Program Name: Tools for Remote CF Care Delivery: Application of QI Science with LOI 2022

Brief Program Overview/Description: The Cystic Fibrosis Foundation (CF Foundation) is requesting Applications (RFA) with a Letter of Intent (LOI) for innovative, multi-site quality improvement projects that aim to test tools and processes facilitating remote CF care delivery. The CF Foundation is supporting a broad research portfolio to understand the use of telehealth and remote monitoring. This portfolio includes clinical trials and observational research studies that will either directly or indirectly acquire data from home devices or collected samples to assess the feasibility and reliability of remote monitoring. These studies will not address how to implement these technologies into clinical care and their impact on patient/family experience. This RFA with LOI request will increase our understanding of the processes and pragmatic considerations for home spirometry, respiratory sample collection, and remote acquisition of other clinical data in a real-world CF care setting. It is requested that three or more care programs collaborate and that patients/families are included as project team members. Study participants in other CF Foundation or CF Foundation Therapeutics Development Network sanctioned studies would not need to be excluded.
Please note: This is a one-time Request for Applications (RFA) with a LOI. Full applications will be solicited by invitation only after review of LOI.

Funding Amount: Applicants may request funding up to $250,000 per year for up to two (2) years, plus an additional twelve (12) percent indirect costs. Additional information can be found in Section III below.

Eligibility Requirements:

- Candidates must be U.S. citizens or U.S. permanent residents (must have obtained permanent residency prior to the time of application).
- Additional eligibility requirements can be found in Section IV below

Key Dates:

Published	February 7, 2022
LOI Submission Deadline	March 23, 2022*
LOI Applicant Notified	mid-April 2022
Full Application Deadline	June 15, 2022*
Committee Review Date	early September 2022
Notification to Applicants	September 28, 2022
Earliest Project Start Date	November 1, 2022

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*We highly encourage all applicants to pre-register their profile, institution, contacts, and Title of their application at least two weeks prior to the application deadline. This will help to ensure the CFF Grants & Contracts Team is able to assist all applicants with any potential system-related queries prior to the Application Deadline.

I. About the Cystic Fibrosis Foundation

The mission of the CF Foundation is to cure CF 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 awards are offered to support meritorious research ranging from basic laboratory investigation to clinical management of CF.

II. Program Overview

Background:

CF is an autosomal recessive, multisystem disease. Close to 85% of the 34,000 children and adults in the US affected by the disease receive care at a CF Foundation-accredited program. Programs deliver specialized care that emphasizes interdisciplinary collaboration among physicians, nurses, dietitians, social workers, respiratory therapists, pharmacists, and other sub-specialists as needed. Care is managed using clinical practice guidelines, routine pulmonary function testing, monitoring height and weight, and collection of throat cultures or sputum samples and blood draws. This model of care requires careful planning to ensure each care team member is available to meet with the patient/family and that the patient/family commit their time to travel and engage in lengthy appointments.

The onset of the SARS-CoV-2 (COVID-19) pandemic globally disrupted health care delivery and pushed clinicians and patients/families to use telehealth despite little or no experience. Historically, in the US, telehealth was rarely used to deliver CF care, but internationally, it has been used more broadly. In Australia, telehealth usage for rural and remote communities has been shown to have high patient satisfaction, to increase clinic attendance, and to increase the detection and treatment of pulmonary exacerbations.[1-3] To meet the needs of a growing adult patient population, alleviate cost and time burdens, and in the context of many patients experiencing better health after initiation of CFTR modulator therapy, the CF Foundation recognizes that the integration of innovative care delivery systems, like telehealth and remote monitoring, will be necessary to achieve more efficient and personalized care.

