



Program Name: CFF NIH K-Boost Award 2022

Brief Program Overview/Description: The CFF seeks to attract and develop junior faculty who will establish research careers in cystic fibrosis (CF). The primary purpose of the K-Boost Award is to provide supplemental funding to qualified and promising scientists early in their faculty careers who have obtained K funding (e.g.: K08, K23, K25) from the NIH in areas that reflect the CFF research priority areas.

Funding Amount: Funding of up to \$50,000 per year may be requested (indirect costs are not allowable). Funding may be requested for up to five (5) years to coincide with the associated active NIH K Award.

Eligibility:

- Candidates must be U.S. citizens or U.S. permanent residents (must have obtained permanent residency prior to the time of application).
- Applicants must be independent investigators.
- The applicant must have an active NIH K award with at least twelve months of remaining funding at the time of applying for CFF support.
- Institutional administered K awards (e.g. KL2) that do not undergo an external review process are not eligible.
- The application must be clearly relevant to advancing the CFF mission.

Key Dates:

Published	February 11, 2022
LOI Submission Deadline	N/A
LOI Applicant Notified	N/A
Full Application Deadline	Rolling
Committee Review Date	N/A
Notification to Applicants	4 to 8 weeks post submission
Project Start Date	As determined by applicant (the award period end date must align with active NIH K Award end date)

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I. About the Cystic Fibrosis Foundation

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

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

II. Program and Award Overview

The CFF seeks to attract and develop junior faculty who will establish research careers in cystic fibrosis (CF). The primary purpose of the K-Boost Award is to provide supplemental funding to qualified and promising scientists early in their faculty careers who have obtained K funding (e.g.: K08, K23, K25) from the NIH in areas that reflect the CFF research priority areas.

During the term of the award, awardees will focus their research efforts on topics directly related to CFF research priorities. The goal of this program is to provide supplemental support for research costs or additional salary support for key personnel to NIH K awards that meet these criteria. The supplement will support research that emphasizes either basic or clinical areas relevant to the CFF mission.

III. Funding Amounts

- Funding of up to \$50,000 per year may be requested (indirect costs are not allowable).
- Awards may be approved for up to a five (5) year period to align with the associated active NIH K Award. Funding for future years is contingent upon submission and approval of a renewal progress report to CFF and the availability of funds.

IV. Eligibility

- Candidates must be U.S. citizens or U.S. permanent residents (must have obtained permanent residency prior to the time of application).
- Applicants must be independent investigators.
- The applicant must have an active NIH K award with at least twelve months of remaining funding.
- Institutional administered K awards (e.g. KL2) are not eligible.
- The application must be clearly relevant to advancing the CFF mission.

V. Mentorship Requirements

Not applicable to this RFA

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

The landscape of CF has changed significantly over the past 30 years since the identification of the CFTR gene. In 2012, Kalydeco™ (VX-770), the first drug to target the basic CFTR defect, was approved for a small subset of people with CF and clearly demonstrated that CFTR modulating drugs can improve clinical parameters such as sweat chloride, lung function, and body weight. Since that time, additional CFTR modulating drugs have been approved that continue to change the course of disease for the nearly 90% of people who will benefit from them. CFF realizes the changing needs of the community and places a high priority on supporting research that will improve our understanding of disease pathogenesis, especially in the setting of CFTR modulators, such as defects in airway defense, microbial adaptation to the CF lung, mucociliary clearance and airway hydration, and extrapulmonary manifestations of the disease. CFF will prioritize funding for projects that will lead to a better understanding of disease mechanisms and pathophysiology that contribute to the development of new prevention and treatment strategies.

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

- 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)
- Mechanisms of defective MCC and ASL that are relevant for therapeutic applications.
- Biological mechanisms involved in lung allograft dysfunction/rejection and transplant immunology
- Improved understanding of acquisition, detection, pathogenesis, host-pathogen interactions, and treatment approaches for difficult to treat CF infections (i.e. NTM, MDR Pseudomonas, MRSA, Aspergillus, Burkholderia, Stenotrophomonas). 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 will be deprioritized for funding.
- Approaches to understand and treat CF-related GI complications, including liver disease and the impact of nutritional deficiencies
- Effects of endocrine system dysfunction in CF, especially projects focused on biological underpinnings of Cystic Fibrosis Related Diabetes (CFRD) and CF bone disease

Microbiology-focused applications that do not utilize clinically relevant strains and samples or do not address host responses to the organism as part of the application will receive a lower relevance score.

VII. Review and Award

Applications will be reviewed by a CFF internal committee. Awards are based upon the availability of funds, the scientific merit of research applications, the potential of the candidate for a career in CF research and the relevance to CFF's mission. Additional evaluation criteria may also be considered depending on the type of proposal submitted to CFF. All awards are made in compliance with the applicable regulations and policies of CFF.

VIII. Submission Information

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 “**CFF NIH K-Boost Award 2022**” program. Click on the “Apply” button in the column on the far right to open the application form.

Applicants may stop at any point but must click the “**Save**” button at the bottom of each page *before exiting* in order to save their progress. When you wish to return to your draft application, please do not go through the “Funding Opportunities” tab. Instead, go to the “My Applications” tab in the right corner of the main page. When you are in the “My Applications” tab you will be able to find all your draft applications by clicking on the “Draft Applications” module.

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

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, 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 page 9.**

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 and Contracts Office must have a copy of the applicant institution’s current W-9 and 501(c)3 letter, or other documentation verifying its Federal tax status and will not issue Award Letters to Awardees if these documents are not received and on file.

