, Letters of Support and/or Collaboration should be provided and uploaded as Appendices (in Section #10).

7. **Abstracts/Relevance:** In the space provided online for abstracts, provide a statement of no more than 2,000 characters (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 Infection Research Initiative Research Priorities**
     All applications are reviewed and scored not only on scientific merit but also on relevance to Infection Research Initiative research priorities.

     Provide a statement of no more than to 3,000 characters (including spaces) summarizing how the research addresses one or more of identified research priorities for a non-scientific audience who may or may not have a background in the subspecialty of the proposed research (see Section II of these guidelines). Describe how your project will impact the mission of the Infection Research Initiative. Describe how you will engage the CF Community in your research.

8. **Budget Summary:** Fill in the start and end date and applicable amounts for support requested by completing the online fields (Period 1). One (1) year of funding may be requested. *Note: The Budget Detail and Budget Justification templates downloaded in Section #2 must 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 your application). Refer to Section L. ORGANIZATION ASSURANCES & CERTIFICATIONS in these guidelines for details.

10. **Research Plan & Supporting Documents:** In this section, upload the completed templates downloaded in Section #2 above. 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. **Research Plan (template available for download)**
       • 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.
       • Research Plans are limited to five (5) 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.

       a. **Hypotheses and Specific Aims:** State concisely and realistically the intent of the proposed research and the hypothesis to be tested. Do not exceed one page. The focus of applications must be aligned with one or more of the identified research priorities.
       b. **Background and Significance:** Briefly describe the background of the present proposal. 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.
       c. **Preliminary Studies:** Summarize any preliminary work pertinent to this application that has been undertaken by the Principal Investigator(s) and/or information that will establish the competence and/or experience of the investigator(s) to pursue the proposed study. Titles, complete references and supplemental charts, graphs, etc., may be submitted in the Appendix.

d. **Planning Period Statement of Work:** Provide details on the tasks that will be performed during the planning period. Include details on who will be responsible to complete the task and the general timeline to complete each task.

e. **Limitations and Potential Pitfalls**: Discuss the potential difficulties and limitations of the proposed procedures and alternative strategies for achieving the aims.

f. **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.

g. **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).

B. **Planning Period Statement of Work (template available for download)**
Provide details on the tasks that will be performed during the planning period. Include details on who will be responsible to complete the task and the general timeline to complete each task.

C. **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 each page, indicate the year or period as well as start and end dates for the proposed budget period. **Up to one (1) years of funding may be requested**. If there are subcontracts, each subcontract requires a separate Budget Detail and Budget Justification. (Be sure the Budget Detail matches the online budget summary in Section #8).

- **Budget Detail – Direct Costs**
  Salary & Benefits – List the names and positions of all professional and non-professional personnel involved in the project, whether or not salaries are requested. Indicate the percent effort on the project for all personnel. For each individual, be sure to complete all fields on the Budget Detail in full on the template provided. In accordance with National Institutes of Health (NIH) policy, salary requests may not use an institutional base salary in excess of the current federal salary cap of $192,300; when calculating salary requests, the NIH cap must be adhered to. 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 patient care if they are not listed under personnel. Under budget justification, briefly

describe services to be performed, the number of days, rate of compensation, per diem and any other associated costs.

Subcontractors – Detailed budgets for each subcontract, including indirect costs, 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 $25,000 of each subcontract per project period. Negotiations of subcontracts are between the applicant institution and the subcontractor.

Travel – Describe the purpose of any CF-relevant travel. Please note expenses for travel outside the North American continent for domestic applicants, 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 that exceed 30% of the total budget requested require prior approval from CFF. Additional travel expenses may be requested and will be considered on a case-by-case basis. Registration fees associated with conferences should be listed under "Other Expenses."

Other Expenses – Itemize other expenses by major categories, such as, publication costs, conference registration fees, computer charges, and other costs (e.g., meeting materials, and other reasonable costs associated with meeting planning and community engagement), etc. Justify all items.

- **Budget Detail - Indirect Costs**
  Indirect Costs up to twelve (12) percent may be requested from CFF. Indirect costs may be requested for all expenses except for the following:
  o Computer software
  o Software licenses

  Applicants may request indirect costs on the first $25,000 of each subcontract for the project period.

