Cystic Fibrosis Lung Transplant Consortium

Letter of Intent (LOI) and Full Application

POLICIES AND GUIDELINES

Published: June 21, 2019
Letter of Intent Deadline: August 2, 2019
Full 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.

II. BACKGROUND
Although median predicted survival in CF has steadily increased over the last several decades, lung transplantation remains an important consideration for many individuals with CF and end stage lung disease. New approaches to improve long term outcomes following lung transplantation are needed due to only modest improvements in median survival after lung transplant in addition to the challenge of chronic lung allograft dysfunction (CLAD). In addition, variations in the selection and care of lung transplant candidates suggests opportunities exist to identify best practices that may improve access to transplant and patient outcomes in the short-term.

III. AWARD OVERVIEW AND FUNDING
CFF will provide up to $130,000 per year, plus indirect costs of 12%, for up to three years to establish a clinical and translational network of CF lung transplant centers (CFLTCs). United States residents and residents of Canada are welcome to apply.

Applications for support of these projects requires a two-step process. Applicants must first submit a letter of intent (LOI) by the deadline of August 2, 2019. Upon notification of acceptance, selected applicants will be invited to submit a full application.

CF Lung Transplant Center Qualifications:
- Transplant Center qualifications and experience
- Research facilities and transplant research experience
- Research staff focused on lung transplant research
- Experience in CF
- Ability to perform specialized procedures and collect biospecimens
- Institutional environment supportive of transplant research

Funding Overview
The size of the center and required number of personnel may impact the total funding amount. This amount can support a Research Coordinator (RC) position devoted to lung transplantation (or a portion of two RCs devoted to lung transplantation to ensure appropriate coverage), and up to 10% of the Principal Investigator (PI) and other key investigator’s effort to protect time for consortium work. The distribution of these funds is at the discretion of the PI and could include administrative support, technical support, or specialized training if they are shown to advance consortium activities. If the funding is used to support other staff, there must be assurances of the
commitment, continuity and availability of the PI and RC to participate in the observational study and all other network affairs, including conduct of clinical studies and trials that emerge from the consortium.

While additional funding will be granted for specific larger research projects, this funding is designed to assure the availability of CFLTC site research staff to participate in core CFLTC projects. Years two and three of funding will be dependent upon satisfactory progress. CFF may elect to base a percentage of the second year of funding and all subsequent funding years on performance during the preceding year.

Additional funding to the site may be available from the following sources:
- Selected site will be provided supplementary funding for the support of specialized services provided to the CFLTC (e.g. cell and RNA isolation and other methods for immunophenotyping).
- Compensation will be provided for selected committee responsibilities.
- Conduct of interventional clinical trials.

IV. OBJECTIVES AND SCOPE

The objective of this proposal is the establishment of a clinical and translational research network of CFLTC to facilitate the study of lung transplant for CF and other lung diseases to improve access, clinical care, and long-term outcomes of individuals with CF who undergo lung transplant. The initial award is designed to provide support for research personnel which will allow sites to successfully contribute to projects with the following goals:

1. Initiate an observational study of lung transplant candidates and recipients to identify and develop best practices for the care of CF lung transplant recipients. Sites will be expected to share their clinical protocols to identify the variations in practice and thereby inform discussions on standardizing post-transplant care, with the goal of improving quality of care and providing a baseline on which interventions can optimally be tested. Critical to the observational study will be the sites’ contribution to a longitudinal database of detailed pre and post-transplant clinical information that will enable observational studies of post-transplant complications and their associated risk factors. Clinical data will include but are not limited to demographics and insurance information, medication use, as well as pulmonary diagnostic tests including pulmonary function, imaging and bronchoscopy results, complications, and treatments. Data from lung transplants for all patients with CF, and a selected population of patients who receive transplant for other indications will be included.

2. Create a biorepository of prospectively collected, serial samples of blood, urine, bronchial washes and bronchoalveolar lavage, and when feasible, bronchial brushes and transbronchial biopsies. Samples in the biorepository will be linked to the database to facilitate discovery of biomarkers for transplant complications with a focus on CLAD.