- Applicants from for-profit organizations must submit a copy of the applicant institution’s W-9 and IRS documentation verifying the organization’s Federal tax status. Awards are not issued prior to having these documents on file with the CFF Grants and Contracts Office.
- Non-U.S. applicants must provide a copy of the W-8BEN-E form (required). In addition, a tax equivalency letter should be uploaded, if available. If a tax equivalency letter is not available, applicants must upload a letter stating this documentation is not available.

International Applicants (if applicable):

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

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

Applicants who have provided these documents within the past 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 CFF Grants and Contracts Office will contact applicants if documents are outdated or missing.

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

CONTACTS

Please note: The INSTITUTION tab must be completed prior to adding internal contacts to ensure that the contacts are properly associated with the applicant institution.

Complete the required contact fields by searching by name for existing contacts at your institution for each role. If the desired institutional contact is not available in the system, you may select “Add Internal Contact” to create a basic contact profile in order to add the individual to your application.

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

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. CFF NIH K-Boost Awards approved through this RFA are for a maximum of five (5) years. The total budget request cannot exceed \$50,000 per year (indirect costs are not allowable).

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 associated project, whether or not salaries are requested in the K-Boost. Indicate the percent effort on the combined NIH-K and planned CFF K-Boost 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 \$199,300. 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 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 Grants & Contracts Office. Travel expenses may not exceed \$1,500 per person, per year. Registration fees associated with conferences 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 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 “External Requests” tab near the top right of the screen and navigate to the subcontract activity to complete the entry. After completing the subcontract budget activity, please select “Pending PI

Acceptance”, as well as “Submit” to ensure the subcontractor budget is included as part of the main application budget.

For applications that include a subcontract with a third party, the applicant may request indirect costs on the first \$25,000 of each subcontract per project period. Negotiations of subcontracts are between the applicant institution and the subcontractor.

Budget Detail – Indirect Costs

Indirect costs 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:

- Summary of Research Goals and Personal Statement
- Summary Statement for the current K Award. (Note: The applicant must also submit a copy of the entire K Award in Appendices.)
- Budget Justification
- NIH Biographical Sketch
- Other Support (NIH format)
- Facilities Available
- NIH K Funding Alignment Table
- Critique Response

Summary of Research Goals and Personal Statement

There is a one (1) page limit. Please provide a personal statement regarding your career interest in CF research, the goals of the NIH K award research proposal and how the CFF NIH K-Boost Award will further support the research outlined in the NIH K award.

Summary Statement of Current NIH K Award

Please upload the summary statement associated with the NIH K Award.

Active NIH K Award Application

Please upload the complete active NIH K Award application. This includes (but is not limited to):

- Face Page
- Project Summary/Abstract
- Project Narrative
- References
- Facilities and Other Resources
- Senior/Key Persons
- Biographical Sketches
- Budget and Justification
- Introduction to Application
- Candidate Information and Goals for Career Development
- Specific Aims
- Research Strategy
- Training in the Responsible Conduct of Research
- Plans and Statements from Mentor and Co-Mentor(s)
- Letters of Support from Collaborators, Contributors, and Consultants
- Description of Institutional Environment

- Institutional Commitment to Candidates Research Career Development
- PHS Human Subjects and Clinical Trials Information
- Vertebrate Animals
- Resource Sharing
- Authentication of Key Biological and/or Chemical Resources

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). Since the Budget form will reflect the level of effort applied to the full NIH-K and K-boost effort, the justification should clarify when salary requested from CFF does not match the level of effort on the overall project.

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 online application. Applications that were submitted to governmental funding agencies in other countries should submit the reviewer critiques provided by the funding agency.

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.

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.

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.

NIH K Award Alignment Table

Complete and upload the NIH K Award Alignment Table form. If the first year of the CFF funding period request is less than 6 months of the current NIH K-award period, the budget must be prorated by the months remaining. If the first year of the CFF funding period is equal to or greater than 6 months of current NIH K-award period, the total of \$50,000 maximum may be requested.

Critique Response

Complete and upload the Critique Response form. This should be a high-level response to the summary statement. Any major weaknesses should be addressed. There is a 5 page limit.

APPENDICES

Appendices are restricted to the following 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.

***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 Grants and Contracts 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 Grants and Contracts 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 Grants and Contracts Office.

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

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

Validation and Submission

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

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

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

IX. Other Information

Not applicable to this RFA

X. Contact Information

For technical support and program/content information:

Primary CFF Grants and Contracts contact Angela Minucci at aminucci@cff.org or 301-841-2614

Secondary CFF Grants and Contracts contact Edwin Gregorian at egregorian@cff.org or 301-841-2614

For scientific questions:

Elizabeth Yu, Ph.D. at eyu@cff.org

XI. Electronic Application Checklist

Application deadline (rolling): through December 31, 2022 by 5:00 PM (Eastern)

Submit online to: <https://awards.cff.org>

Face Page which includes:

- Signatures
 - Principal Investigator (Co-PI's are not required to sign)
 - The Official authorized to sign on behalf of the Awardee Institution
- Applicant/PI information (online)
- Complete Institution and PI Contact Information, including correct mailing address (online)
- Organization Assurances (check those that apply online/complete the required information)
 - Human Subjects Certification
 - Recombinant or Synthetic Nucleic Acid Molecules/Biosafety Information
 - Research Involving Animals Approvals

Research Plan, Supporting Documents and Appendices:

- Abstracts ~ Summary of Relevance
- Summary of Research Goals and Personal Statement
- Summary Statement of Current NIH K Award
- Active NIH K Award Application
- Budget Justification
- Biographical Sketch(es) of Key Personnel
- Other Support
- Facilities Available
- NIH K Funding Alignment Table
- Verification of Applicant Institution's Tax Status
 - W-9
 - Federal (IRS) tax status letter or equivalent tax status letter
- Appendices (upload as PDF documents, if applicable)
 - 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