Program Name: Path to a Cure (PTAC) Research Grant – Spring 2022

Brief Program Overview/Description: Path to a Cure: Research Grants are intended to facilitate or enable the development of new information that may contribute to the development of new therapies for CF, especially projects focused on advancing CFTR repair and replacement strategies. Proposals must be hypothesis driven and contain sufficient preliminary data to justify support from the Cystic Fibrosis Foundatiton. However, proposals that aim to develop tools or reagents that are not typically hypothesis driven but may facilitate research that could lead to a cure will be considered through this mechanisms. Information derived from such studies will hopefully lead to submission to other funding agencies, such as the National Institutes of Health (NIH).

Funding Amount: Funding of up to **$150,000** per year, plus an additional twelve percent (12%) of indirect costs may be requested. Awards may be approved for up to a two (2) year period.

Eligibility:

- United States residents and applicants from outside the United States are welcome to apply.
- Applicants must be independent investigators (an individual who is out of fellowship training and whose institution allows them to submit applications for research funding as a Principle Investigator).
  - Candidates who are clinical fellows should apply to the CFF Clinical Fellowship program for the appropriate year.
  - Candidates who are postdoctoral fellows should apply to the CFF Postdoctoral Research Fellowship program.
- Additional eligibility requirements can be found in Section IV and Section VI (Goals of Research) below.

Key Dates:

Published	March 25, 2022
LOI Submission Deadline	N/A
LOI Applicant Notified	N/A
Full Application Deadline	May 19, 2022*
Committee Review Date	August 2022
Notification to Applicants	September 2022
Earliest Project Start Date	November 1, 2022

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*We strongly encourage all applicants pre-register their profile, institution, contacts, and Title of their application at least two weeks prior to the application deadline. This will help to ensure the CFF Grants & Contracts Management and Administration (GCMA) Office is able to assist all applicant with any potential system-related queries prior to the Application Deadline.

I. About the Cystic Fibrosis Foundation

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

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

II. Program and Award Overview

Path to a Cure: Research Grants are intended to facilitate or enable the development of new information that may contribute to the development of new therapies for CF, especially projects focused on advancing CFTR protein or gene repair and replacement strategies. **Applicants seeking to submit proposals focused on topics such as mucociliary clearance and airway hydration, infection and inflammation, or non-lung manifestations of disease should apply through the General Research and Research Training Program.** Proposals must be hypothesis drive and contain sufficient preliminary data to justify support from the Cystic Fibrosis Foundatiton. However, proposals that aim to develop tools or reagents that are not typically hypothesis driven but may facilitate research that could lead to a cure will be considered through this mechanisms. Information derived from such studies will hopefully lead to submission to other funding agencies, such as the National Institutes of Health (NIH).

Research Grant 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, will not be reviewed nor funded through this award mechanism and applicants should instead submit their proposals under the Clinical Research Award or Clinical Pilot and Feasibility Award mechanisms. Please refer to the Policies and Guidelines of each of these programs on the CFF website (www.cff.org).

III. Funding Amounts

- Funding of up to $150,000 per year, plus an additional twelve percent (12%) indirect costs may be requested.
- Awards may be approved for up to a two (2) year period. Funding for Year 2 is contingent upon submission and approval of a renewal progress report and the availability of funds.

IV. Eligibility

- U.S. residents and applicants from outside the U.S. are welcome to apply.
- International applicants and institutions are required to submit additional information in accordance with USA Patriot Act and the U.S. Department of Treasury Anti-Terrorist Financing Guidelines (see section VI.10.L below).
- Applicants must be independent investigators.
    - Candidates who are clinical fellows should apply to the CFF Clinical Fellowship program for the appropriate year.
    - Candidates who are postdoctoral fellows should apply to the CFF Postdoctoral Research Fellowship program.
- Applications must focus on one or more of the research areas of interest outlined in Section VI below.
- Applicants who are already funded or seeking funds through the RRT Research Grants program may apply to the Path to a Cure: Research Grant program. However, in order to uphold a scientifically

diverse portfolio, programmatic reviews will occur for all applicants (Principle Investigators) who have active CFF Research Grant funding.