Context:

Over the last two decades, the CF Foundation has supported program participation in research (Success with Therapies Research Consortium, Real-World Research) and learning networks (CF Learning Network, Lung Transplant and Transition Regional Dissemination Network), as well as quality improvement collaboratives (Learning and Leadership Collaborative) to improve care and test delivery innovations. These networks and collaboratives are organized to implement proven, evidence-based best practices and to test innovations that will result in improvement in key clinical and patient reported outcomes. They provide training and infrastructure to self-organize, share knowledge and know-how, use structured quality improvement methods (The Model for Improvement, Clinical Microsystems), implementation science, and employ timely and accurate data to drive testing and learning. At the onset of the pandemic, programs in these networks and collaboratives, along with others, rapidly adopted the use of telehealth and remote monitoring which quickly disseminated across the care center network.

Goals:

The goal of this RFA with LOI is to identify innovative, multi-site quality improvement projects considered highly relevant to advancing reliable remote monitoring processes in CF clinical care. Primary areas of interest are projects that address the processes and pragmatic considerations for home spirometry and respiratory sample collection in a real-world CF care setting; however, other innovative types of remote monitoring and care delivery will also be considered. Primary areas of interest to consider can be found in Section VI below. A limited number of LOIs that address a primary area of interest or innovative model of remote care delivery will be invited to submit full applications. Applications that do not specify how the project can benefit people with CF and advance innovative remote care delivery and/or are deemed

nonresponsive to areas of interest will not be invited for a full application. Work in this space will inform future grant offerings and is intended to be shared broadly with the CF community.

References:

1. Wood J, Mulrennan S, Hill K, Cecins N, Morey S, Jenkins S. Telehealth clinics increase access to care for adults with cystic fibrosis living in rural and remote Western Australia. Journal of Telemedicine and Telecare. 2017;23(7):673-679. doi:10.1177/1357633X16660646.
2. Vagg T, Shanthikumar S, Morrissy D, Chapman WW, Plant BJ, Ranganathan S. Telehealth and virtual health monitoring in cystic fibrosis. Curr Opin Pulm Med. 2021;27(6):544-553. doi: 10.1097/MCP.0000000000000821. PMID: 34431789.
3. Logie K, Welsh L, Ranganathan SC. Telehealth spirometry for children with cystic fibrosis. Arch Dis Child. 2020;105(12):1203-1205. doi: 10.1136/archdischild-2019-317147. PMID: 31694805.

III. Funding Amounts

- Funding of up to **$250,000 per year for up to two (2) years**, plus an additional twelve percent (12%) indirect costs may be requested to support integrated, multi-center projects collaborating around a common theme or topic.
    - A lead PI must submit one application on behalf of all participating investigators.
    - The budget must include a lead site with the other participating sites as subcontractors.
- Funding for Year 2 is contingent upon submission and approval of a renewal progress report and the availability of funds.

Direct costs may be requested for:

- Salary and Benefits
- Project supplies
- Equipment (i.e., home devices or sample collection material)
- Computer software/licenses
- Office supplies (i.e., shipping costs and material)
- Project-related patient/family expenses
- Support for multidisciplinary and multi-site collaborations, including travel
- Travel costs for the North American CF Conference (NACFC)
- Publication costs
- Honoraria/consultant fees for patient/family partners/advisors

Direct costs for the following are unallowable:

- Tuition
- Standard of care testing performed in the hospital/clinic setting

Indirect Costs up to twelve (12) percent may be requested from CF Foundation. Indirect costs may be requested for all expenses except for the following:

- Equipment (single items over US$5,000 in value)
- Computer software/licenses

***Applicants may request indirect costs on the first $25,000 of each subcontract per year.**

IV. Eligibility Requirements

- 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 members of a CF Foundation accredited CF care center
- Patient/family partners/advisor(s) must be included as a member of the project team or as a consultant

- Industry-sponsored research projects are not eligible to apply through this program and instead should consider applying to the Therapeutics Development Awards program. For additional information, please contact grants@cff.org and copy Kathryn Sabadosa at ksabadosa@cff.org.

V. Mentorship Requirements

Not applicable to this RFA

VI. Goals/Projects of Interest/Priority Areas

The objective of this RFA is to fund highly meritorious, multi-site (3 or more programs) quality improvement projects that seek to advance remote monitoring processes in routine CF clinical care. Primary areas of interest include home spirometry and remote (i.e., outside of the CF clinic setting, including mail-in or curbside drop-off) respiratory sample collection (e.g., sputum/oropharyngeal swabs) in a real-world setting. Other innovative types of remote monitoring and care delivery will also be considered.