3. Each CFLTC site will be expected to conduct clinical trials with the network including:
• Enrollment of eligible subjects, accurate collection, storage, and shipping of biospecimens completion of study procedures, appropriate reporting of adverse events, and compliance with regulatory guidelines.
• Entry, verification, and transmission of clinical study data to the CFLTC database.
• Additional activities may include serving as lead site for studies that use the clinical database and biorepository, performance of specialized procedures for biomarker and outcome measure development and contribution to the development of clinical protocols for conduct by the network.

4. Ideally the consortium will include approximately 10-15 CFLTC sites with a subset of sites with specialized expertise in translational clinical research. Further expansion by adding other care centers may be considered in the future.

5. This program will provide infrastructure support to ensure the ability of staff to collect and contribute data and specimens to the projects outlined above.

6. When needed, separate awards to support conduct of additional trials or specialized procedures will be offered.

Paramount to success of the network and a requisite for funding include the following shared principles:

• Protecting the safety and rights of individuals and patients involved in clinical research is essential.
• The network sites commit to maximize the efficient use of resources for study development and conduct in addition to optimizing patient access to clinical trials of therapeutic approaches.

V. STUDY PERFORMANCE METRICS AND QUALITY IMPROVEMENT

Once a site is operational, the Coordinating Center will assist the CFLTC Steering Committee in the development and management of an ongoing site evaluation process. Minimum guidelines and criteria for assessment of performance for study conduct will be established by the CFLTC Steering Committee. The criteria established will be the primary objective in nature (e.g. enrollment, timeliness of IRB approval and contract execution, timeliness and completeness of clinical data entry). Sites will be requested to enter enrollment and start-up metrics information into a database on a quarterly basis to ensure that the Coordinating Center and CFF have a clear picture of current activities at a site. Additional criteria will allow some input by the Coordinating Center and biorepository director to evaluate such key factors as site responsiveness, protocol violations, and data and sample quality.

Reports will be provided to each site that will allow each site to see how their enrollment numbers compare to other sites. These reports should be used to initiate Quality Improvement Initiatives, when applicable.

Each CFLTC site will be expected to participate in a CF Lung Transplant Learning and Leadership Collaborative if they have not previously participated in one.
VI. REVIEW AND AWARD

Applications will be reviewed by a CFF ad hoc review committee. 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 review committee, and CFF Program Officers. All awards are subject to compliance with applicable regulations and CFF policies.

Applications will be evaluated on:
- Transplant Center qualifications, experience, volume and waitlist details
- Available research facilities and previous transplant research experience
- Narrative describing vision for site’s contribution to CFLTC
- Ability of research staff to focus on lung transplant research within the CFLTC
- Experience and volume of lung transplant performed in the last five years for CF
- Expertise in lung transplant related specialized research procedures
- Institutional environment supportive of transplant research

Additional expectations:
- Ability to network with other lung transplant centers
- Institutional commitment to facilitate the contract process
- Provide regular updates on study team changes, site capabilities and study participation
- Responsive to requests for information from the CFF or coordinating center
- Participation on committees
- Attendance at transplant consortium meetings

CFF may withdraw applications receiving low scores, and/or those deemed nonresponsive to the program announcement prior to the review meeting.

VII. SUBMISSION INFORMATION & GENERAL TIMELINE

A Letter of Intent (LOI) must be submitted and approved prior to submitting a full application.

Submit online submission at proposalCENTRAL: http://proposalcentral.com/

**General Timeline:**
- LOI Submission Deadline ________________________________ August 2, 2019
- LOI Applicant Notified ________________________________ mid-August 2019
- Full Application Deadline ________________________________ September 27, 2019
- External Review Meeting ________________________________ November 2019
- Notification to Applicants ________________________________ December 2019
- Earliest Start Date for Awarded Projects ___________________ January 1, 2020
VIII. LETTER OF INTENT SUBMISSION GUIDELINES

LOI Submission Deadline:  **Friday, August 2, 2019 at 5:00 PM (ET)**

LOI must be submitted online at proposalCENTRAL:  [https://proposalcentral.com/](https://proposalcentral.com/)

The LOI will be considered incomplete if it fails to comply with these instructions, or if the submitted material is insufficient to permit adequate review. CFF reviews LOIs 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

Log-in at proposalCENTRAL:  [https://proposalcentral.com/](https://proposalcentral.com/).

