Program Name: CFF NIH K-Boost Award

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	March 3, 2020
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)

Table of Contents:

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

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

II. **Program and Award Overview**
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 CFF supports research that spans the CF research spectrum, from basic bench science to computational analyses to clinical research. As such, research advancing CF care, treatment, or research is highly relevant and will be considered. More specific priorities identified by the CFF and the CF community include, but are not limited to, the following areas of interest:
- Molecular characterization of CFTR mutations other than F508del
- 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)
- Novel means for restoring CFTR function
  - Fundamental studies that will enable gene editing/repair strategies to be used in therapeutic applications
  - Delivery methods for nucleic acids, and protein to the lung and other affected tissues
  - Cellular targets for CFTR correction

- Airway progenitor cells, airway stem cell niche
- Mechanisms associated with nonsense mutations and means to overcome them, specifically mRNA stability and translational regulation
- 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)
- Studies that investigate both the mechanistic underpinnings and clinical and real-world impact of CF disease complications (lung, GI tract, liver, pancreas, reproduction, mental health, endocrine, pain management, bone and joint health, etc.)
- Strategies to improve care and quality of life and reduce the treatment burden of people with CF
- Assessment and validation of biomarkers, clinical trial tools, outcome measures and efficacy endpoints
- Characterization of CF disease manifestations and management in the era of highly effective modulator therapy
- Novel interventions that improve CF patient care and outcomes
- Translational or clinical studies in lung transplant research
- Studies designed to translate laboratory findings of disease pathogenesis/treatment to clinical evaluation

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

Application deadline (rolling): through December 31, 2020 by 5:00 PM (Eastern)

Submit online through proposalCENTRAL: https://proposalcentral.com/
(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 proposalCENTRAL will be reviewed.

General Timeline:
Application Deadline _____ Rolling
Review _____ 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)

IX. Letter of Intent Guidelines
Not applicable to this RFA

X. Full Application Guidelines
Applications must be submitted online at proposalCENTRAL: https://proposalcentral.com/

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 proposalCENTRAL, the system will compile them into a single PDF file in the correct sequence as shown in Section XIII. ELECTRONIC APPLICATION CHECKLIST.

Log-in at proposalCENTRAL: https://proposalcentral.com/

First-time applicants must register to create a username and password for proposalCENTRAL and will need to complete a profile online before applying. If you are registered and cannot remember your password, click on the **"Forgot Your Username/Password?"** link below the **"Application Login"** fields.

Award opportunities, including this Request for Applications (RFA), are listed on the opening screen, but you must be logged in first to see them.

Select the gray tab labeled "**Grant Opportunities**" found in the upper right-hand side of the page.

Locate the listing for the **"CFF NIH K-Boost Award"** program. Click on the "**Apply Now**" 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 before exiting in order to save their work. When logging in to continue, click on the blue tab, **"Proposals"**, and then the **"Edit"** button.

The following sections are listed in the navigation menu to the left of the application screen. Click on each section and follow the directions.

1. **Title Page**: Enter the title of your project, active NIH K Award number, and respond to the additional questions listed.

2. **Download Templates & Instructions**: Download the available templates applicable to the project, fill them out and upload them when completed in Section #10. Templates available 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 Section 9.I. Appendices.)
   - Budget Detail
   - Budget Justification
   - NIH Biographical Sketch
   - Other Support (NIH format)
   - Facilities Available
   - NIH K Funding Alignment Table

3. **Enable Other User to Access this Proposal:** Complete this section online if you wish to designate access to another individual, such as an assistant who has registered on proposalCENTRAL. Enter the email address of the individual and in the "**Permissions**" column, use the pulldown menu to select the type of access you wish to give. Please note that only delegates who are granted **"Administrator"** rights can submit applications on behalf of the applicant. Click on **"Accept Changes".**

4. **Applicant/PI:** 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,

click the **"Edit Professional Profile"** button and follow the instructions. If a profile was not completed, enter the required information and click **"Save".**

5. **Institution & Contacts:** If a profile was completed upon registration, the Principal Investigator's (PI) institution will be preloaded as Lead Institution. If a profile was not completed, enter the required information and click **"Save".** Be sure to use the full legal name of the institution.

6. **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 2,000 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.

7. **Budget Summary:** Fill in the start and end date and applicable amounts for each year of support requested by completing the online fields (Period 1, 2, 3, etc.). Funding of up to $50,000 (direct costs only) per year may be requested. Allowable costs are outlined below in Section 9.C. *Note: A separate Budget Detail and Budget Justification, downloaded in Section 2, must be completed and uploaded in Section 9 for each year of support requested. The amounts included in the uploaded Budget Detail must match the amounts entered in the Budget Summary online.*

8. **Organization Assurances:** Select the type of assurances that are applicable to the project and provide all required information (i.e. IRB, IACUC, and/or IBC/rDNA approval letter and status at the time of submitting the application). Refer to Section K. ORGANIZATION ASSURANCES & CERTIFICATIONS in these guidelines for details.

9. **Research Goals & Supporting Documents:** In this section, upload the completed templates downloaded in Section #2 above in PDF format. Fill out the fields describing the attachment, select the attachment type from the pulldown menu, enter a description for the attachment in the corresponding field, choose the file to be uploaded, and click the "Upload Attachment" button to upload the file. Do this for each attachment.