Important issues to address include, but are not limited to:

- Feasibility, reliability, and broad applicability of executing remote monitoring and care delivery processes in:
    - Diverse clinical settings
        - Program setting, e.g., geographic location, size, adult vs pediatrics,
        - Reason for visit, e.g., routine care vs. urgent care
    - Different subpopulations of patients/families
        - Adult vs pediatric
        - Medical risk and psychosocial risk
        - Under-represented, social and economic vulnerability
- Patient/family experience/acceptability/barriers of collecting and processing samples, performing tests, sharing results, and incorporation in treatment and care decisions, e.g., surveys, focus groups, interviews
- Reliability of processes for real-world clinical data capture, sharing, reporting, and use in treatment decisions and planning inclusive of, but not limited to:
    - Use of electronic medical records
    - Patient/family portals
    - Integration of interdisciplinary care

This RFA seeks to promote collaboration between investigators with complementary expertise, distinct patient/family populations, and/or shared knowledge and common resources.

VII. Review and Award

Applications will be reviewed and scored by a CF Foundation ad-hoc review committee. Funding of awards is based on the priority score awarded to each application and the recommendations of the review committee. Funding decisions are based on the relevance of the proposed study to the goals of the Foundation, alignment with specific research priorities, and enhancing the existing CF Foundation project portfolio. All awards are subject to compliance with applicable regulations and CF Foundation policies and are contingent upon the availability of CF Foundation funds.

Proposals should clearly demonstrate how the project will advance the evolution of the CF care model to adapt to changing patient needs without compromising clinical outcomes or patient experience of care.

Applications will be evaluated on the following:

- Relevance to the priority areas stated above

- Number and types of programs collaborating as well as composition of the project team from each program
- Methodologic rigor of and rationale for the quality improvement approach including clarity of desired outcomes and analytic plans
- Merit, feasibility, and applicability to the clinical care setting of the project as described in the applicant's Project Plan
- PI's background and experience in QI and working with patient/family advisors or improvement partners
- Adequate facilities for the project
- Manner in which individual applicants integrate into the larger collaboration
- Synergy among the groups and value added by each collaborator
- Process by which individual applicants will communicate and collaborate (e.g., sharing care algorithms, best practices, patient/family feedback, and data collection and reporting)

Low priority scores in the reviews commonly result from the following shortcomings of the application:

- Failure to address the evaluation criteria described above
- Incomplete application or documentation
- Inadequate explanation of project design or methods
- Failure to describe potential relevance
- Failure to document the necessary skills or training to accomplish the goals of the proposal
- Failure to identify access to resources outlined in the application
- Insufficient justification for collaboration or inadequate description of how the collaboration will be executed
- Failure to incorporate input from patients/families in project development or outcomes of interest
- Failure to demonstrate awareness of and plans for coping with key problems and pitfalls associated with the proposed project

CF Foundation may withdraw applications receiving low scores, and/or those deemed nonresponsive to the program announcement before the review committee meeting. In these cases, CF Foundation will notify applicants if their application has been withdrawn without discussion.

Awardees are required to provide CF Foundation with annual progress and financial reports.

VIII. Submission Information

A Letter of Intent (LOI) must be submitted and approved prior to submitting a Full Application. Applicants may only submit one LOI and one full application.

Submit online at https://awards.cff.org
(Refer to Section IX and X of these guidelines for specific submission instructions)

An application will be considered incomplete if it fails to comply with the instructions, or if the submitted material is insufficient to permit adequate review. CF Foundation reviews applications electronically, and only documents submitted online at https://awards.cff.org will be reviewed.

Specific requests regarding a programmatic deviation from these guidelines must be submitted to the Program Officer Kathryn Sabadosa (ksabadosa@cff.org) for approval prior to submitting the application. Contact information for technical questions is provided below.

