CYSTIC FIBROSIS FOUNDATION

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

Program Name: 2025 CFF/NIH R01-Unfunded Award

Brief Program Overview/Description: In an effort to assure that all meritorious CF-related research is supported, CFF has developed the CFF/NIH R01 -Unfunded Award mechanism to provide bridge funding. The objective of this Request for Applications (RFA) is to support excellent CF-related research projects that have been submitted to and approved by the NIH (or governmental funding agencies in other countries) but cannot be supported by available funds. In order to be eligible for this program, applications must fall within the upper 40th percentile (1%-40%). (Please note that unfunded R21 projects are no longer accepted through this mechanism. Investigators should consider revising and submitting these projects through the Research Grant/Path to a Cure Research Grant funding mechanisms that are accepted May and December each year.)

Funding Amount: The maximum award amount is $125,000 per year for up to two years (Direct Costs Only); indirect costs are not allowable. *Note: the level of funding will be determined by CFF following review by the designated medical/scientific advisors.*

Eligibility:

- The application must have been reviewed by an NIH study section and presented to an institute council within 12 months of applying for CFF support.
- Applications must have been submitted to NIH as an R01 and fall within the upper 40th percentile (1-40%). If an application has been submitted to NIH multiple times, the most recent submission must have been scored inthe upper 40th percentile to be considered.
- Unfunded resubmitted applications (A1 or other) may be submitted through this mechanism, however, may be subject to additional scrutiny.
- A project may only receive funding through the CFF/NIH-Unfunded mechanism one time. If a project has received funding through this mechanism previously, it cannot be resubmitted, even if it has gone back to the NIH (or other governmental funding agency).
- *Additional eligibility requirements can be found in Section IV below.*

Key Dates:

Published	February 11, 2025
Full Application Deadline	Rolling through December 1, 2025
Review	Ad-hoc basis (typically 8-10 weeks after submission)
Full Application Notification	Ad-hoc basis (typically 2-4 weeks after review is complete)
Project Start Date	As determined by applicant (at least 120 days after the submission)

**The project start date should be the 1st of the month, and the end date should be the last day of the month. If you are unable to start on the 1st of the month, please contact the GCMA contact listed on the top of page 1.*

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 theopportunity to lead long, fulfilling lives by funding research and drug development, partnering with the CFcommunity, 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

CFF has developed its research program to complement work at the National Institutes of Health (NIH). Support from CFF, through various mechanisms, is intended to provide support for the development of sufficient preliminary data to make CF-related applications highly competitive in the NIH review process. However, as a result of funding constraints on the NIH, coupled with the growing interest in CF research, occasions arise in which highly meritorious grants are submitted to the NIH but not funded. In an effort to assure that all meritorious CF-relevant research is supported, CFF has developed the CFF/NIH R01 - Unfunded Award mechanism to provide bridge funding. The objective of this Request for Applications (RFA) is to support excellent CF-relevant research projects that have been submitted to and approved by the NIH (or governmental funding agencies in other countries) but cannot be supported by available funds. In order to be eligible for this program, applications must fall within the upper 40th percentile. (Please note that unfunded R21 projects are no longer accepted through this mechanism. Investigators should consider revising and submitting these projects through the Research Grant/Path to a Cure Research Grant funding mechanisms that are accepted May and December each year.)

CFF does not intend to assume the role of the NIH or other governmental funding agencies, but instead wishes to ensure that the momentum in CF research is not irreversibly slowed due to budget constraints. The CFF/NIH R01-Unfunded Award offers a temporary mechanism for continuing highly meritorious projects until support can be obtained. The CFF will continue to vigorously encourage the NIH to assume support of meritorious CF-related projects.

