CYSTIC FIBROSIS FOUNDATION

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

Program Name: 2026 Fall Pilot and Feasibility Award

Brief Program Overview/Description: Pilot and Feasibility Awards are intended to support projects that will develop and test new hypotheses and/or new methods (or those being applied to the problems of cystic fibrosis (CF) for the first time), and to support promising new investigators as they establish themselves in research areas relevant to CF. The intent of these awards is to enable investigators to collect sufficient data to compete successfully for support from the NIH or other funding agencies.

Pilot and Feasibility studies that may be high risk but high reward when it comes to advancing our understanding of the disease or impacting patient care are encouraged to apply through this mechanism. **Applications for continued funding of a project, or long-term support of an investigator, will not be considered through this program.** Projects that are an extension of previous work should be submitted through the Research Grant mechanisms.

Applicants seeking to submit proposals focused on topics such as restoration of CFTR protein function or approaches to fix/replace the defective CFTR gene should apply through the Path to a Cure Pilot and Feasibility Award Program.

Funding Amount: Funding of up to $50,000 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 that has completed fellowship training and whose institution allows them to submit applications for research funding as a Principal Investigator).
  - Applicants from for-profit organizations should speak to the Program Officer about eligibility before applying through this mechanism.
- Each laboratory (not PI) may submit only one application per cycle (resubmission vs original). This does not apply to training awards.
- Additional eligibility requirements can be found in **Section IV** below.

Key Dates:

	Fall 2026 Cycle
Published	October 9, 2026
Full Application Deadline	December 8, 2026
Committee Review Date	March 2027
Notification to Applicants	April 2027
Earliest Project Start Date	May 1, 2027

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CYSTIC FIBROSIS FOUNDATION

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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.

Cystic fibrosis affects people of different racial and ethnic backgrounds. Understanding the varied needs and unique journeys of individuals with CF is core to our ability to make a meaningful difference in the lives of all people with CF. Improving the representation of people of color within the CF community – including those in the CF research workforce – and addressing health disparities that exist within these groups is critical to the Foundation's mission of serving all people with CF. As PIs prepare application materials, we strongly encourage the consideration of how to support all people with CF.

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

Foundation Resources

The Cystic Fibrosis Foundation offers several tools and resources to help researchers fast-track progress toward new scientific knowledge of and therapies for cystic fibrosis, and to align their research methods and goals with the community's priorities. Some of the resources available for use are listed below. For more information on Tools and Resources for the CF Foundation research community, please visit: www.cff.org/for-researchers

CF Foundation Biorepository – Cystic fibrosis biological samples are available to qualified researchers to help develop promising new studies that will support CF research and aid in drug development and drug discovery.
National Resource Centers – These Centers provide study sponsors and investigators centralized expertise in outcome measures for CF translational and clinical research
Whole Genome Sequencing Project Data Requests - The CF Foundation's Whole Genome Sequencing (WGS) project contains WGS data from over 5,000 people with cystic fibrosis in the United States that is linked with data from the CF Foundation Patient Registry

II. Program and Award Overview

Pilot and Feasibility Awards are intended to support projects that will develop and test new hypotheses and/or new methods (or those being applied to the problems of cystic fibrosis for the first time), and to support promising new investigators as they establish themselves in research areas relevant to cystic fibrosis. The intent of these awards is to enable investigators to collect sufficient data to compete successfully for support from the NIH or other funding agencies.

Pilot and Feasibility studies that may be high risk but high reward when it comes to advancing our understanding of the disease or impacting patient care are encouraged to apply through this mechanism. **Applications for continued funding of a project, or long-term support of an investigator, will not be considered through this program**. Projects that are an extension of previous work should be submitted through the Research Grant mechanisms.

Applicants seeking to submit proposals focused on topics such as the restoration of CFTR protein function or approaches to fix/replace the defective CFTR gene should apply through the Path to a Cure Research Pilot and Feasibility Award Program.

Pilot and Feasibility Award 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 studies using data from the CF Foundation Patient Registry and interventional studies, may not be reviewed nor funded through this award mechanism and should instead submit their proposals under the Clinical Pilot and Feasibility Award mechanism. Please refer to that program's Policies and Guidelines on the CF Foundation website (www.cff.org).