General Timeline:

Published _____February 7, 2022
LOI Submission Deadline _____ March 23, 2022*
LOI Applicant Notified _____ mid-April 2022
Full Application Deadline _____ June 15, 2022*
Committee Review Date _____ early September 2022
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Earliest Project Start Date _____ November 1, 2022

*We highly encourage all applicants pre-register their profile, institution, contacts, and title of their application at least two weeks prior to the application deadline. This will help to ensure the CF Foundation Grants & Contracts Team is able to assist all applicant with any potential system-related queries prior to the Application Deadline.

IX. Letter of Intent Guidelines

LOIs Submission Deadline: Wednesday, March 23, 2022 at 5:00 PM (EDT)

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 "LOI 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. ***Please note:*** Applicants should register their profile using the "Domestic Institution" to ensure that your profile aligns properly with the institutions where the project will be conducted. We also request that as you begin your application, you enter the title of your project, if available. If you are registered and cannot remember your password, click on the **"Forgot Password?"** link below the **"Login"** fields.

Once logged in, the award opportunities, including this Request for Applications (RFA), will be listed in the **Funding Opportunities** tab on the opening screen.

Locate the listing for the **"Tools for Remote CF Care Delivery: Application of QI Science with LOI 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.

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 approval letter and status at the time of submitting the application) in this section.

CONTACT PROFILE

If a profile was completed upon registration, the fields in this section will already be populated with the information entered in your Professional Profile. If you need to make any changes, you may update your profile in this section.

Once updated you must "**Save and Validate**" prior to returning to continue your submission

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 pre-loaded 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. You may find your EIN by referencing the Institutional W-9 or equivalent documentation. If the EIN/TIN is not located in our system, you have the option to 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 CF Foundation 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 CF Foundation Grants and Contracts Office.

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 project 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 each abstract, provide a statement of no more than 2,000 characters (including spaces) explaining the subject of the project 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 CF Foundation and the general public of the nature of this work. Applicants should not include any confidential or proprietary information, including intellectual property, in the lay abstract.
- **Clinical Abstract**: This statement will be used to inform the CF care community.
- **Summary of Relevance to CF Foundation mission**: All applications are reviewed and scored not only on scientific merit but also on relevance to CF Foundation's mission:

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

  Provide a statement of no more than 3,000 characters (including spaces) summarizing the relevance of the proposed research to the health and well-being of CF patients, for a scientific audience who may or may not have a background in the subspecialty of the proposed research.

BUDGET

Select the "**Open**" button under the Budget tab and complete the relevant budget categories for each year of funding. Fill in the applicable amounts for each year of support requested by completing the online fields (Periods 1 and 2). All Awards issued through the "Tools for Remote CF Care Delivery 2022" program are awarded for up to 2 years, up to:

- $250,000/year in direct costs (plus an additional 12% indirect costs)

Be sure to click "**Save**" prior to closing the budget window.

LOI UPLOADS

Download the available template applicable to the proposal, upload the completed template in PDF format to the corresponding attachment type within this section. The template available for download is:

- LOI Project Description

LOI Project Description (template available for download)

Upload the completed template in PDF format providing, at a minimum, Title, Introduction, Methods, and Anticipated Impact of Results **(maximum of three (3) pages not including the literature cited).**

Components should include

- Descriptive title of the proposed project
- Name, role, and email for project team members at each participating program
- Introduction (nature of the problem, current knowledge/studies, rationale used to develop intervention/theory of change, specific aims of the project)
- Methods (Description of context (clinic, patient/family population), intervention(s), approach used to assess impact of process change and/or outcomes, measurement plan, plan for analysis and integration of data from multiple sites, and ethical considerations)
- Anticipated results, measures/outcomes of interest
- Discussion of anticipated limitations, broad applicability, sustainability, spread and scale
- Assurances that the required equipment/facilities are available to perform the project

- Literature Cited**:** References should be numbered in the sequence that they appear in the text. Each citation must include the names of authors, the name of the journal or book, volume number, page number and year of publication (titles are optional).

