CYSTIC FIBROSIS FOUNDATION

For application technical support, please contact: aminucci@cff.org

Program Name: 2024 Health Equity Team Science Award with LOI

Brief Program Overview/Description: The Health Equity Team Science Awards are offered to provide support for multi-investigator research projects that have the potential to make an important contribution to improving the health equity in the CF population, allowing them to attain the highest level of health. The Health Equity Team Science Award requires at least two—and up to four – related research projects (each led by a separate principal investigator with a separate application) that share a well-defined theme and overall objective. Proposed projects may be designed using clinical (observational/interventional), translational, epidemiologic, and/or implementation science methodology.

Definition of Health Equity and Health Equity Research: The National Institute on Minority Health and Health Disparities defines health equity as "the principle underlying the continual **process** of assuring that all individuals or populations have optimal opportunities to attain the best health possible. Applying the principle of health equity requires that barriers to promoting good health are removed and resources are allocated among populations and/or communities proportional to their need(s)." The agency further notes that "applying a health equity lens in science requires an intentional effort to ensure that **research** is designed explicitly to promote fairness, opportunity, quality, and social justice in access, interventions or treatments, and outcomes." Further information about health equity research are available on the NIMHD website .

Funding Amount: Each applicant may request funding of up to $200,000 per year for up to four (4) years, plus an additional twelve (12) percent indirect costs per year. The lead institution may request up to $50,000 in additional direct costs per year to support an administrative core.

Translation Supplement: Applicants may request an additional $25,000 additional direct costs over the entire project period to support the translation of validated Patient Reported Outcome Measures (PROMs) or the use of interpreters. This supplement may only be applied to validated PROMs utilized during the proposed research study. The applicant must demonstrate the need for the translation supplement or interpreter to successfully complete the proposed research aims.

Eligibility:

- Applicants must speak with program staff prior to submission to ensure the project design is in line with the goals of this RFA. Failure to do so will result in the administrative withdrawal of the proposal.
- At least two (2) but no more than four (4) PIs may be included on a team. Co-investigators may be at the same or different institutions; however, each PI must submit a separate application.
- United States residents and applicants from outside the United States are welcome to apply.
- Applicants must be independent investigators. An independent investigator is an individual who is out of fellowship training and whose institution allows them to submit applications for research funding as a Principal Investigator. Clinical fellows and postdoctoral fellows may not be listed as a lead PI on any project.
- *Additional eligibility requirements can be found in Section IV below.*

Key Dates:

	2024 Cycle
Published	February 9, 2024
LOI Deadline	April 23, 2024
LOI Applicant Notified	July 2024
Full Application Deadline	September 17, 2024
Committee Review Date	December 2024

Notification to Applicants	Late January 2025
Earliest Project Start Date	March 1, 2025

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.

Diversity, Equity, and Inclusion

Cystic fibrosis affects people of all racial and ethnic backgrounds. Diversity, equity, and inclusion (DEI) are core to our ability to make a meaningful difference in the lives of all people with CF. Improving the representation of people of color within the CF community – including those in the CF research workforce – and addressing health disparities that exist within individuals who identify in these groups is critical to the Foundation's mission of serving all people with CF. Making clinical trial design and engagement more inclusive of people of color with CF will be critical for improving treatment options and health outcomes for individuals who identify in these groups. In the U.S., Black and Hispanic people with CF account for a disproportionate number of individuals with rare/understudied CFTR mutations (variants) that are not amenable to (not responsive) or are not currently approved for treatments that address the underlying cause of the disease. As PIs prepare application materials, we strongly encourage the consideration of how to support inclusion of diverse participants, including plans for community engagement to improve trust and enhance recruitment with people with CF who are underrepresented in CF research.

CF Foundation Resources

The Cystic Fibrosis Foundation supports the development of helpful tools and resources to assist the research community in accelerating the progress toward new scientific knowledge of and new therapies for cystic fibrosis. Some of the resources available for use are listed below.
For more information on Tools and Resources for the CFF research community, please visit: https://www.cff.org/for-researchers

- CFF Patient Registry Data
- CFF Biorepository
- Community Voice – Getting Community Input
- National Resource Centers
- Whole Genome Sequencing Project Data Requests

II. Program and Award Overview

Program Overview

The CF Foundation has committed to equity, racial justice, diversity, and inclusion as core principles guiding our work to meet the CFF Mission. CFF acknowledges that social constructs like gender, race and ethnicity, and systemic barriers are deeply rooted in the health care system and contribute to poorer outcomes for Black, Hispanic, and other communities of color as well as members of the LGBTQIA+ community. Health inequities within the CF community exist and lead to disparities in mortality, quality of life, severity of CF disease and/or CF complications, delayed diagnosis, and access to treatment. A priority of the CFF is that all pwCF have optimal health outcomes regardless of differences in race or ethnicity, socioeconomic status, geographic locations, sex, sexual orientation or gender, and disability. In 2022, the CF Foundation created the Health Equity Team Science Award to support transdisciplinary health equity research to continue to advance the CFF Mission. Building upon the success of the RFA in 2022, the CFF is offering a second Request for Applications (RFA) for the Health Equity Team Science Award.