III. Funding Amounts

The maximum award amount is $125,000 per year for up to two years (Direct Costs Only); indirect costs are notallowable. *Note: the level of funding will be determined by CFF following review by the designated medical/scientific advisors.*

IV. Eligibility

- The application must have been reviewed by an NIH study section and presented to an institute councilwithin 12 months of applying for CFF support.
- Applications must have been submitted to NIH as an R01 and fall within the upper 40th percentile (1-40%). If anapplication has been submitted to NIH multiple times, the most recent submission must have been scored in the upper 40th percentile to be considered.
- For applications submitted to governmental funding agencies in other countries, in order to be consideredfor this program, the application must have been submitted in the previous 12 months to an NIH R01 equivalent funding program, provide reviewer critiques, provide a report indicating the scores in the upper 40th percentile, and be able to resubmit to the funding agency for funding for this project.
- Unfunded resubmitted applications (A1) may be submitted through this mechanism, however, may be subject to additional scrutiny.
- A project may only receive funding through the CFF/NIH-Unfunded mechanism one time. If a project has received funding through this mechanism previously, it cannot be resubmitted, even if it has gone back to the NIH (or other governmental funding agency).
- The original NIH application must be clearly relevant to advancing the CFF mission.
- The investigator should not be receiving other funding for this work. **If other funding is obtained**

(through NIH or other funding bodies) for this work or the resubmission of the NIH (or other funding body) application is approved for funding, the CFF award must be relinquished.

- If awarded, a revised application must be submitted to the funding agency within one (1) year of receivingthe CFF award. Failure to do so will result in the loss of support. Documentation showing resubmission must be provided to CFF as part of the renewal progress report and/or final scientific report.
- Applicants must be from a non-profit or academic institution; for-profit entities are **not** eligible to apply. For-profit entities should visit Industry Funding Opportunities for more information.

V. Mentorship Requirements

Not applicable to this RFA

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

The landscape of CF has changed significantly over the past 30+ years since the identification of the CFTR gene. The introduction of CFTR modulators, small molecule drugs that target the basic CFTR defect, has led to unprecedented improvement in health for many people with CF. 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.). In addition to correcting the basic defect, CFF realizes the needs of the community and places a high priority on supporting efforts that improve our understanding of disease pathogenesis, such as defects in airway defense, microbial adaption to the CF lung, mucociliary clearance and airway hydration, and extrapulmonary manifestations of the disease that may not be completely corrected by CFTR modulators. We therefore encourage investigators to review the list below for basic and translational science areas of interest to the CFF.

Investigators working in the following areas are particularly encouraged to submit an application for consideration:

- Developing novel means for repairing and/or replacing the mutant CFTR.
- Evaluating outcomes of inserting a CFTR “superexon” or cDNA into the native locus with particular emphasis on gene regulation, expression, and transcription termination.
- Developing and optimizing the chemistry and formulation of nucleic acid delivery vehicles, both viral and non-viral, that can target disease relevant cells and tissues.
- Characterization of cellular targets for CFTR correction, including airway progenitor cells and other affected epithelial tissues (biliary tract, GI tract, pancreas).
- Characterizing and validating potential targets that regulate CFTR mRNA stability and translation, which includes understanding the pathways and mechanisms that regulate nonsense mediated decay (NMD), premature termination codon (PTC) recognition, splicing, and translation termination.
- Evaluating codon optimization strategies to enhance CFTR protein longevity, stability, and function.
- Understanding of how modulators impact disease pathogenesis across all stages of life as well as the cellular and molecular changes that cannot be reversed by modulators, which may include direct and indirect influences of CFTR modulation on the airway milieu, including resident pathogens, inflammation and inflammatory cell function, mucin structure (tethered and secreted), airway surface liquid (ASL), and mucociliary clearance (MCC), as well as extrapulmonary manifestations.
- Biological mechanisms involved in chronic lung allograft dysfunction (CLAD), rejection and transplant immunology.
- Improved understanding of acquisition, detection, pathogenesis, host-pathogen interactions, and treatment approaches for difficult to treat CF infections (i.e. MDR Pseudomonas, Burkholderia, Stenotrophomonas). *
- Approaches to understand and treat nutritional deficiencies and CF-related GI complications, including intestinal, pancreatic, and hepatobiliary disease across the lifespan.

- Effects of endocrine system dysfunction in CF, especially projects focused on biological underpinnings of Cystic Fibrosis Related Diabetes (CFRD), CF bone disease, and sexual & reproductive health.