   A. **Summary of Research Goals and Personal Statement (template available for download)**
      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.

   B. **Summary Statement of Current NIH K Award (upload as PDF document)**
      Please upload the summary statement associated with the NIH K Award.

C. **Active NIH K Award Application (upload as PDF document)**
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

D. **Budget Detail and Budget Justification (separate templates available for download)**
Fill out the Budget Detail and Budget Justification templates for each year of support requested.
- If fewer than six (6) months remain in the current funding year of the NIH K Award (at the time of application), the budget should be prorated for that time period.
- If greater than six (6) months remain in the current funding year of the NIH K Award (at the time of application), the applicant may request the full year of CFF NIH K-Boost funding.

In the space provided on each page, indicate the year or period as well as start and end dates for the proposed budget period. Funding of up to $50,000 (direct costs only) may be requested.

Be sure that the Budget Detail matches the online budget summary in Section #7 above.

Budget Detail – Direct Costs
Salary & 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 $197,300 when calculating salary requests, the NIH cap must be adhered to. 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.

Subcontractors - The total cost of each subcontract (directs costs only) should be listed under "Other Expenses" and included in the applicant's direct costs. Separate Budget Details and Justifications must be provided for each subcontract, for each year of support (complete and upload a Budget Detail and Budget Justification template for each subcontract). Negotiations of subcontracts are between the applicant institution and the subcontractor.

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.

Travel – Describe the purpose of any CF-relevant travel. Please note: expenses for travel outside the North American continent for domestic applicants, including travel to Hawaii, Puerto Rico, and other U.S. territories are not allowable expenses without prior written approval from the Grants and Contracts Office. Travel expenses are limited to $1,500 per person per year.

Registration fees associated with conferences should be listed under "Other Expenses."

Patient Research Costs – Funds may be requested for patient research costs specifically related to the proposed research. Services that are considered "routine care" (as defined by the U.S. Department of Health and Human Services) may not be included in the project budget. The basis for estimating funds requested in this category must be justified and applicants must provide detailed information regarding the proposed costs (e.g., number of procedures, cost per procedure, ancillary costs). The scientific need for patient research costs will be considered in the review. Negotiation of these costs are between the applicant institution and the service provider.

If approved as part of the application, patient research costs are capped at the amount requested in the budget and under no circumstances is CFF responsible for any costs that are later determined non-covered by third party insurers. Applicants and applicant institutions acknowledge that CFF is solely a provider of funding for the research performed under an approved award and not a sponsor of the research as defined by the FDA (21 CFR §312.3(b)).

Consumable Supplies – Itemize supplies e.g. disposables, reagents, 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.

Other Expenses – Itemize other expenses by major categories, such as subcontracts, duplication costs, publication costs, conference registration fees, computer charges, and other research costs (e.g., recruitment flyers, brochures, patient travel cost reimbursement, and reasonable patient stipends for participation), etc. Justify all items.

Budget Detail – Indirect Costs
Indirect costs are not allowable.

Budget Justification
Describe costs listed in the Budget Detail. Use major categories, such as Salary & Benefits, Consultant Costs, Major Equipment, etc.

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

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

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

H. **NIH K Award Alignment Table (template available online)**
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.

I. **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.

J. **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.

K. **Appendices (upload materials as PDF documents, if applicable)**
Appendices are restricted to the following two (2) 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.

10. **PI Data Sheet:** Fill in the required fields, save and exit.

11. **Print Face Pages:** Follow the prompts on the screen to generate and print a Face Page. The Face Page will be populated automatically with data entered in the online application (applicant's name, institution, title of application, etc.). The Face Page must be signed by the Principal Investigator and Authorized Institutional Official and uploaded in Section #9. Co-Principal Investigators, if any, are not expected to sign the Face Page.

12. **Validate:** Upon completing the application, click on the "Validate" button on the main screen. Attend to any omissions/errors as prompted onscreen, and then click "Validate" again.

13. **Submit:** Click on the gray button with blue lettering. **Submit** CFF will not receive your application unless the "Submit" button is clicked.

Confirmation: Applicants will receive an e-mail confirmation from proposalCENTRAL (not from CFF) that the Application was successfully submitted. This e-mail will be your only acknowledgement. If you do not receive this confirmation, please contact proposalCENTRAL immediately to ensure that your submission was submitted and processed.

XI. Other Information
Not applicable to this RFA

XII. Contact Information

For technical support with the online application:
proposalCENTRAL at pcsupport@altum.com or
800-875-2562 on weekdays, 8:00 a.m. to 5:00 p.m. (Eastern)

For program/content information:
CFF Grants and Contracts at grants@cff.org or 301-841-2614

XIII. Electronic Application Checklist

Application deadline (rolling): through December 31, 2020 by 5:00 PM (Eastern)

Submit online through proposalCENTRAL: https://proposalcentral.com/

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 - (complete online)
☐ Summary of Research Goals and Personal Statement (upload)
☐ Summary Statement of Current NIH K Award (upload)
☐ Active NIH K Award Application (upload)
☐ Budget Detail (upload)
☐ Budget Justification (upload)
☐ Biographical Sketch(es) of Key Personnel (upload)
☐ Other Support (upload)
☐ Facilities Available (upload)
☐ NIH K Funding Alignment Table (upload)
☐ Verification of Applicant Institution's Tax Status (upload)
    ☐ 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