For application technical support, please contact mcarlino@cff.org

Program Name: 2025 Path to a Cure (PTAC) – Collaborative Research Grant

Brief Program Overview/Description: Path to a Cure: Collaborative Research Grants are intended to facilitate research that will contribute to the development of new therapies or therapeutic strategies to treat CF, with an emphasis on advancing *CFTR* gene repair and replacement approaches. Collaborations that bring new investigators and technologies into the CF research community will be given highest priority. Proposals must include preliminary data to justify support from the Cystic Fibrosis Foundation.

Funding Amount: Total direct cost for the Collaborative Research Grant may not exceed $1,000,000 per year for up to three (3) years. The application must consist of at least two (2) projects, each led by an independent investigator. The lead institution may request up to $25,000 direct costs per year to support an administrative core, however total direct costs may not exceed the $1,000,000 cap per year. An additional twelve percent (12%) of indirect costs per year may be requested.

Eligibility:

- Applicants **must** speak with program staff prior to submission to ensure the research aims are in alignment with the research priorities described in this RFA. **Due to the significant increase in grant applications received by CFF, failure to receive presubmission approval from CFF staff will result in the administrative withdrawal of the proposal.**
- 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).
- Additional eligibility requirements can be found in Section IV and Section VI (Goals of Research) below.
- Applications collaborating with a for-profit entity in a non-majority role may be considered. The applicant **must** be the academic institution, and for-profit entities should be noted as subcontracts.

Key Dates:

Published	July 14, 2025
Full Application Deadline	**November 20, 2025**
Committee Review Date	February, 2026
Notification to Applicants	April, 2026
Earliest Project Start Date	May 1, 2026

Table of Contents:

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: Collaborative Research Grants are intended to support an integrated, multi-investigator collaborative research program with a well-defined central focus to advance the priorities of the PTAC Initiative. Collaborations that bring new investigators into the CF research community are a high priority. A single Collaborative Research Grant proposal must have at least two, and may include up to four, related research projects (each led by a separate PI) that share a well-defined theme and overall objective. Proposals must contain sufficient preliminary data to justify support from the Cystic Fibrosis Foundation.

Each project supported through this mechanism must contribute to the common unifying theme of the overall Collaborative Program. Each individual project should reflect a scientifically meritorious research effort. However, the individual research projects should be clearly interrelated and synergistic so that the outcomes of the Collaborative Program will offer a distinct advantage over pursuing individual research projects separately. Multi-institution collaborative applications are encouraged where synergy is clearly described. However, Collaborative Programs may include multiple investigators at the same institution.

In addition to research projects, administrative support may be requested ($25,000 per year) to support the day-to-day activities across the program, communications among project sites, contractual activities (if any), and other non-research program costs.

A single application is required for the Collaborative Research Grant proposal. A lead PI must submit the application on behalf of all participating collaborators. Each project that is part of the Collaborative Program must provide an independent Research Plan, Detailed Budget Worksheet and Budget Justification, which will be incorporated into the single application's overall Budget Detail entered in the application system per **Section X. BUDGET** below.

Proposals that include methodologies requiring human subjects or samples 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.

III. Funding Amounts

- In total, applicants may request up to $1,000,000 in direct costs per year for up to three (3) years, plus an additional twelve percent (12%) in indirect costs. The application must consist of at least 2 projects, each led by an investigator.
- The lead site for the Collaborative Research Program may request up to $25,000 direct costs per year to support an administrative core.
- Funding for Years 2 and 3 are contingent upon submission and approval of a renewal progress report and the availability of funds.

IV. Eligibility

- Applicants **must** speak with CFF program staff prior to submission to ensure the research aims are in alignment with the research priorities as described in this RFA. **Failure to do so will result in the administrative withdrawal of the proposal.**
- 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 X.INSTITUTION below).
- 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).
- 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 other CFF funding mechanisms may apply to this RFA, but the research programs must be scientifically distinct.
- Competitive renewals for the Collaborative program will be considered. Application for, and/or award of, additional external funding to complement the submitted research program may be included in the renewal review criteria.
- Applications collaborating with a for-profit entity in a non-majority role may be considered. The applicant **must** be the academic institution, and for-profit entities should be noted as subcontracts.

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 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 site mutations, indels, etc.).

Projects supported through the Path to a Cure: Collaborative Research Grant should be ambitious in scope and utilize cutting-edge technologies and strategies that have the potential to inform or translate into novel therapies to restore CFTR protein function by fixing and/or replacing the defective CFTR gene. Multi-institution collaborations are strongly encouraged.

Emerging areas of interest with high priority to the CF Foundation:

- Developing novel means of repairing and/or replacing the mutant CFTR gene, with an emphasis on approaches with utility for multiple *CFTR* mutations
- Characterizing and validating cellular targets that facilitate delivery of nucleotide-based therapies to specific cells, including airway progenitor cells and other affected epithelial tissues (biliary tract, GI tract, pancreas)
- Developing and optimizing the properties and formulation of nucleic acid therapies and their delivery vehicles, both viral and non-viral, that can target disease relevant cells and tissues
- Comprehensively evaluating the roles of pulmonary cell types in CF disease pathogenesis (i.e. ciliated cells, club cells, ionocytes, etc.) and the regions of the lung that are necessary to target with a genetic-based therapy to prevent, halt, or reverse disease
- Developing 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.

