



Program Name: 2023 Path to a Cure (PTAC) – Pioneer Award with Letter of Intent (LOI)

Brief Program Overview/Description: The Path to a Cure: Pioneer Award is intended for exceptional investigators developing paradigm shifting technologies that could ultimately lead to a cure for CF. Proposals should be ambitious and utilize cutting edge techniques and strategies. Proposals must align with the goals of the Path to a Cure initiative. Applicants are strongly encouraged to contact CFF program staff as soon as possible to evaluate project scope and ensure alignment with PTAC priorities.

Funding Amount: Applicants may propose an amount necessary to complete the proposed research, plus an additional twelve percent (12%) of indirect costs. Up to three (3) years of funding may be requested.

Eligibility:

- United States residents and applicants from outside the United States are welcome to apply.
- Applicants must be established independent investigators who have received one or more national, peer-reviewed research grant(s) with a duration of at least three (3) years (mentored awards or training grants do not qualify).
- Applicants must first submit a letter of intent before a full submission will be accepted.
- *Additional eligibility requirements can be found in **Section IV** below.*

Key Dates:

| | |
|---------------------------------|--|
| Published | Jan/Feb 2023 |
| LOI Submission Deadline | Rolling |
| LOI Notification and Discussion | 2-4 weeks after receipt |
| Full Application Deadline | As agreed upon/closes on December 15, 2023 |
| Committee Review Date | 3-6 weeks after application receipt |
| Notification to Applicants | 3-6 weeks after review |
| Earliest Project Start Date | As agreed upon |

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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

The Pioneer Award is intended to support paradigm shifting technologies that have the potential to cure CF at the cellular and/or genetic level. Proposals should be ambitious and utilize cutting edge techniques and strategies. A history of CF research is not required. However, applicants new to CF are encouraged to collaborate or establish a dialogue with members of the CF research community. Proposals must align with the goals of the *Path to a Cure* initiative outlined in section VI. While not required, a multidisciplinary team of investigators are encouraged to jointly apply as a collaboration if the project maintains a single primary focus. Applications with multiple independent projects should be submitted through the PTAC Collaborative Research Grant mechanism (<https://www.cff.org/researchers/path-cure-collaborative-research-grant>).

Building and maintaining a comprehensive CF research community is a significant priority for the CFF. To accomplish this goal, Pioneer Awardees should anticipate participating in CFF conferences and meetings. At a minimum, applicants are expected to attend the North American CF Conference (NACFC). We also strongly encourage the attendance of students and trainees at NACFC. Applicants may request additional funds to attend conferences not affiliated with the CF Foundation (see section X for more information).

Two-Part Application Program

In order to ensure a proposed project is consistent with the goals of the CFF, investigators who are seeking support through the Path to a Cure initiative are strongly encouraged to contact the CF Foundation to discuss the research program and its applicability to the *Path to a Cure* initiative. Potential applicants must submit a letter of intent (LOI) before a full application will be accepted. Upon receipt and review of the LOI, CFF program staff will schedule a video conference with the applicant to discuss the proposed project in greater detail, if necessary. Applicants will be notified if a full application will be accepted or if other funding mechanism would be more appropriate.

Proposals that include methodologies requiring human subjects or samples 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

- Applicants should request a funding amount necessary to complete the proposed research project. It is anticipated that the scope of work and requested funding will exceed a CFF Research Grant or a typical NIH R01 award. An additional twelve percent (12%) indirect costs may be requested.
- Up to three (3) years of funding may be proposed. Continued support will be based upon achievement of the scientific aims, yearly goals of the proposal, and the availability of funds. A competitive renewal may be submitted upon completion of the initial program period.

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 information on page 6 and page 9 below).
- Applicants must be established independent investigators who have received one or more national, peer-reviewed research grant(s) with a duration of at least 3 years (mentored awards or training grants do not qualify).
- A letter of intent (LOI) must be submitted in advance of a full application. Additional information on submitting an LOI can be found below. Applicants are strongly encouraged to contact CFF staff prior to LOI submission to determine project eligibility.
- Applications must focus on one or more of the research areas of interest outlined in Section VI below.
- Applicants are expected to participate in regularly scheduled conference calls with the CFF and an external advisory committee.
- Industry-sponsored research projects are not eligible to apply through this program and instead should consider applying to the Therapeutics Development Awards program <https://www.cff.org/Research/Researcher-Resources/Awards-and-Grants/Research-Awards/Industry-Funding-Opportunities/>.