- **Budget Justification**
  Describe and justify the line items in the Budget Detail. Use major categories, such as Personnel, Consultant Costs, Equipment, etc.

D. **Biographical Sketch(es) of Key Personnel (template available for download)**
   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.

E. Other Support (template available for download)

Complete and upload an "Other Support" form, for all key project personnel, beginning with the Principal Investigator. There is no page limitation.

F. Facilities Available (template available for download)

Describe the facilities and equipment available at the applicant's institution that will be used for this project, such as laboratory, clinical, animal, computer, office, etc. Provide any additional information about the environment, including any support services available that will be utilized. Describe their pertinent capabilities, proximity and anticipated extent of use. If facilities or equipment at a consultant's or collaborative site will be used, they should be identified and clearly described. There is no page limit. Use continuation pages, if necessary.

G. Results of Past and Current CFF/CFFT Support (template available for download)

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 years. Please note that the following information must be included with each research project identified:
- CFF/CFFT Award #
- Principal Investigator (PI)
- CFF/CFFT Project Title
- Applicant's Title on Project
- Project Start/End Dates
- Total CFF/CFFT Award Amount
- Results of Support

H. Names and Addresses of References for Junior Investigators (template available for download)

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.

I. CFF Patient Registry Data Request (if applicable)

Researchers who wish to request Registry data for their proposed clinical research study must complete and submit the "Application for CFFPR Data and Confidentiality Agreement" application to datarequests@cff.org prior to submitting their full application to CFF. The formal application for CFF Patient Registry Data Requests can be found at https://www.cff.org/Research/Researcher-Resources/Tools-and-Resources/Patient-Registry-Data-Requests/

Note: The application must be submitted using the online system available from the link above and the email from the system indicating receipt of the application must be uploaded to the submission. Funding is contingent upon approval to access registry data.

J. CFF Biorepository Clinical Specimen Confirmation Letter (if applicable)
Since 2006, the Cystic Fibrosis Foundation has collected and stored samples from a variety of clinical trials. The CF Foundation has developed a database that combines information from these samples with data from CF clinical trials and the CF Foundation Patient Registry to create a unique and specific sample profile. To request clinical samples to use in the proposed study, download and complete the template from https://www.cff.org/Research/Researcher-Resources/Tools-and-Resources/CFFT-Biorepository/. Applicants must supply a letter from the clinical research program manager confirming samples are available for their use with their LOI submission. For more information, contact Linh Do, CF Foundation clinical research program manager, at ldo@cff.org or 301-841-2648.

Note: Applicants must upload the confirmation letter provided by the CFF Clinical Research Program Manager to the application. Funding is contingent upon approval and availability to access clinical specimens.

K. Verification of Applicant Institution's Tax Status (upload as PDF document)
The 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 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 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.

L. Organization Assurances & Certifications (if applicable and available, upload as PDF documents as Appendices)
Research Involving Human Subjects: CFF policy pertaining to the protection of individuals as research subjects requires that for each proposal awarded, 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 found at https://www.hhs.gov/ohrp/regulations-and-policy/index.html. IRB status must be indicated on the "Organization Assurances" section of the application in proposalCENTRAL. CFF will not release awarded funds until this certification of IRB approval is received and on file with the Grants and Contracts Office. This certification of IRB approval, if available at the time of application, should be included as an appendix to the application. For interventional and

observational studies involving human subjects, the IRB submission date must occur within 30 days following award notification.

Research Involving Recombinant or Synthetic Nucleic Acid Molecules: All research involving recombinant or synthetic nucleic acid and human gene transfer studies supported by CFF must meet the requirements contained in the document *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (updated April 2016).* This publication and announcements of modifications and changes to the *NIH Guidelines* are available from the Office of Science and Policy, National Institutes of Health, 6705 Rockledge Drive, Ste 750, MSC 7985, Bethesda, MD, 20892-7985 or online at http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines.

The purpose of the *NIH Guidelines* is to specify practices for the construction and handling of: (i) recombinant nucleic acid molecules; (ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, or (iii) cells, organisms, and viruses containing such molecules.