V. Mentorship Requirements

Not applicable to this RFA

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

The landscape of CF has changed significantly over the past 30 years since the identification of the *CFTR* gene. In 2012, Kalydeco™ (VX-770), the first drug to target the basic CFTR defect, was approved for a small subset of people with CF and clearly demonstrated that CFTR modulating drugs can improve clinical parameters such as sweat chloride, lung function, and body weight. Since that time, additional CFTR modulating drugs have been approved that conotinue to change the course of disease for the nearly 90% of people who will benefit from them. However, there is still a significant unmet need for people with CFTR mutations that either do not respond to modulators, do not generate sufficient quantities of protein for correction, or block protein synthesis (i.e. premature stop codon mutations, splice mutations, insertion/deletion mutations etc.). To ensure all people with CF have access to effective CFTR-directed therapies, the CF Foundation announced the Path to a Cure Initiative in 2019.

Projects supported through the Path to a Cure initiative should focus on foundational concepts and strategies, novel tools and methods, and/or technologies that have the potential to inform or ultimately translate into novel therapies to restore CFTR protein function or fix/replace the defective CFTR gene. The CF Foundation will continue to support research programs focused on characterizing CFTR mutations other than F508del, sturcutural studies of CFTR, and mechanisms action of CFTR modulators. However, the following emerging areas of interest represent the highest priority to the CF Foundation:

- Identifying, characterizing, and validating potential targets to promote nonsense mutation suppression, which includes understanding the pathways and mechanisms that regulate translation termination and nonsense mediated decay (NMD)
- Developing novel means of repairing and/or replacing the mutant CFTR gene
- Characterization of cellular targets for CFTR correction, including airway progenitor cells and other affected epithelial tissues (biliary tract, GI tract, pancreas)
- Developing and optimizing the chemistry and formulation of nucleic acid delivery vehicles, both viral and non-viral, that can target disease relevant cells and tissues
- Comprehensive evaluation of the role of various pulmonary cell types in CF disease pathogenesis (i.e. ciliated cells, club cells, ionocytes, etc.) and the region of the lung that is necessary to target with a genetic-based therapy to prevent, halt, or reverse disease
- Methods to overcome barriers that limit delivery of genetic therapies to disease relevant cells and tissues
- Cell, tissue, and animal models to discover and develop nucleic acid delivery vehicles and/or methods of restoring or repairing CFTR
- Tools and assays to pre-clinically evaluate the efficacy and safety of restoring functional CFTR through gene repair, gene replacement, small molecules, or any other novel method

Note: Applicants seeking to submit proposals focused on other CF relevant topics, including but not limited to mucociliary clearance and airway hydration, infection and host-pathogen interactions, lung allograft dysfunction/rejection, CF-related GI complications, CFRD and other endocrine abnormalities should apply through the general Research Award Program (https://www.cff.org/researchers/research-grants).

VII. Review and Award

All applications are evaluated by CFF's Path to a Cure (PTAC) 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 PTAC Committee.

Funding decisions are based on the relevance of the proposed study to the goals of the Foundation, alignment with specific research priorities, and enhancement to the existing CFF project portfolio. All awards are subject to compliance with applicable regulations and CFF policies and are contingent upon the availability of CFF funds.

All applications will be reviewed and scored by the PTAC Committee. CFF may withdraw applications receiving low scores, and/or those deemed nonresponsive to the program announcement before the review meeting. In these cases, CFF will notify applicants if their application has been withdrawn without discussion. Applications that have not been discussed (or triaged) in two review meetings will not be accepted for further consideration by CFF. In order to resubmit unfunded applications during future application cycles, applicants must address reviewer critiques.

Chief causes for assigning low priority scores to applications during review include the following:

- Insufficient information or documentation
- Inadequate statement of hypothesis, experimental design or methods
- Failure of the applicant to demonstrate awareness of and plans for coping with key problems and pitfalls associated with the proposed research
- Insufficient or improper controls
- Failure of the applicant to describe potential relevance of the proposed study to issues in CF
- Failure of the applicant to document the necessary skills or training to accomplish the goals of the proposal
- Failure of the applicant to meet all of the criteria described in the policy statement for a given award

VIII. Submission Information

Applicants may only submit one (1) Research Grant application in 2022
Applications deadline: Thursday, May 19, 2022 by 5:00 PM (Eastern)

Submit online through http://awards.cff.org
(Refer to Section X of these guidelines for specific submission instructions)

An application will be considered incomplete if it fails to comply with the instructions, or if the submitted material is insufficient to permit adequate review. CFF reviews applications electronically, and only documents submitted online at http://awards.cff.org will be reviewed.