V. Mentorship Requirements

Not applicable to this RFA

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

Small molecule CFTR modulators that directly target the mutant protein are powerful therapies that will likely benefit 90% of people with CF in the near future. 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.

Academic programs supported through the Path to a Cure: Pioneer Award will focus on the following areas of interest:

- Development of novel means of repairing and/or replacing the mutant *CFTR* gene, particularly approaches that correct multiple CF-causing mutations
- Identification, development and optimization of delivery vehicles that can target disease relevant cells and tissues, specifically strategies to target airway basal cells
- Methods to overcome barriers that limit delivery of genetic therapies to disease relevant cells and tissues, such as CF mucus, immunologic responses, intracellular barriers, etc.
- Strategies to enhance engraftment and retention of cellular therapies in the airway epithelium
- Optimization of tools, assays and novel models to pre-clinically evaluate the efficacy and safety of restoring functional CFTR through gene repair or replacement

Applications focused on CFTR structure/function, CFTR trafficking, alternative ion channels, mucolytics and mucociliary clearance, small molecule therapies, and oligonucleotide therapies will not be accepted through this mechanism. Alternative funding options, such as the general PTAC program (link to academic PTAC page) and RRT (link), are available and should be considered.

VII. Review and Award

Prior to submission of an LOI, applicants are encouraged to discuss the project with CF program staff. Upon receipt of the LOI, CFF program staff will typically schedule a video conference with the applicant to

review and discuss the proposed project. Applicants will prepare a comprehensive presentation that details the goals and aims of the project, key personnel, and projected budget. Co-investigators, collaborators, and lab personnel should participate in the video conference. External reviewers may participate in the video conference to advise the CFF. There are two main goals for the meeting: 1) to determine if the proposed project should proceed to a full application and 2) serve as a forum for the CFF and external advisors to provide feedback and guidance on the proposed project. Full applications are evaluated by an ad hoc 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 Committee. Funding decisions are based on the relevance of the proposed study to the goals of the Foundation, alignment with specific research priorities, and enhancing the existing CFF project portfolio. All awards are subject to compliance with applicable regulations and CFF policies and are contingent upon the availability of CFF funds.

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

- Insufficient alignment of the proposed research with PTAC priorities
- Inadequate statement of hypothesis, experimental design or methods, or preliminary data
- 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 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

A Letter of Intent (LOI) must be submitted and approved prior to submitting a Full Application

Submit online through <http://awards.cff.org>

First-time applicants must register to create a username and password for “awards.cff.org” and will need to complete a profile prior to submitting an application. If you are registered and cannot remember your password, click on the “**Forgot Password?**” link below the “**Login**” fields.

(Refer to Sections IX and 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 will be reviewed.

General Timeline:

| | |
|---------------------------------|--|
| LOI Submission Deadline | Rolling/ closes on December 15, 2023 |
| LOI Notification and Discussion | 2-4 weeks after receipt of LOI |
| Full Application Deadline | As agreed upon/closes on December 15, 2023 |
| Committee Review Date | 3-6 weeks after application receipt |
| Notification to Applicants | 3-6 weeks after review |
| Earliest Project Start Date | As agreed upon |

IX. Letter of Intent Guidelines

LOI Submission Deadline: Rolling

Submit online through <http://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

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. 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 "**2023 Path to a Cure (PTAC) – Pioneer Award with LOI**" 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, and select the number of periods being requested

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 Grants & Contracts Management and Administration (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.

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 contacts not associated with the applicant institution may also be added. These contacts are considered additional contributors involved in the proposed research plan. These may include consultants, collaborators, or subcontractors. In order to add contacts external to the applicant institution, please select the appropriate “Add Subcontractors” or “Add Consultants/Collaborators” button(s) and add the contacts in the table, then click “Save”.