***Note**: If applicable, funding is contingent upon approval and ability to access clinical specimens and/or data.*

Submission

Prior to selecting "Submit", please complete a thorough review of the entire LOI. The "Submit" button will trigger validation on all required fields and identify any errors. Only the Principal Investigator will need to sign at the LOI stage. After selecting Submit, the applicant will receive an email asking them to sign the application FacePage electronically using Adobe Sign.

X. Full Application Guidelines

Full Application Deadline: Wednesday, June 15, 2022 at 5:00 PM (EDT)

A Letter of Intent (LOI) must have been submitted and approved prior to receiving an invitation to proceed with a Full Application

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

If the LOI submission is approved to proceed to a full application submission, the application will have already been pre-loaded in the system. Log in with your existing credentials to access the application.

Your draft application will by listed under "**My Applications**", then within the "**Draft Applications**" section. Upon locating the draft application, you may select it to begin your submission.

Applicants may stop at any point but must click the **"Save"** button before exiting in order to save their progress.

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 "**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.

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 approval letter and status at the time of submitting the application) in this section.

Please note: If the applicant is new to CF research, Letters of Support and/or Collaboration should be provided and uploaded as Appendices.

***Please ensure that you review and comply with the Organizational Assurances and Certifications as cited below.**

CONTACT PROFILE

If a profile was completed during the LOI, 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 pre-loaded 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. You may find your EIN by referencing the Institutional W-9 or equivalent documentation. If the EIN/TIN is not located in our system, you have the option to 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.

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.

If added during the LOI, this will be pre-populated but can be changed during the full application. 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 each abstract, 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 CF Foundation and the general public of the nature of this work. Applicants should not include any confidential or proprietary information, including intellectual property, in the lay abstract.
- **Clinical Abstract**: This statement will be used to inform the CF care community.
- **Summary of Relevance to CF Foundation mission**: All applications are reviewed and scored not only on scientific merit but also on relevance to CF Foundation's mission:

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

  Provide a statement of no more than 3,000 characters (including spaces) summarizing the relevance of the proposed research to the health and well-being of CF patients, for a scientific audience who may or may not have a background in the subspecialty of the proposed research.

BUDGET

Select the "**Edit Budget**" button under Application Budget, to enter and begin completion of the application's budget detail for each year of funding being requested. Awards funded through this RFA are for a maximum of two (2) years.

- For collaborative research, the cumulative budget **may not exceed $250,000 in direct costs (plus 12% indirect costs) for up to 2 years**. This amount is inclusive of the cost of any subcontracts. If the lead site is collaborating with another center within their same institution, a single detailed budget is to be submitted in the Grants Management System for each year requested. If the collaboration is with an external institution (performing part of the proposed aims), this would be budgeted as a subcontractor.
- Services that are part of routine medical care (as defined by the U.S. Department of Health and Human Services) may not be included in the project budget. Whenever possible, the price of services (e.g., X-rays, EKGs, PFTs, etc.) provided by the institution should be negotiated to the lowest possible non-profit price.
- Separate professional fees for interpretation of data (e.g., from X-rays, lab tests, PFTs) may not be included when such interpretation is performed by the named investigator(s), co-investigator(s), or consultants as part of the project, other than in exceptional circumstances. In such cases, justification for these fees must be described in detail in the budget justification template.
- Hospitalization costs of project participants cannot be included in this budget.

The following budget categories are offered under this program:

Salary & Benefits - List the names, positions, and percent effort of all professional and non-professional personnel involved in the project, whether or not salaries are requested. For each individual, be sure to complete all fields on the Budget Detail in full on the template provided. In accordance with National Institutes of Health (NIH) policy, salary requests may not use an institutional base salary in excess of the current federal salary cap of **$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 Costs – (Honoraria/consultant fees for patient/family partners/advisors) - Patients and families involved in the development or evaluation of the proposed projects should be offered

reimbursement for their participation. Budget should include patient/family roles, but it is not necessary to include individual names.