III. Funding Amounts

- Funding of up to $50,000 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.
- Applicants must be independent investigators (an individual that has completed fellowship training and whose institution allows them to submit applications for research funding as a Principal Investigator).
    - Applicants whose appointment is dependent on a senior investigator (non-independent faculty positions) must include a biosketch and letter of support from the laboratory PI clearly indicating the affiliation and support for the application. Failure to provide these materials may result in the application being withdrawn.
    - Candidates who are clinical fellows should apply to the CF Foundation Clinical Fellowship program for the appropriate year.
    - Candidates who are postdoctoral fellows should apply to the CF Foundation Postdoctoral Research Fellowship program.
- Each laboratory (not PI) may submit only one application (research grant or pilot and feasibility award) per cycle (resub vs original). This does not apply to training awards.
- Applicants may only submit for one research grant and one pilot and feasibility award in a 12-month period. Each application must describe a research project that is distinct.
- PIs with a combined total of CF Foundation research support exceeding $200,000 per year in direct costs (excluding Research Development Program, National Resource Center, Therapeutic Development Network, and Care Center Awards) with an end date more than six (6) months from the application deadline must receive Program Officer approval before an application will be considered.
- Applications from for-profit entities may (under select circumstances) be considered through this program. Prior to beginning an application, applicants must contact the Program Officer found in Section XII to discuss eligibility. Failure to do so may result in withdrawal of the proposal. Note that if selected for funding, funding of companies would take the form of an investment vehicle, such as equity or debt instruments, or a milestone-based contract, with a preference for equity instruments.

V. Mentorship Requirements

Not applicable to this RFA

VI. Goals of Research Currently of Interest to CF Foundation/Priority Areas

With highly effective CFTR modulators now available for nearly 90% of people with CF in the U.S., and with more individuals living into adulthood, it is critical for the Foundation to define research priorities that address the evolving needs and challenges of this growing population. The Cystic Fibrosis Foundation regularly assesses its key research priorities to ensure we are on track to accomplish our mission to cure cystic fibrosis and to provide people with CF the opportunity to lead long lives. Applicants are encouraged to align submissions to the priorities described below in order to maximize their potential for being funded. Projects that do not directly align with the RFA topics may be considered but will be subject to administrative review upon submission to assess alignment with CF Foundation goals and priorities and may receive a modified or abbreviated review based on the outcome of that assessment.

Research Priorities for the Fall 2026 RFA

CF Related Diabetes (CFRD):

Projects that will improve our understanding of the biological underpinnings of the development and progression of CFRD, including:

- Exocrine/Endocrine interactions including:
  - Impact of exocrine pancreatic disease on endocrine pancreas function
  - Absent/altered acinar cell signaling
  - Incretins and entero-insular axis
- Altered/remodeled islet structure, including innervation and vasculature, that impacts islet function
- Cellular pathways involved in islet maintenance
- Genes and pathways contributing to increased risk of development of CFRD
- Role of CFTR-modulators in the prevention, delayed development, or disease reversal of CFRD

Gastrointestinal Complications

- Understanding mechanisms underlying significant CF-related GI symptoms with a goal of identifying targets for therapeutic intervention.
- Identification of gastrointestinal tissues/cells that need to be prioritized for systemic CFTR gene correction.
- Impacts of CFTR function on fluid characteristics (e.g., viscosity, ionic concentrations, volume, pH), flow dynamics and mucus abnormalities that lead to CF-relevant GI manifestations.
- Elucidating pathophysiology and/or development of therapeutic approaches directed at correcting nutritional deficiencies in CF.

Pulmonary Manifestations

- Explore the role of mucus volume reductions strategies in improving transduction and transfection efficiency of nucleic acid-based delivery systems to airway epithelial cells.
- Identify and begin to understand mechanisms that contribute to the development of Chronic Lung Allograft Dysfunction (CLAD) to inform potential therapeutic interventions that will reduce development and ultimately improve CF post-transplant outcomes.

Infection

Assess the potential of novel antimicrobial approaches to fully eradicate chronic *Pseudomonas* in people with CF. Determine the mechanism(s) limiting phage effectiveness *in vivo*, including projects that address the disconnect between *in vitro* vs *in vivo* phage killing efficacy

For all infection-related research proposals, CF Foundation highly recommends:

- Use of clinically relevant CF bacterial isolates
- Modelling environments that closely resemble the CF lungs whenever possible

- Consideration of HEMT use within CF populations, particularly its impact on lung microbiology and bacterial communities

Proposals focused solely on basic pathogen biology – without clear relevance to developing new treatments or improving outcomes for people with CF – may be deprioritized for funding.

Topics viewed as a low priority for this cycle. Due to evolving clinical needs and saturation within the current research portfolio, the following topics are considered low priority for basic and translational research during this application cycle. This list will be reviewed and updated regularly to reflect shifts in clinical understanding and the progression of existing projects, which may prompt future research needs in these areas.

- Evaluation of non-CFTR targets specifically ENaC, TMEM16a and solute carrier gene family members for the modulation of CF disease
- CF sinus disease
- Acute rejection in lung transplantation
- Bone disease/bone health
- Chronic kidney disease
- Gut microbiome
- GI cancers
- Genome sequencing of clinical isolates
- Phage host range determination
- Fungal pathogens
- Staphylococcus aureus

Projects that do not address a priority topic listed above but have the potential to lead to a better understanding of disease mechanisms and pathophysiology or will focus on strategies and methods with the potential to develop new prevention and treatment strategies may be submitted, but will be reviewed for portfolio alignment.