BUDGET

Select the “**Open**” button under the Budget tab and complete the relevant budget categories for each year of funding. Fill in the applicable amounts for each year of support requested by completing the online fields (Period 1, 2, 3). The total budget request should be the amount deemed necessary to complete the proposed research, plus an additional twelve percent (12%) of indirect costs.

Be sure to click “**Save**” prior to closing the budget window.

LOI UPLOADS

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

- LOI Project Description
- Biographical Sketches for Key Personnel
- LOI Budget Justification

LOI PROJECT DESCRIPTION (TEMPLATE AVAILABLE FOR DOWNLOAD)

Upload a PDF copy of the completed document providing, at a minimum, the Hypothesis, Specific Aims, Significance, Expected Outcomes, and assurances that the required laboratory biosafety equipment/facilities are available to perform the studies. There is a two (2) page limit for this description (not including the literature cited). Components should include:

- Descriptive Title of the proposed research
- Clear rationale for the project, including expected significance of the project for the CF community and how it advances the CFF mission
- Hypothesis and specific aims
- Brief overview of proposed research design/approach

BIOGRAPHICAL SKETCH(ES) OF KEY PERSONNEL (NIH TEMPLATE AVAILABLE FOR DOWNLOAD)

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.

BUDGET JUSTIFICATION – PROPOSED (TEMPLATE AVAILABLE FOR DOWNLOAD)

Complete and upload this document to provide justification for the proposed amounts.

Submission

Prior to selecting “**Sign & Submit**”, please complete a thorough review of the entire LOI. The “Sign & Submit” button will trigger validation on all required fields and identify any errors. You will receive an e-mail requesting your signature through Adobe Sign. Please ensure to complete the Adobe Sign to fully submit your LOI.

X. Full Application Guidelines

A Letter of Intent (LOI) must have been submitted and approved prior to receiving an invitation to proceed with a Full Application

Submission Deadline: As agreed upon

Applications must be submitted online at <http://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>

If the LOI submission is approved to proceed to a full application submission, the application will have already been pre-loaded in the system. Log in with your existing credentials to access the application.

Your draft application will be listed under “**My Applications**”, then within the “**Draft Applications**” section. Upon locating the draft application, you may select it to begin your submission.

Applicants may stop at any point but must click the “**Save**” button before exiting in order to save their progress.

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.

Please note: Only select the “**Sign & Submit to AIO**” button after the application has been fully completed. This will trigger validation on all required fields and send the application to your Authorized Institutional Official “**AIO**” for review and signature.

GENERAL

Enter the title of your project, enter the project end date, select the number of periods being requested and 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. Also, provide a response to any additional listed questions.

***Please ensure that you review and comply with the below Organizational Assurances and Certifications as cited at the end of this section on page 10.**

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 contacts not associated with the applicant institution may also be added. These contacts are considered additional contributors involved in the proposed research plan. These may include consultants, collaborators, or subcontractors. In order to add contacts external to the applicant institution, please select the appropriate “Add Subcontractors” or “Add Consultants/Collaborators” button(s) and add the contacts in the table, then click “Save”.

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

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.

The following budget categories are offered under this program:

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 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 **\$212,100**. 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 any CF-relevant travel. Please note: expenses for travel outside the North American Continent, including travel to Hawaii, Puerto Rico, and other U.S. territories are not allowable expenses without prior written approval from the CFF GCMA Office. **Travel expenses may not exceed \$1,500 per person per year to attend the North American CF Conference. An additional \$1,500 per year per person may be requested to attend conferences not affiliated with the CF Foundation.** Please list each attendee and conference as separate line items. Registration fees associated with conferences are in addition to this allowance should be listed under “Other Expenses”.

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

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 “**BUDGET**” tab of the application and click the “Open” button next to each listed subcontractor. 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

LOI UPLOADS

This section will allow access to the documentation uploaded at the LOI stage.