General Timeline:

Application Deadline _____ May 19, 2022*
Review _____ August 2022
Notification to Applicants _____ September 2022
Earliest Start Date for Awarded Projects _____ November 1, 2022

*We strongly encourage all applicants pre-register their profile, institution, contacts, and Title of their application at least two weeks prior to the application deadline. This will help to ensure the CFF Grants & Contracts Management and Administration (GCMA) Office is able to assist all applicant with any potential system-related queries prior to the Application Deadline.

IX. Letter of Intent Guidelines

Not applicable to this RFA

X. Full Application Guidelines

Applications must be submitted online at https://awards.cff.org

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 awards.cff.org, the system will compile them into a single PDF file. You may preview this file by selecting "Application Full Print", as well as exporting the compiled PDF file.*

To login, please visit: http://awards.cff.org

For all first-time applicants in the new Grants Management System, we ask that you pre-register to create a username and password for "http://awards.cff.org" and complete a profile prior to submitting an application. ***Please note:*** Applicants should register their profile using the "Domestic Institution" or "International Institution" options to ensure that your profile aligns properly with the institution where the project will be conducted. We also request that as you begin your application, you enter the title of your project, if available. If you are registered and cannot remember your password, click on the **"Forgot Password?"** link below the **"Login"** fields.

Once logged in, the award opportunities, including this Request for Applications (RFA), will be listed in the **Funding Opportunities** tab on the opening screen.

Locate the listing for the "**Path to a Cure (PTAC) Research Grant – Spring 2022**" program. Click on the "Apply" 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 at the bottom of each page *before exiting* in order to save their progress. When you wish to return to your draft application, please do not go through the "Funding Opportunities" tab. Instead, go to the "**My Applications**" tab in the right corner of the main page. When you are in the "**My Applications**" tab you will be able to find all your draft applications by clicking on the "Draft Applications" module.

The following sections are displayed as tabs across the application screen. Click on each section and follow the directions. Click "**Save**" as you complete each section.

GENERAL

Enter the title of your project, enter the project start and end dates, select the number of periods being requested, and complete any additional questions. Also, please complete the organizational assurances indications (i.e. IRB, IACUC, and/or IBC/rDNA approval letter and status at the time of submitting the application) in this section.

*Please ensure that you review and comply with the below Organizational Assurances and Certifications as cited at the end of this section on page 11.

CONTACT PROFILE

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, you may update your profile in this section. Once updated you must "**Save and Validate**" prior to returning to continue your submission.

INSTITUTION

If a profile was completed upon registration, the applicant's/principal investigator's institution will be preloaded as the Lead Institution. Domestic applicants must verify their institution by entering the

Employer Identification Number (EIN) or Tax Identification Number (TIN) to search the system for the correct institution. If the EIN/TIN is not located, you may add the legal institution. Please also confirm if the project site is the same as the legal institution.

Verification of Applicant Institution's Tax Status (upload as PDF documents):
The CFF GCMA Office must have a copy of the applicant institution's current W-9 and 501(c)3 letter, or other documentation verifying its Federal tax status and will not issue Award Letters to Awardees if these documents are not received and on file.

- Applicants from for-profit organizations must submit a copy of the applicant institution's W-9 and IRS documentation verifying the organization's Federal tax status. Awards are not issued prior to having these documents on file with the CFF GCMA 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.

International Applicants (if applicable):
Applicants whose institution is not a United States based-entity will be contacted to provide additional information and completion a CFF International Institution Form. The completion of this form also includes submission of the following documentation:

- A copy of the institution's most recent Mission Statement.
- A copy of the institution's tax status documentation or equivalent, or a letter stating it is not available.
- A brief description of other sources of support, such as official awards, private endowments, and commercial activities, received by the institution.
- A copy of the institution's Standard Operating Procedure(s) or relevant policy to ensure that funds provided are neither distributed to terrorists or their support networks, nor are funds used for activities that support terrorism or terrorist organizations.
- For-profit institutions must submit a complete list of key employees, members of the governing board, and/or other senior management.

Applicants who have provided these documents within the past three (3) years are not required to resubmit them. However, if any of the above documents have been updated since they were previously submitted, please upload any updated documents. The CFF GCMA Office will contact applicants if documents are outdated or missing.

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

CONTACTS

Please note: The INSTITUTION tab must be completed prior to adding internal contacts to ensure that the contacts are properly associated with the applicant institution.
Complete the required contact fields by searching by name for existing contacts at your institution for each role. If the desired institutional contact is not available in the system, you may select "**Add Internal Contact**" to create a basic contact profile in order to add the individual to your application.