CFF policy pertaining to recombinant and synthetic nucleic acid research requires that the applicant institution certify in writing that an IBC has reviewed and approved the procedures involving recombinant and synthetic nucleic acids in accordance with the *NIH Guidelines*. IBC status must be indicated on the "Organization Assurances" section of the application in proposalCENTRAL. CFF will not release awarded funds until this certification of IBC approval is received and on file with the Grants and Contracts Office. This certification of IBC approval, if available at the time of application, should be included as an appendix to the application.

Research Involving Animals: Award 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. IACUC status must be indicated on the "Organization Assurances" section of the application in proposalCENTRAL. CFF will not release awarded funds until this certification of IACUC approval is received and on file with the Grants and Contracts Office. This certification of IACUC approval, if available at the time of application, should be included as an appendix to the application.

M. **International Institution Form (template available for download, if applicable)**
Applicants whose awardee 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 or equivalent, if institution is a nonprofit.

- 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. *If your institution does not have a relevant policy, please provide a statement signed by an institutional official indicating that award funds will not be used to 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.

N. **Appendices (upload materials as PDF documents, if applicable)**
   Appendices are restricted to the following categories*:
- Signed Letters of Support and/or Collaboration:
  o If the applicant is not a CF Center Director or Co-Director, a letter of support from the Center Director is required if requesting support for planning of a clinical research project.
  o If there are Co-Investigators, a letter of collaboration is required from each.
  o Investigators new to CF research are required 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.
- Certification of IRB approval, or other applicable organization assurances documents such as IACUC and IBC Approval Letters, 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 may be uploaded in PDF format.
- Other materials pertinent to the proposal, not already described

*No other types of appendices will be reviewed.

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 your application, click on the "**Validate**" button on the main screen. Attend to any omissions/errors as prompted onscreen, and then click "**Validate**" again.

14. Submit: Click on the gray button with blue lettering. **Submit** CFF will not receive your application until and 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

Full Application Deadline: Friday, September 27, 2019 at 5:00 PM (ET)

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

The complete application must be submitted online, and no other documents will be reviewed.

FULL APPLICATION
Face Page (upload) which includes:
☐ Signatures
    ☐ Principal Investigator (Co-PI's are not required to sign)
    ☐ The Official authorized to sign on behalf of the Applicant 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
    ☐ Research Involving recombinant or synthetic nucleic acid molecules
    ☐ Research Involving Animals
Research Plan, Supporting Documents and Appendix:
☐ Abstracts ~ Summary of Relevance ~ Keywords - (complete online)
☐ Research Plan - (upload)
    ☐ Hypothesis and Specific Aims
    ☐ Background and Significance
    ☐ Preliminary Studies
    ☐ Planning Period Statement of Work
    ☐ Limitations and Potential Pitfalls
    ☐ Consultants Arrangements
    ☐ Literature Cited (not included in Research Plan page limitation)
☐ Planning Period Statement of Work
☐ Budget Detail for each year and subcontract, when applicable - (upload)
☐ Budget Justification for each year and subcontract, when applicable - (upload)
☐ Biographical Sketches of Key Personnel - (upload)
☐ Other Support for all key personnel (NIH Format) - (upload)
☐ Facilities Available - (upload)
☐ Results of Past and Current CFF/CFFT Support - (upload)
☐ Letters of Reference for Junior Investigators - (invite referees to submit via ProposalCENTRAL)
    Note: applicant will not be able to see the letters
☐ Names and Addresses of References for Junior Investigators - (upload)
☐ CFF Biorepository Clinical Specimen Request Confirmation letter
☐ CFF Patient Registry Data
    ☐ Notification of submission of Application for CFFPR Data
☐ Verification of Applicant Institution's Tax Status - (upload)

- ☐ W-9 (U.S. applicants) or W-8BEN-E (non-U.S. applicants)
- ☐ 501(c)3, IRS Form 147C or equivalent tax status letter
- ☐ International Institution Form (non-U.S. based entities only) - (upload, if applicable)
  - ☐ Institution's most recent Mission Statement
  - ☐ Institution's Tax Exemption Letter, if institution is not-for-profit
  - ☐ 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 documents, if applicable)
  - ☐ Signed Letter(s) of Support and/or Collaboration
  - ☐ Certification of IRB approval, or other applicable organization assurances documents such as IACUC and IBC Approval Letters, 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
  - ☐ Other materials pertinent to the proposal, not already described (e.g. Registration documentation for Investigator-Initiated Clinical Trials)