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 CF Foundation Grants and Contracts Office. Travel expenses may not exceed **$2,000 per person, per year**. Additional travel expenses may be requested and will be considered on a case-by-case basis. Registration fees associated with conferences should be listed under "Other Expenses."

Consumable Supplies - Itemize supplies e.g. test kits, devices, packing materials, etc., in separate categories and give the estimated cost of each category.

Major Equipment - List all items of equipment greater than **$5,000** requested and the cost of each item. If funds are requested to purchase equipment that is equivalent to items listed under "Facilities Available", justify the duplication. Justify any item of equipment for which the need may not be obvious.

Other Expenses - Itemize other expenses by major categories, such as duplication costs, publication costs, minor equipment (under $5,000), shipping expenses, computer charges, conference registration fees, etc.

Patient Research Costs – (Project-Related Patient/Family Costs) **-** Funds may be requested for patient costs specifically related to the proposed project. 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 need for patient/family 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 CF Foundation responsible for any costs that are later determined non-covered by third party insurers. Applicants and applicant institutions acknowledge that CF Foundation 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)).

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 of up to twelve percent (12%) may be requested from CFF. Indirect costs may be requested for all expenses except for the following:

- Major equipment (single items over $5,000 in value)
- Computer software
- Software licenses

- Tuition

LOI UPLOADS

This section will allow access to the documentation uploaded at the LOI stage.

FULL APPLICATION UPLOADS

Download the available templates applicable to the project, upload the completed templates in PDF format to the corresponding attachment types within this section. Templates available for download include:

- Collaboration Detail Template (required for multi-site studies; if applicable)
- Research Plan
- Critique Response (LOI)
- Budget Justification
- Biographical Sketches of Key Personnel
- Other Support
- Facilities Available
- Results of past and current CFF/CFFT Support

Collaboration Detail Template (template available for download, if applicable)

On the provided template please list each collaborator, including their institute and responsibilities or resources they are dedicating to the project.

Research Plan (template available for download)

- Key figures and legends must be included in the Research Plan. If uploaded as Appendices, they will NOT be reviewed.
- At the top of each page, type the PI's name. Each page must be sequentially numbered at the bottom.
- Research Plans are limited to eight (8) single-sided pages, not including the Literature Cited. Applications exceeding this page limit 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 specific and informative.
    - **a. Specific Aims:** State concisely and realistically the intent of the proposed project and the specific aim(s). Do not exceed one page. The focus of applications should be aligned with the mission of the CF Foundation: 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.
    - **b. Background and Significance**: Briefly describe the background of the present proposal. Critically evaluate existing knowledge and specifically identify the gaps that the project is intended to fill. Concisely state the importance and rationale of this project by relating the specific aims to longer-term objectives. This section should also show the potential importance of the proposed work to advance remote monitoring in the real-world CF clinical care setting.
    - **c. Preliminary projects/studies**: Summarize any preliminary work pertinent to this application that has been undertaken by the Principal Investigator(s) and/or information that will establish the competence and/or experience of the investigator(s) to pursue the proposed project.
    - **d. Design and Methods**: Provide a detailed discussion of the project design and methods to be used to accomplish specific aims. Please discuss study aims. Provide a description of quality improvement or implementation science methodology and application to address project aims. Describe care algorithms/protocols or interventions to be tested. Discuss your proposed process and outcome measures of interest, data collection and analyses, and if applicable use of improvement charts (run and control charts, p-charts). Include a timeline for full project and if applicable, plan and frequency of testing, tracking cycles of change and reporting progress across sites.

e. **Limitations, Broad Applicability, Sustainability, Spread and Scale:** Discuss potential difficulties and/or limitations of the proposed approach to achieve aims. Point out potential opportunities for broad applicability and sustainability. Discuss potential for spread and scale across the CF care center network.
f. **Literature Cited**: References should be numbered in the sequence that they appear in the text and listed at the end of the Project Plan. Each citation must include the names of authors, the name of the journal or book, volume number, page number and year of publication (titles are optional).

Critique Response (template available for download, if applicable)
Provide a point-by-point response to the limitations noted in the critiques of the LOI, using the template provided.