Projects that focus on strategies and methods with the potential to inform or ultimately translate into novel therapies to restore CFTR protein function or fix/replace the defective CFTR gene as well as those that improve our understanding of disease mechanisms and pathophysiology in a manner that will lead to development of new prevention and treatment strategies may be prioritized for funding.

**Projects focused on individual pathogens not listed above or that solely explore basic biology of pathogens that will not have direct applicability to the development of new treatment strategies or improve outcomes for people with CF may be deprioritized for funding.* Infection/microbiology-focused applications should utilize clinically relevant strains and specimens or address host responses to the organism as part of the application.

VII. Review and Award

Since applications to this program have already been reviewed and scored by an NIH (or other governmentalagency) study section, CFF medical/scientific advisors will focus on the following points:

- Relevance of the proposed study to issues in CF
- Adequacy of the budget
- Potential for future support by the NIH (or other governmental funding agencies)

Note that A1 applications (or those applications that have previously been through one round of review at the NIH (or other governmental agency) may be subject to additional scrutiny to ensure that the proposed bridge funding will improve the applicant's chances of success on the next resubmission.

All awards are subject to observance of CFF policies and Terms and Conditions in addition to applicable Federal regulations or equivalent regulations in the Awardee Institution's country, based on the type of research involved. All awards and ongoing support are also contingent upon the availability of CFF funds.

VIII. Submission Information

Application Deadline: Rolling through December 1, 2025

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:

Full Application Deadline	Rolling through December 1, 2025
Review	Ad-hoc basis Ad-hoc basis (typically 8-10 weeks after submission)
Full Application Notification	Ad-hoc basis (typically 2-4 weeks after review is complete Project Start
Date	As determined by applicant (at least 120 days after the submission)

The project start date should be the 1st of the month, and the end date should be the last day of the month.
If you are unable to start on the 1st of the month, , please contact the GCMA contact listed on the top of page 1.

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 CFF/NIH R01 -Unfunded 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* 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 clickingon 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.

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 through Adobe Sign.

GENERAL

Enter the title of your project, enter the project start and end dates, and complete any additional questions.
***Please ensure that you review and comply with the Organizational Assurances and Certifications as cited below.**

CONTACT PROFILE

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.

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 yourprofile 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.

Note: When choosing an institution, please select the institution where the applicant will plan to complete their project.

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 ifthese documents are not received and on file.

- Applicants from for-profit organizations must submit a copy of the applicant institution's W-9 and IRSdocumentation 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):
For international applicants, you will need to answer an eligibility question specifying if you are an independent investigator. If answering yes, CFF may require an additional letter of support to be added to the application to verify eligibility.

Applicants whose institution is not a United States based-entity will be required to provide additional information and complete the CFF International Institution Form as part of the Full Application stage. Refer to International Institution Form section below.

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".

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 scientificmerit 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 withCF 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 nothave 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'sbudget detail for each year of funding being requested. CFF/NIH-Unfunded Awards approved through this RFA are for a maximum of two (2) years. The total budget request cannot exceed $125,000 per year (indirect costs are not allowable). ****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.***

The following budget categories are offered under this program:

Salaries & Benefits - List the names and positions of all professional and non-professional personnel involved in the project, whether or not salaries are requested. Indicate the percent effort on the project for all personnel. For each individual, be sure to complete all fields on the Budget Detail in full on the template provided. In accordance with National Institutes of Health (NIH) policy, salary requests may not use an institutional base salary in excess of the current federal salary cap of **$225,700 (FY2025)**. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all funding agenciesand foundations.

Consultant Expenses - Give the name and institutional affiliation of any consultant who has agreed to serve in this capacity, including statisticians and physicians in connection with acquiring patient samples 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.

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. Registration fees associated with conferences 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 unitcare 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 subcontracts, duplication costs, publication costs, 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.

Budget Detail – Indirect Costs

Indirect costs are not allowable.