FULL APPLICATION UPLOADS

Download the available templates applicable to the project, upload the completed templates in PDF format 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
- Critique Response
- Results of Past and Current CFF/CFFT Support
- International Institution Form

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.
- Hypothesis and Specific Aims:** State concisely and realistically the intent of the proposed research and the hypothesis to be tested. The specific aims should be relevant to the mission of the Cystic Fibrosis Foundation. Do not exceed one page.
 - Background and 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.
 - Preliminary Results:** If applicable, provide a detailed discussion of any preliminary results.
 - Experimental Design and Methods:** Provide a detailed discussion of the experimental design and methods to be used to accomplish the specific aims. Describe the protocols, including methods for new techniques, and explain potential advantages over existing methodologies. Discuss the data expected to be obtained and the means by which data will be analyzed and interpreted. If clinical 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 Research Grant applications are reviewed by CFF's Research and Research Training Committee, applications that include methodologies requiring

sampling of materials from human subjects will only be considered under this mechanism if the sampling method constitutes 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. **Goals:** Yearly goal and milestones should be included. These will be used to evaluate progress and to determine if additional funding is warranted. If helpful, a timeline or Gantt chart can be included.
- 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).

BIOGRAPHICAL SKETCH(ES) OF KEY PERSONNEL (TEMPLATE AVAILABLE ONLINE)

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

OTHER SUPPORT (TEMPLATE AVAILABLE ONLINE)

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

FACILITIES AVAILABLE (TEMPLATE AVAILABLE ONLINE)

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

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.

RESULTS OF PAST AND CURRENT CFF/CFPT SUPPORT (TEMPLATE AVAILABLE ONLINE)

The Principal Investigator (PI) and any Co-Principal Investigator(s), if applicable, are requested to identify the results of past and current CFF/CFPT support (e.g., subsequent funding from other sources, journal articles, and invited presentations) and the CFF/CFPT 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/CFPT 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

INTERNATIONAL INSTITUTION FORM (IF APPLICABLE)

Applicants whose institution is not a United States based-entity must complete the CFF International Institution Form. The completion of this form also includes submission of the following documentation:

- Institution's mission statement
- If the Institution is a nonprofit organization, provide government-issued documentation of the Institution's nonprofit status, if available, as well as governing documents (such as a Charter, Statute, or By-Laws) detailing the funding and expenditures related to activities outlined in the Mission Statement of the Institution compared to activities outside of the mission of the Institution
- If the Institution is a for-profit organization, provide a complete list of key employees, members of the governing board, and/or other senior management as well as any governing documents (such as an Articles of Association or Organization) detailing the funding and expenditures of the Institution
- A complete and accurate Form W-8 signed by the institutional official within the last three years. While CFF issues grant funding to 501(c)(3) and nonprofit institutions, CFF also issues contract award funding to other kinds of institutions.
- A description of external sources of support, including the names of individuals and organizations providing the Institution with major donations, official awards, private endowments, and/or commercial activities
- Standard Operating Procedure(s) or relevant policy to ensure that all awarded funds, including but not limited to CFF funds, are used in compliance with all applicable U.S. anti-terrorist financing, privacy and asset control statutes, regulations and executive orders, resulting in the Institution neither distributing awarded funds to terrorists nor supporting their networks, organizations, or activities (*If your institution does not have a relevant policy, please provide a statement signed by an institutional official indicating that all award funds, including but not limited to CFF funds, will be used in compliance with applicable U.S. anti-terrorist financing, privacy and asset control statutes, regulations and executive orders, resulting in funds never being used to support terrorist networks, organizations and/or activities. In the alternative, if the institution does not have this policy, CFF can provide an Anti-Terrorism Certification Form to be signed by the institutional official*).

Applicants who have provided these documents within the past one (1) year is 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 CF Foundation 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.**

APPENDICES (UPLOAD MATERIALS AS PDF DOCUMENTS, IF APPLICABLE)

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

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

***Organizational Assurances and 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 Face Page electronically using Adobe Sign. Once signed by the PI, the Face Page will then be routed to the AIO contact that is listed on the application for review and signature.

XI. Other Information

Not applicable to this RFA

XII. Contact Information

For technical support:

Primary CFF GCMA Office contact Nicholas Appleton at nappleton@cff.org or 301-841-2614

For program and scientific questions:

John Sheridan, Ph.D. at jsheridan@cff.org