First-time applicants must register to create a user name and password for proposalCENTRAL and will need to complete a profile 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 “Lung Transplant Consortium” program. Click on the “Apply Now” button in the column on the far right to open the application.

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.

2. **Download Templates & Instructions:** Download the available templates applicable to the project, fill them out and upload them when completed in Section #8. Templates available include: LOI Cover Sheet, Biographical Sketch(es) of Key Personnel, Response to Prior LOI Critique (if resubmission), and LOI Project Description.

3. **Enable Other Users 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 information in the required fields and click “Save”.

5. **Institution:** 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. **Budget Summary:** Fill in the start date and end date and applicable amounts for each year of support requested by completing the online fields (Period 1, 2, 3). All Lung Transplant Consortium Awards are awarded for a maximum of three (3) years, up to:
   - **$130,000/year in direct costs** (plus 12% indirect costs) for up to three years. Total maximum requested award amount is $436,800 for all three years.

7. **Attachments:** Complete the templates downloaded from Section #2 and upload them here as PDF documents. Below are instructions specific to each template.

   **A. LOI Cover Sheet (template available for download)**
   The Principal Investigator and any Co-Investigators (if applicable) are required to sign where indicated. (The Applicant Institution’s Authorized Institutional Official’s signature is not required for the LOI).

   The completed LOI Cover Sheet must be uploaded with the submission.

   **B. Biographical Sketch(es) of Key Personnel (NIH template available for download)**
   CFF defines “key project personnel” as any individual with an advanced degree who will play an instrumental role in the research project. An NIH Biographical Sketch form should
be completed for each key project personnel and uploaded as PDF. The maximum length for each biosketch is five (5) pages.

C. LOI Project Opportunity Summary (template available for download)
Upload a PDF copy of the completed document. Maximum of 3 pages (not including the literature cited). A brief summary of your potential to participate as a CFLTC should be completed using the “Opportunity Summary Form Template” available for download on proposalCENTRAL.

Each site should complete a two – three-page summary one short paragraph addressing each of the following seven topics:
1. Transplant center qualifications, experience, volume and waitlist details
2. Available research facilities and previous lung transplant research experience
3. Narrative describing vision for site’s contribution to CFLTC Consortium
4. Ability of research staff to focus on lung transplant research with the CFLTC
5. Experience and volume of lung transplant related specialized research procedures
6. Expertise in lung transplant related specialized research procedures
7. How institutional environment is supportive of transplant research

8. Validate: Upon completing your LOI, click on the “Validate” button on the main screen. Attend to any omissions/errors as prompted onscreen, and then click “Validate” again.

9. Print Face Pages: Face Pages are not required for the LOI. Continue to Section #11.

10. Submit: Click on the gray button with blue 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 LOI was successfully submitted. This e-mail will be your only acknowledgement. If you do not receive this confirmation, please contact proposalCENTRAL immediately to ensure the LOI was submitted.

III. FULL APPLICATIONS GUIDELINES

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

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

Applications received without an approved LOI will not be reviewed.
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 “Cystic Fibrosis Transplant Consortium w/LOI” 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. In addition, please indicate **YES/NO** if you are a new CF investigator.
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 Center Description and Vision, Critique Response, Budget Detail, Budget Justification, Biographical Sketches of Key Personnel, Other Support, Facilities Available, Results of Past and Current CFF/CFFT Support, International Institution Form (if applicable), and Appendices.

3. **Enable Other User to Access this Proposal:** Complete this section online if you wish to designate access to another individual, such as an assistant who has registered on proposalCENTRAL. Enter the email address of the individual and in the “Permissions” column, use the pulldown menu to select the type of access you wish to give. Please note that only delegates who are granted “Administrator” rights can submit applications on behalf of the applicant. Check the “Auto Notify” box and then “Save”.

4. **Applicant/PI:** If a profile was completed upon registration, the fields in this section will already be populated with the information entered in your Professional Profile. If you need to make any changes, click the “Edit Professional Profile” button and follow the instructions. If a profile was not completed, enter the required information and click “Save”.