Budget Justification (template available for download)
Describe costs listed in the Budget Detail. Use major categories, such as Salary & Benefits, Consultant Costs, Supplies, 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.

Biographical Sketches for Key Personnel (template available for download)
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. (CF Foundation defines "key personnel" as any individual with an advanced degree that will play an instrumental role in the accomplishment of the research project.) Do not exceed five (5) pages per person.

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

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

Results of Past and Current CFF/CFFT Support (template available for download)
Identify the results of past and current CFF/CFFT support (e.g., subsequent funding from other sources, journal articles, and invited presentations) and the CFF/CFFT award from which they resulted for the past five 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

Appendices (upload as PDF documents)
Appendices are restricted to the following three (3) categories*:

- Signed Letters of Support and/or Collaboration: A Letter of Collaboration from all PIs should be uploaded and included in the application.
- Certification of IRB approval if available at the time of application.
- Up to three (3) reprints of the applicant's work relating to the general area of improvement and innovation in the proposal may be uploaded in PDF format.

***No other types of Appendices will be reviewed.**

***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.

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 Face Page electronically using Adobe Sign. Once signed by the PI, the Face Page 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 deadline.

XI. Other Information

Not applicable to this RFA

XII. Contact Information

For technical support and program/content information:
Primary CF Foundation Grants and Contracts contact Erik Warnke at ewarnke@cff.org or 301-841-2667
Secondary technical support contact Nadia Mohaghegh at nmohaghegh@cff.org or 301-907-2510
Grants & Contracts General Line: 301-841-2614

For scientific questions:
Kathryn Sabadosa, MPH at ksabadosa@cff.org

XIII. Electronic Application Checklist

LOI Submission Deadline: Wednesday, March 23, 2022 at 5:00 PM (EDT)
Full Application Deadline: Wednesday, June 15, 2022 at 5:00 PM (EDT)

Application must be submitted online at: awards.cff.org

LETTER OF INTENT

- ☐ LOI Project Description - (upload)

FULL APPLICATION

Face Page (upload) which includes:

- ☐ Signatures
  - ☐ Lead Principal Investigator (Co-PI's are not required to sign)
  - ☐ The Official authorized to sign on behalf of the Applicant Institution
- ☐ Applicant/PI information - (online)
- ☐ Complete Institution and PI Contact information, including correct mailing address - (online)
- ☐ Organization Assurances (check those that apply online)
  - ☐ Human Subjects Certification - Minimal patient risk only

Research Plan, Supporting Documents and Appendix:

- ☐ Abstracts ~ Summary of Relevance ~ Keywords - (complete online)
- ☐ Collaboration Detail (upload, if applicable)
- ☐ Research Plan - (upload)
  - ☐ Specific Aims
  - ☐ Background and Significance
  - ☐ Preliminary Results
  - ☐ Project Design and Methods
  - ☐ Limitations and Potential Pitfalls
  - ☐ Consultants/Collaborative Arrangements
  - ☐ Literature Cited (not included in Research Plan page limitation)
- ☐ Critique Response LOI - (upload, if applicable)
- ☐ Budget Detail for each year and for each subcontract, when applicable - (complete online)
- ☐ Budget Justification for each year and for each subcontract, when applicable - (upload)
- ☐ Biographical Sketches of Key Personnel - (upload)
- ☐ Other Support for all key personnel (NIH Format) - (upload)
- ☐ Facilities Available - (upload)
- ☐ Results of Past and Current CFF/CFFT Support – (upload)
- ☐ Verification of Applicant Institution's Tax Status - (upload)
  - ☐ W-9
  - ☐ 501(c)3, IRS Form 147C or equivalent tax status letter
- ☐ Appendices - (upload as PDF documents, if applicable)
  - ☐ Signed Letter(s) of Support and/or Collaboration
  - ☐ Certification of IRB approval, or other applicable organization assurances documents such as IACUC and IBC Approval Letters, if available at the time of application
  - ☐ Up to three (3) reprints of the applicant's work relating to the general area of improvement and innovation in the proposal