Additional optional contacts **not** associated with the applicant institution may also be added. These contacts would be considered as additional contributors involved in the proposed research plan. These may include subcontractors*, consultants, or collaborators. If the desired external contact is not available in the system, you may select "**Add External Contact**" to create a basic contact profile in order to add the individual to your application.

**Adding a subcontractor contact to your application will create a Subcontract budget activity (see BUDGET section below for details).*

REFERENCES (if applicable)

This section will appear if you have selected "**Yes**" for the question on the **GENERAL** tab "**Are you a junior investigator?**"

Letters of Reference for Junior Investigators*: CFF defines "junior investigator" as any individual who has not received a CFF Research Grant or NIH equivalent (e.g. R01, R21, R23) as a Principal Investigator OR is within their first five (5) years of their first academic appointment at the level of Assistant Professor or equivalent. Letters of Reference for junior investigators must be submitted by the following individuals:

- **The Chair of the Applicant's Department at the Applicant Institution** – The letter of reference from the Department Chair should indicate the release of sufficient space and facilities for the work described, as well as guarantee the time commitment of the investigator to the project. If the applicant is currently a fellow, the letter of reference should include confirmation of the pending faculty-level appointment.
- **At least two (2) other individuals** familiar with the applicant's scientific interests and abilities.

Letters of Reference must be submitted prior to submission of the application. To invite Referees, go to the "**REFERENCES**" tab of the online application, and first search for the referee using the lookup field. If the referee is not located in the system you may select "**Add Referee**" to create a basic contact profile in order to add the individual to the application. Once added, this will generate automated emails (with instructions) sent to each Referee. 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 http://awards.cff.org 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.

***Investigators who have received a prior CFF/CFFT Research Grant, Pilot and Feasibility Award or NIH equivalent, are not required to submit Letters of Reference; however, if they are new to CF research, Letters of Support and/or Collaboration should be provided as uploads in the FULL APPLICATION UPLOADS tab.**

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 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 CF the opportunity to lead long, fulfilling lives by funding research and drug development, partnering with the CF community, and advancing high-quality, specialized care.

Provide a statement of no more than 3,000 characters (including spaces) summarizing the relevance of the proposed research to the health and well-being of CF patients, for a scientific audience who may or may not have a background in the subspecialty of the proposed research.

BUDGET

Select the "**Edit Budget**" button under Application Budget, to enter and begin completion of the application's budget detail for each year of funding being requested. Research Grants funded through this RFA are for a maximum of two (2) years. The total budget request cannot exceed $150,000 per year plus an additional twelve (12%) of indirect costs.

Salaries & Benefits - List the names, positions, and percent effort of all professional and non-professional personnel involved in the project, **whether or not salaries are being requested**. For each individual, be sure to complete all fields on the Budget Detail in full on the template provided. In accordance with National Institutes of Health (NIH) policy, salary requests may not use an institutional base salary in excess of the current federal salary cap of **$203,700**. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all funding agencies and foundations.

Consultant Costs - Give the name and institutional affiliation of any consultant who has agreed to serve in this capacity, including statisticians and physicians in connection with the project if they are not listed under personnel. In the budget justification, briefly describe services to be performed, the number of days, rate of compensation, per diem and any other associated costs. Qualifying consultants are individuals that are generally not employed at the applicant institution and/or are consulting independently to the project.

Travel - Describe the purpose of travel being requested. Please note: For North American applicants, expenses for travel outside the North American Continent, including travel to Hawaii, Puerto Rico, and other U.S. territories are not allowable expenses without prior written approval from the CFF GCMA Office. **Travel expenses may not exceed $1,500 per person per year**. Registration fees associated with conferences are in addition to this allowance should be listed under "Other Expenses". Applicants are encouraged to attetnd the North American CF Conference each year to present their work.

Consumable Supplies - Itemize supplies e.g. glassware, chemicals, animals, in separate categories and give the estimated cost of each category. If animals are involved, state the number, unit purchase cost, and unit care cost.

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

Other Expenses - Itemize other expenses by major categories, such as duplication costs, publication costs, minor equipment (under $5,000), computer charges, conference registration fees, etc. Tuition costs may be requested for personnel supported through this study but may not exceed **$10,000** per person per year.