5. **Institution & Contacts:** If a profile was completed upon registration, the Principal Investigator’s (PI) institution will be preloaded as 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. **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, 3). Up to three (3) years 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.

7. **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 N. ORGANIZATION ASSURANCES & CERTIFICATIONS in these guidelines for details.

8. **Center Description & 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. **Center Description and Vision for Contribution to CFLTC (template available for download)**
   Page limit: Five single sided pages, not including literature cited. Use up to one page to provide details for review criteria 2 and 3 listed below. Use up to a half page for responses to criteria 1, 4-7.

   **Review Criteria:**
   1. Transplant center qualifications, experience, volume and waitlist details
   2. Available research facilities and previous lung transplant research experience
   3. Narrative describing vision for site’s contribution to CFLTC Consortium
   4. Ability of research staff to focus on lung transplant research with the CFLTC
   5. Experience and volume of lung transplant related specialized research procedures
   6. Expertise in lung transplant related specialized research procedures
   7. How institutional environment is supportive of transplant research

   Include sufficient information to permit effective review. Information should be presented in a clear and concise manner, while being specific and informative. Key figures and legends must be included in the Center description.

   **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.

B. **Critique Response (template available for download)**
   Provide a point-by-point response to the limitations noted in the critiques of the LOI, using the template provided.

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 three (3) 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 #7).
Budget Guidelines

- **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 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 $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 $5,000 requested and the cost of each of each item. Large items of equipment ($30,000 and above) are allowable under this program. 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 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 may not exceed $2,000 per person, per year. 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.”

  **Patient Research Costs** – Funds may be requested for patient research costs specifically related to the proposed research and not considered routine care. The
basis for estimating funds requested in this category should be justified and applicants must provide detailed information regarding the proposed costs (e.g., number of procedures, cost per procedure, ancillary costs). The scientific need for patient research costs will be considered in the review. Negotiation of these costs are between the applicant institution and the service provider.

If approved as part of the application, patient research costs are capped at the amount requested in the budget and under no circumstances is CFF or CFF responsible for any costs that are later determined non-covered by third party insurers. Applicants and applicant institutions acknowledge that CFF is solely a provider of funding for the research performed under an approved award and not a sponsor of the research as defined by the FDA (21 CFR §312.3(b)).

**Consumable Supplies** – Itemize supplies e.g. disposables, reagents, 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, conference registration fees, computer charges, and other research costs (e.g., recruitment flyers, brochures, patient travel cost reimbursement, and reasonable patient stipends for participation), etc. Justify all items.

- **Budget Detail - Indirect Costs**
  Indirect Costs up to 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

  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. Verification of Applicant Institution’s Tax Status (upload as PDF document)
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 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.

I. 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 CFF 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 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://www.hhs.gov/ohrp/regulations-and-policy/index.html. 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 CFF 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](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 CFF 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.

**J. 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.*

**K. Appendices (upload materials as PDF documents, if applicable)**

Appendices are restricted to the following categories*:  
- **Signed Letters of Support and/or Collaboration:**
If the applicant is not a CF Center Director or Co-Director, a letter of support from the Center Director is required.

If there are Co-Investigators, a letter of collaboration is required from each.

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 (e.g. Registration documentation for Investigator-Initiated Clinical Trials).

*No other types of appendices will be reviewed.*

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

10. **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.

11. **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.

12. **Submit:** Click on the gray button with blue lettering. 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
IV. ELECTRONIC APPLICATION CHECKLIST

LOI Submission Deadline: Friday, August 2, 2019 at 5:00 PM (ET)
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.

LETTER OF INTENT
- Signed Cover Sheet - (upload)
- Biographical Sketch(es) of Key Personnel - (upload)
- LOI Project Opportunity Summary - (upload)

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, - (online)
- Organization Assurances (check those that apply online)
  - Human Subjects Certification
  - Research Involving recombinant or synthetic nucleic acid molecules
  - Research Involving Animals

Supporting Documents and Appendix:
- Center Description and Vision– (upload)
- Critique Response– (upload)
- 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)
- 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)