- Optimizing tools, assays and models, including human tissue-based approaches, to pre-clinically evaluate the efficacy and safety of restoring functional CFTR through gene repair, gene replacement, small molecules, or any other novel method
- Evaluating the impacts of genetic manipulation on target cells, duration of efficacy, and the rates of cellular turnover in the lung

VII. Review and Award

All applications will be evaluated by a CFF *ad-hoc* Committee. Funding decisions will 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 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.

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.

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
- Lack of synergy between the individual projects of the Collaborative Program
- 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 (lead PI and individual project PIs) may only submit one (1) Collaborative Research Grant application in 2024

Applications deadline: November 20, 2025 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 _____ November 20, 2025
Review _____ February 2026
Notification to Applicants _____ April 2026
Earliest Start Date for Awarded Projects _____ May 1, 2026

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: https://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 "**2025 Path to a Cure (PTAC) – Collaborative Research Grant**" 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.**

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©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 are required to provide additional information and complete a CFF International Institution Form. The completion of this form also includes submission of additional documentation.

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".

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, then select the blue button to open a pop-up window in order to add the referees in the table. You must click "Invite" in order to trigger the e-mail to the referee. The referee(s) will be sent an e-mail asking them to Accept or Decline the invitation to submit a letter of reference and will be provided instructions to submit the letter. **The applicant will be alerted if a referee Declines the invitation; please make sure to check this tab regularly to see the status of the references.** 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. Collaborative Research Grants funded through this RFA are for a maximum of three (3) years. The total budget request cannot exceed $1,000,000 per year plus an additional twelve (12%) of indirect costs. The lead institution may request up to $25,000 per year support the administrative core (see Other Expenses below).

Note: *The budget detail for each year entered in this section of the online application must be the total combined budget for the collaborative program. The budget detail for each individual project will be collected in the Estimated Budget Detail section below as individual uploads.*

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 **$225,700 (FY2025)**. 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 to attend conferences not affilicatge with the CF Foundation.** Please list each attetndee 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. Support for an administrative core may be requested by the lead institution and may not exceed $25,000 per year, however total direct costs per year may not exceed $1,000,000 per year.

Subcontractors Summary – 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

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 (per each individual project)
- Estimated Budget Detail (per each individual project)
- Collaboration Details (Collaboration Program Description)
- Project Plan (Communication Plan)
- Research Plan (per each individual project)
- Biographical Sketches for Key Personnel
- Other Support
- Facilities Available
- Results of Past and Current CFF/CFFT Support
- Critique Response (if resubmission)

BUDGET JUSTIFICATION (per each individual project)

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. A Budget Justification is required for each individual project in the collaboration and for each year, as well as a combined Budget Justification for the entire program. Please upload each budget justification as separate attachments.

ESTIMATED BUDGET DETAIL (per each individual project)

Any collaborative projects that are internal to the applicant institution must provide an uploaded Budget Detail for each year requested. Please upload each budget detail as separate attachments, uniquely labeled. External collaborative projects, if applicable, fall under the Subcontractor category and would enter the Budget Detail and Justification per the **BUDGET** section above.

COLLABORATION DETAILS (COLLABORATIVE PROGRAM DESCRIPTION)

Page limit: **Five (5)** single-sided pages. Applications exceeding this page limit may not be reviewed. The summary should clearly identify:

- The PI who will assume the overall lead of the program and describe how the PI will coordinate with the other PIs.
- The overarching aims of the proposal with the PI name for each project under the collaboration.
- Clearly articulate and outline the goals and importance of each individual project.
- An explanation of how synergy between projects contributes to the overall aims of the collaboration.
- A description and justification of any consultants or external collaborations as applicable.
- An explanation of how funds for the administrative core will be utilized (if being requested)

Note: *Consultant agreements or outside collaborations are allowed but should be justified.*

PROJECT PLAN (COMMUNICATION PLAN)

Page limit: **Two (2)** single-sided pages. Applications exceeding this page limit may not be reviewed. The plan should clearly outline:

- How research activities will be coordinated among investigators.
- How the collaborative nature of the program will be maintained.
- How reagents, equipment, resources and data will be shared within the program.
- How conflict and scientific disagreements will be managed and resolved.

RESEARCH PLAN (per each individual project)

Page limit: **Twelve (12)** single-sided pages **each (one for each individual project)**, not including the Literature Cited. Applications exceeding this page limit will not be reviewed. Collaborative programs must include at least two (2) projects (including the lead project). 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.

- ***Note:** Please upload each twelve-page Research Plan individually, clearly labeled to identify the project it is related to.* 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.
  - **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 this RFA as outlined in section VI. 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. 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.

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 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

Please note: Only select the "**Submit to Authorized Institution Official for Acceptance**" 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 attestation within the system.

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 Submit to Authorized Institution Official for Acceptance 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. Resources and Other Information

- CFF Funding Opportunities Newsletter
- Grants Management System – How to User Guides

XII. Contact Information

For technical support and program/content information:
Primary CFF GCMA Office contact Mike Carlino at mcarlino@cff.org or 301-841-2614

For scientific questions:
Patrick Thibodeau, Ph.D. at pthibodeau@cff.org