Subcontractors Summary – If applicable, detailed budgets and budget justifications for each subcontract, including indirects, must be provided for each year of support. Subcontractors are added in the prior section entitled **CONTACTS**. The lead/prime applicant (PI) and/or Grants Officer can initiate/complete the subcontract budget. After adding Subcontractor(s), in order to access the subcontract budget activity, please select the "**External Requests**" tab near the top right of the screen and navigate to the subcontract activity to complete the entry. After completing the subcontract budget activity, please select "**Pending**

PI Acceptance", as well as "**Submit**" to ensure the subcontractor budget is included as part of the main application budget.

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.

Budget Detail – Indirect Costs

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

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

FULL APPLICATION UPLOADS

Download the available templates applicable to the project, upload the completed templates to the corresponding attachment types within this section. Templates available for download include:

- Budget Justification
- Research Plan
- Biographical Sketches for Key Personnel
- Other Support
- Facilities Available
- Results of Past and Current CFF/CFFT Support
- Critique Response (if resubmission)

BUDGET JUSTIFICATION

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

RESEARCH PLAN

Page limit: **Twelve (12)** single-sided pages, not including the Literature Cited. Applications exceeding this page limit will not be reviewed. Type the PI's name in the space available in the header of the document. The template available will track page numbers at the bottom.

- Include sufficient information to permit effective review without reference to previous applications. Information should be presented in a clear and concise manner, while being specific and informative.
- Key figures and legends must be included in the Research Plan and should be of sufficient quality and size to be evaluated by the reviewer. If uploaded as Appendices, they will NOT be reviewed.
- If the application is a resubmission of an earlier one, revisions must be clearly indicated by a change in font, bolded or underlined. **CFF will not review resubmissions that have not been revised.**

a. **Hypothesis and Specific Aims:** State concisely and realistically the intent of the proposed research and the hypothesis to be tested. The specific aims should be relevant to the mission of the Cystic Fibrosis Foundation. Do not exceed one page.
b. **Background and Science:** Describe the background. Critically evaluate existing knowledge and specifically identify the gaps that the project is intended to fill. Concisely state the importance and rationale of this research by relating the specific aims to longer-term objectives. This section should also show the potential importance of the proposed work to CF, in particular those areas listed as areas of special interest to CFF. In addition, describe the relationship of the proposed work to your

long-term career goals. Preference will be given to applicants who express an interest in a long-term career in CF-related research.

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

d. **Experimental Design and Methods:** Provide a detailed discussion of the experimental design and methods to be used to accomplish the specific aims. Describe the protocols, including methods for new techniques, and explain potential advantages over existing methodologies. Discuss the data expected to be obtained and the means by which data will be analyzed and interpreted. If clinical samples are included in the research plan, provide details of the methods for patient selection. Discuss potential pitfalls and/or limitations of the proposed procedures and alternative approaches to achieve aims. Point out any procedures, situations or materials that may be hazardous to personnel or patients and the precautions to be exercised. Since PTAC Research Grant applications are reviewed by CFF's PTAC Committee, applications that include methodologies requiring sampling of materials from human subjects will only be considered under this mechanism if the sampling method constitutes minimum patient risk (e.g., venipuncture, nasal cell brushing) and patient samples or data are anonymous.

   Describe the level of risk and measures taken to assure patient anonymity to the PI and other professional personnel, unless the PI or other professional personnel are care providers. Note: Interventional studies involving human subjects cannot be supported through this program and should instead apply as a Clinical Research Award or Clinical Pilot and Feasibility Award.

e. **Consultant Arrangements**: If the proposed project includes consultant arrangements and/or collaboration with other individuals outside the applicant's group, describe the working relationships and support this description by letter(s) of intent signed by collaborating individual(s). If clinical material required by this award is to be furnished by other individuals, include a statement from these individuals agreeing to their participation and precautions taken to ensure anonymity of patients.

f. **Literature Cited:** References should be numbered in the sequence that they appear in the text and listed at the end of the Research Plan. Each citation must include the names of all authors, title, the name of the journal or book, volume number, page number and year of publication (titles are optional).

BIOGRAPHICAL SKETCH(ES) OF KEY PERSONNEL

Complete and upload an NIH Biographical Sketch for all key project personnel, beginning with the Applicant/Principal Investigator. International applicants can upload a biosketch that is equivalent in content to the NIH template provided. (CFF defines "key personnel" as any individual with an advanced degree that will play an instrumental role in the accomplishment of the research project.) Do not exceed five (5) pages per person.

OTHER SUPPORT

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

FACILITIES AVAILABLE

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.