Note: Applicants seeking to submit proposals focused on topics such as the restoration of CFTR protein function or approaches to fix/replace the defective CFTR gene should apply through the Path to a Cure Pilot and Feasibility Award (https://www.cff.org/researchers/path-cure-academic-programs .

VII. Review and Award

All applications adhering to RFA guidelines will be reviewed for relevance to the mission, alignment with CF Foundation research priorities outlined in this RFA and for technical merit. Funding of awards is at the discretion of CF Foundation and CF Foundation advisory committees and is based on the priority score awarded to each application and recommendations of the committee, relevance of the proposed study to the goals of the Foundation, and alignment with CF Foundation research priorities. All awards are subject to compliance with applicable regulations and CF Foundation policies and are contingent upon the availability of CF Foundation funds.

The review process will initially assess all applications for their alignment with CF Foundation research priorities using a CF Foundation internal review panel. Applications focused on high priority research topics will be reviewed by an external committee for technical merit and alignment to the CF Foundation mission. Applications not focused on high priority research topics may receive a modified and abbreviated review.

Applications that have not been funded in two review cycles will not be accepted for further consideration by CF Foundation. ***(Exceptions for one additional resubmission may be considered for tenure-track PIs who are pre-tenure with prior approval from the Program Officer).*** In order to resubmit

unfunded applications during future application cycles, applicants must indicate that the application is a resubmission and clearly address reviewer critiques through a response to reviewers and revisions to the research plan.

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

- Failure of the application to address contemporary research priorities in CF
- Application is a continuation or extension of an existing research project
- 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

Application deadline: Tuesday, December 8, 2026, 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. CF Foundation reviews applications electronically, and only documents submitted online at http://awards.cff.org will be reviewed.

General Timeline:

	Fall 2026 Cycle
Application Deadline	December 8, 2026
Committee Review Date	March 2027
Notification to Applicants	April 2027
Earliest Project Start Date	May 1, 2027

*We strongly encourage all applicants to 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 CF Foundation Grants & Contracts Management and Administration (GCMA) Office is able to assist all applicants with 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 documents have been uploaded to awards.cff.org, the system will compile them into a single PDF file. We highly recommend you preview this file by selecting 'Application Full Print', as well as exporting the compiled PDF file to ensure all documents intended to be included are present. If there are any documents missing, please contact the CF Foundation within two (2) business days of submission so we can assist with coordinating updates to the application. After two (2) business days, further revisions will not be accepted.*

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. ***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 "**2026 Fall Pilot and Feasibility Award**" 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* 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 of 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 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 whether the project site is the same as the legal institution.

Verification of Applicant Institution's Tax Status (upload as PDF documents):
The CF Foundation 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 CF Foundation 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 may be required to provide additional information and complete a CF Foundation 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 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. 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*: CF Foundation defines "junior investigator" as any individual who has not received a CF Foundation/CFFT Research Grant or NIH equivalent (e.g., R01, R21, R23) as a Principal Investigator AND is within their first five years of their first academic appointment at the level of Assistant Professor or equivalent.

Letters of Reference for junior investigators must be submitted by the following individuals:

- **The Chair of the Applicant's Department at the Applicant Institution** – The letter of reference from the Department Chair should indicate the release of sufficient space and facilities for the work described, as well as guarantee the time commitment of the investigator to the project. If the applicant is currently a fellow, the letter of reference should include confirmation of the pending faculty-level appointment.
- **At least two (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 to add referees in the table. You must click "Invite" 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 not 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 CF Foundation/CFFT Research Grant or NIH equivalent, are not required to submit Letters of Reference; however, if they are new to CF research, Letters of Support and/or Collaboration should be provided 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, in addition to relevance and project alignment statements, are required, as follows:

- **Project Alignment to Research Priorities and Expected Outcomes:** Clearly articulate how the proposed research advances one of the identified research priorities in Section VI of the RFA. Identify up to three specific outcomes anticipated upon completion of the project, demonstrating its potential to contribute meaningfully to the field.
- **Lay Abstract**: This statement will be used to inform the non-scientific departments of CF Foundation 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 CF Foundation mission**: All applications are reviewed and scored not only on scientific merit but also on relevance to CF Foundation'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. Pilot and Feasibility Awards funded through this RFA are for a maximum of two (2) years. The total budget request cannot exceed $50,000 per year plus an additional twelve percent (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 **$228,000 (FY2026)**. 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 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 CF Foundation GCMA Office. **Travel expenses may not exceed $1,500 per person per year**. Registration fees associated with conferences are in addition to this allowance and should be listed under "Other Expenses". Applicants are encouraged to attend 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 indirect cost, 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), 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 CF Foundation. 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 CF Foundation/CFFT Support
- Critique Response (if resubmission)