FULL APPLICATION UPLOADS

Download the available templates applicable to the project, upload the completed templates, as well as the additional application components as outlined below. All documents must be uploaded in PDF format to the corresponding attachment types within this section. Templates available for download include:

- Budget Justification
- Response to NIH Summary Statement
- Research Plan – Revised
- Other Support
- 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(s). ***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.***

COPY OF NIH (OR OTHER GOVERNMENTAL FUNDING AGENCY) UNFUNDED APPLICATION

A PDF copy of the entire unfunded grant application should be uploaded to the application.

COPY OF NIH SUMMARY STATEMENT (OR EQUIVALENT)

A PDF copy of the entire NIH Summary Statement associated with the unfunded grant application must be uploaded to the application. Applications that were submitted to governmental funding agencies in other countries should submit the reviewer critiques provided by the funding agency.

RESPONSES TO NIH SUMMARY STATEMENT

Please provide a point-by-point response to the critiques noted in the NIH Summary Statement (or reviewer critiques provided by the funding agency) and specific plans to address identified weaknesses. There is no page limit to the responses; however, be as concise and succinct as possible.

REVISED RESEARCH PLAN

Page limit: Ten (10) single-sided pages, not including the Literature Cited. Applications exceeding this pagelimit will not be reviewed. Include sufficient information to permit effective review without reference to previous applications. Information should be presented in a clear and concise manner,

while being specificand 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(s). If uploaded as Appendices, they will NOT be reviewed.
- Type the PI's name in the space available in the header of the document. The template available will trackpage numbers at the bottom.

The Revised Research plan **should not** be a copy of the submitted NIH (or other governmental funding agencyin another country) unfunded application. Instead, **this section should highlight the scope of work and experiments that will be completed using the funds from CFF if the award is funded**. This section should specifically address weaknesses noted in the NIH Summary Statement (or reviewer critiques provided by the funding agency) as well as the reduced CFF budget. The Revised Research Plan must also include a clear strategy for resubmission of the original application to the funding agency. The plan may include the followingcomponents:

a. **Hypothesis and Specific Aims:** State concisely and realistically the intent of the proposed research andthe 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:** Briefly 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 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:** Discuss 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 the data will be analyzed and interpreted. If human subjects are involved, provide details of the methods for patient selection and care. Discuss potential difficulties 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 minimal patient risk (e.g., venipuncture, nasal 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.
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 letter 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).

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.

RESULTS OF PAST AND CURRENT CFF/CFFT SUPPORT

The Principal Investigator (PI) and any Co-Principal Investigator(s), if applicable, are requested to identify theresults 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

INTERNATIONAL INSTUTTION FORM (IF APPLICABLE)

Applicants whose institution is not a United States based-entity must complete the CFF International Institution Form.

- Please attach a current copy of the following documents to your completed form and cite to the relevant page(s) or paragraph(s) in the supporting documentation:
- A Form W-BEN-E or W-8EXP signed by the authorized institutional official within the last three years.
- An anti-terrorism certification 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. Please see the CFF template provided in Appendix A;
- Names and Addresses of all Institutional Officers and Directors (Appendix B);
- Institution's Current Sources of Support, including grants, private endowments, commercial activities, etc. (Appendix C).

Applicants who have provided these documents within the past one (1) year 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 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

Appendices are restricted to the following categories:

- 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.
- Additional NIH (or equivalent) Biographical Sketches, that are not already included in the original application, should be completed/uploaded for any new key personnel named in the CFF application. *Note: CFF defines "key personnel" as any individual with an advanced degree that will plan an instrumental role in the accomplishment of the research project.*

***Organization Assurances & Certifications**

CFF requires, as applicable, that all U.S.-based awardees obtain Institutional Review Board (IRB) approvals forhuman 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 releasepayments 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 orsynthetic 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 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 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, whichrequire 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 errors. Upon submission the ability to edit the application will be locked pending review and approval by your AIO.

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

XI. Resources and Other Information

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

XII. Contact Information

For technical and Grants Management System support:
Primary CFF GCMA Office contact Jodie Chan at jchan@cff.org or 301-841-2614
For scientific/programmatic questions:
Program Officer: Katherine L. Tuggle, Ph.D. ktuggle@cff.org