RESULTS OF PAST AND CURRENT CFF/CFFT SUPPORT

The Principal Investigator (PI) and any Co-Principal Investigator(s), if applicable, are requested to identify the results of past and current CFF/CFFT support (e.g., subsequent funding from other sources, journal articles, and invited presentations) and the CFF/CFFT award from which they resulted for the past five (5) years. Please note that the following information must be included with each research project identified:

- CFF/CFFT Award #
- Principal Investigator (PI)
- CFF/CFFT Project Title
- Applicant's Title on Project
- Project Start/End Dates
- Total CFF/CFFT Award Amount
- Results of Support

CRITIQUE RESPONSE (IF RESUBMISSION)

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

LETTER(S) OF SUPPORT (FOR INVESTIGATORS NEW TO CF RESEARCH, IF APPLICABLE)

Note: Letters of Support are not required for experienced CF investigators, e.g. recipients of past 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. An investigator is considered new to CF if they have not previously (1) published in CF or (2) received extramural funding for a CF-focused research project. A letter of support from the collaborator/consultant should be included with the application, explicitly describing how the proposed work is relevant to CF and how the collaborator/consultant will assist the investigator (such as providing scientific expertise or CF-relevant samples and reagents).

APPENDICES (IF APPLICABLE)

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

- Certification of organization assurances (i.e. IRB, IACUC and IBC approvals), if applicable.
- Up to three (3) reprints of the applicant's work relating to the general area of research in the proposal may be uploaded in PDF format.
- Signed Letters of Support and/or Collaboration: A Letter of Collaboration from Co-PIs, if any, should be uploaded and included in the application.

***Organization Assurances & Certifications**

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

Awardees based outside of the U.S. must comply with the applicable equivalent regulations in their respective countries and provide copies of approvals as soon as they are available. CFF will not release payments until these documents are received and on file with the CFF GCMA Office.

Research Involving Human Subjects: CFF policy pertaining to the protection of individuals as research subjects requires that for each proposal awarded, the awardee institution certify in writing that an Institutional Review Board (IRB) has reviewed and approved the procedures for the use of human subjects, or human organs, tissues and body fluids, in the proposed research, in accordance with the Department of Health and Human Services policies found at https://www.hhs.gov/ohrp/regulations-and-policy/index.html. In the event the IRB has determined a study is exempt, documentation demonstrating the exempt status must also be submitted to the CFF GCMA Office.

Research Involving Recombinant or Synthetic Nucleic Acid Molecules: All research involving recombinant or synthetic nucleic acid and human gene transfer studies supported by CFF must meet the requirements contained in the document *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (updated April 2019*). This publication and announcements of modifications and changes to the NIH Guidelines are available from the Office of Science and Policy, National Institutes of Health, 6705 Rockledge Drive, Ste 750, MSC 7985, Bethesda, MD, 20892-7985 or online at https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf.

Research Involving Animals: Applications submitted to CFF involving the use of animals must meet the guidelines of the National Institutes of Health found at https://grants.nih.gov/grants/olaw/olaw.htm, which require that all proposed studies be reviewed and approved by an Institutional Animal Care and Use Committee (IACUC). In addition, CFF awardee institutions and laboratories must be accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC) and/or have other verifiable assurances that the institution and laboratory meet appropriate standards.

Validation and Submission

Prior to selecting "**Sign & Submit to AIO**", please complete a thorough review of the entire application. The "**Sign & Submit to AIO**" button will trigger validation on all required fields and identify any upload errors or incomplete fields. Upon selecting Sign & Submit to AIO, the ability to edit the application will be locked pending review and approval by your AIO.

After selecting "**Sign & Submit to AIO"**, the applicant will receive an email asking them to sign the application FacePage electronically using Adobe Sign. Once signed by the PI, the FacePage will then be routed to the AIO contact that is listed on the application for review and signature.

To ensure the application is fully signed and submitted ahead of the Application Deadline for this program, please be sure to complete the application, and begin the Sign & Submit to AIO process in advance of the 5:00 PM EST deadline. The status of your application will display "Submitted" once fully signed, to indicate that your application has been received by CFF.

XI. Other Information

Not applicable to this RFA

XII. Contact Information

For technical support and program/content information:
Primary CFF GCMA Office contact Erik Warnke at ewarnke@cff.org or 301-841-2614
Secondary CFF GCMA Office contact Edwin Gregorian at egregorian@cff.org or 301-841-2614

For scientific questions:
John Sheridan, Ph.D. at jsheridan@cff.org