BUDGET JUSTIFICATION

Describe costs listed in the Budget Detail. Use major categories, such as Salaries & 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. ***Budget Justification upload(s) should be provided individually for each year of funding support being requested. These can be uploaded as a single PDF or separate PDF uploads for each year.***

RESEARCH PLAN

Page limit: **Six (6)** 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 (at least 11 pt font) 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. **CF Foundation 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 Significance: Critically evaluate existing knowledge and specifically identify gaps the project intends 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 translational impact of the proposed work to CF, as well as alignment to strategic priorities of the Foundation, as outlined for this RFA. 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: Preliminary data are not required, however, if provided, will be evaluated in the context of the application.

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 Pilot and Feasibility Awards are reviewed by CF Foundation'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 minimal 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: CF Foundation Patient Registry and Interventional studies involving human subjects cannot be supported through this program and should instead apply as a Clinical Pilot and Feasibility Award.

e. **Limitations and Potential Pitfalls**: Discuss potential difficulties and/or limitations of the proposed studies and alternative approaches to achieve aims.
f. **Consultant Arrangements**: If the proposed project includes consultant arrangements and/or collaboration with other individuals outside the applicant's group, describe the working relationships and support this description by letter(s) of intent signed by collaborating individual(s). If clinical material required by this award is to be furnished by other individuals, include a statement from these individuals agreeing to their participation and precautions taken to ensure anonymity of patients.
g. **Literature Cited**: References should be numbered in the sequence 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. For dependent faculty, please also provide a biosketch for the lab PI. International applicants can upload a biosketch that is equivalent in content to the NIH template provided. CF Foundation 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 CF Foundation 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. If an applicant has a current source of funding that will be relinquished if this award is received, please note that in the Other Support document.

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 CF FOUNDATION/CFFT SUPPORT

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

- CF Foundation/CFFT Award #
- Principal Investigator (PI)
- CF Foundation/CFFT Project Title
- Applicant's Title on Project

- Project Start/End Dates
- Total CF Foundation/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. Note: In addition to providing the response to critiques, the research plan must also be revised and clearly marked to show changes from the previous submission. Research plans that are not clearly revised may not be reviewed.

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 CF Foundation/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).

Dependent faculty must provide a letter of support from their laboratory PI clearly indicating the affiliation and their support for the application.

APPENDICES (IF APPLICABLE)
Appendices are restricted to the following categories:
- Signed Letters of Support.
- Signed Letter of Collaboration from Co-PIs, if any.

***Organization Assurances & Certifications**
CF Foundation 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. CF Foundation will not release payments to awardee institutions until these documents are received and on file with the CF Foundation 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. CF Foundation will not release payments until these documents are received and on file with the CF Foundation GCMA Office.

Research Involving Human Subjects: CF Foundation 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 CF Foundation 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 CF Foundation must meet the requirements contained in the document *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (updated April 2024*). 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 CF Foundation 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, CF Foundation 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 submitting your application, please conduct a thorough review of all sections. Once your review is complete, navigate to the **ASSURANCE STATEMENT(S)** tab and enter your initials in the "Applicant Initials" field to provide your attestation. When you click the "**Submit to Authorized Institution Official for Acceptance**" button, the system will validate all required fields and identify any errors. Upon successful submission, the application status will change to "**Pending Authorized Institution Official Acceptance**" and the application will be locked for editing.

Your Authorized Institution Official will receive an automatic notification to review your application. The Authorized Institution Official will access the application through **My Applications > Pending Authorized Institution Official Acceptance module**, review it thoroughly, and enter their initials in the "AIO Initials" field under the **ASSURANCE STATEMENT(S)** tab to provide their attestation. They will then click "**Submit to CFF**" to complete the submission process. No further action will be required from you at this stage unless you are contacted by CF Foundation staff regarding your application.

If revisions are needed while the application is in "**Pending Authorized Institution Official Acceptance**" status, the "**Revise AIO**" button can be clicked, which will revert the application status to "**Draft**" allowing necessary changes before following the standard submission process again.

XI. Resources and Other Information

- CF Foundation Funding Opportunities Newsletter
- CF Foundation Academic Funding Opportunities
- Grants Management System – How to User Guides

XII. Contact Information

For technical support:
Primary CF Foundation GCMA Office contact Mike Carlino at mcarlino@cff.org or 301-841-2671
Secondary CF Foundation GCMA Office contact grants@cff.org or 301-841-2614

For scientific and programmatic questions:
Rebekah Dedrick, Ph.D. at rdedrick@cff.org