Award Overview

The Health Equity Team Science Awards are offered to provide support for multi-investigator research teams that share resources and facilities and collaborate on projects that have the potential to make an important

contribution to health equity in the CF population. A Health Equity Team must have at least two—and up to four – related research projects (each led by a separate principal investigator with a separate application) that share a well-defined theme and overall objective. This support, by providing more accessible resources, is expected to assure a greater productivity than from the separate projects. Research projects may be designed to:

- Test new hypotheses and/or new methods,
- Advance established results with the potential to improve our understanding of or have a positive impact on identified barriers to optimal health outcomes for all people with CF related to race and ethnicity, sexual orientation or gender, or socioeconomic status.
- Utilize population health research methodologies and/or evaluate population-level health interventions.
- Implement best practices, or potential best practices, through hybrid or implementation research methodology.

Each investigator is expected to be a significant contributor and share the responsibility and authority for leading and directing the project. Given the wide-ranging nature of cystic fibrosis care, it is imperative that research teams should include multi-disciplinary investigators. **It is required that each study team include at least one member with a strong track record of publishing in the health equity research field demonstrating established expertise in health equity research.** Investigators are expected to be thought partners on the proposed work, share resources and facilities, carry a nearly equal role in the conduct of the work, and be fundamental to the ability to address the overarching research objective(s). Research themes or objectives should be clearly described and should demonstrate how the team's projects assure greater productivity than if submitted separately.

The Health Equity Team Science Award ***should not*** be used to support multi-site studies where one PI's role is solely to support enrollment, provide samples or data, or serve in a consulting role (please see the CRA or CP&FA RFAs for these projects). We strongly encourage investigators to use this award mechanism to launch interdisciplinary collaborations.

III. Funding Amount

- Each applicant may request funding of up to $200,000 per year for up to four (4) years, plus an additional twelve (12) percent indirect costs per year.
- Awards may be approved for up to a four (4) year period. Funding for Year 2, Year 3, and Year 4 is contingent upon submission and approval of a renewal progress report and the availability of funds.
- The lead institution may request up to $50,000 in additional direct costs per year to support an administrative core. Administrative core duties should include activities to facilitate communication and data sharing between individual PIs.
- One application per study team may request up to $25,000 in additional direct costs over the course of the project to support the translation of a validated PROM.

Direct costs may be requested for:

- Salary and Benefits
- Research supplies
- Equipment
- Research-related subject costs
- Consultant costs
- Support for multidisciplinary collaborations, including travel
- Travel costs for scientific/technical meeting(s)
- Tuition

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

- Equipment (items over $5,000 in value)
- Computer software
- Software licenses

***Applicants may request indirect costs on the first $25,000 of each subcontract for the project period.**

IV. Eligibility

- Applicants must speak with program staff prior to submission to ensure the project design is in line with the goals of this RFA. Failure to do so will result in the administrative withdrawal of the proposal.
- At least two (2) but no more than four (4) investigators may be included on a given project. Co-investigators may be at the same or different institutions.
- United States residents and applicants from outside the United States are welcome to apply.
- Applicants must be independent investigators. An independent investigator is an individual who is out of fellowship training and whose institution allows them to submit applications for research funding as a Principal Investigator. Clinical fellows and postdoctoral fellows may not be listed as a lead PI on any project.
- 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
- Applicants may hold one or more awards at CFF.

V. Mentorship Requirements

Not applicable to this RFA

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

Areas of Emphasis

Areas of Emphasis were informed from discussions and work outputs from the GAP Meeting, External Racial Justice Working Group, the Cost, Utilization, and Social Factor Workshop, and the SHARING Research Working Group. ***Applicants to the Health Equity Team Science Award are highly encouraged, but not required, to submit research projects that address one or more Areas of Emphasis.***

Health Inequities Related to Social Determinants of Health (Access and Utilization, Social Risk Factors)

- Research to overcome challenges or barriers to access of specialized CF care or care coordination
- Research probing the relationship of social risk factors and health outcomes, including projects that study methods to improve screening for social risk factors
- Research on interventions to alleviate social risk factors, including defining barriers and measuring effectiveness
- Research to define and intervene on community and health care system-level factors that generate and sustain health inequities or community-level strategies for reaching CF health equity (e.g., racism, homophobia, discrimination, stigma, social support, and family structure, among others)
- Research on social and economic policies that generate and sustain health inequities or policy-level strategies for reaching CF health equity (e.g., economic stability, education access and quality, healthcare system access and quality, neighborhood and built environment, and social and community context, among others)
- Research on understanding the etiologies behind health disparities with clear implications for intervention (e.g., access to care, mental health, etc.)

Health Inequities Related to Race and Ethnicity

- Research to further understanding of the impacts of genetic ancestry (including understudied/rare variants) on clinical measures and monitoring to optimize CF care and research outputs
- Research related to improving initial CF diagnosis, including better characterization of the understudied/rare variants more commonly occurring in minoritized populations, and/or better understanding of the consequences of delayed or missed diagnosis that have clear implications for intervention
- Research related to better understanding of health disparities associated with CF complications, including infection and pathogen acquisition, lung disease progression, and complications associated with the endocrine and gastrointestinal systems, that have clear implications for intervention
- Projects utilizing community-engaged dissemination and implementation (CEDI) methods or principles to engage marginalized groups in the development or improvement of the implementation or dissemination of evidence-based interventions.
- Research to improve modulator access for rare CF variants that are not currently eligible for modulator therapy.

Health Inequities Related to Sex, Gender, and Sexual Orientation

- Research to support our understanding of inequities relating to sex, gender, and/or sexual orientation
- Research into potential barriers to care (e.g., gaps in provider knowledge/awareness)
- Research evaluating etiologies to guide interventions (mental health, access to care, sex hormones)
- Research into possible links between geographic location's roles in inequities in care for those whose sex, gender identity or sexual orientation may affect their quality or access to care (e.g., access to elective and/or therapeutic abortion, gender affirming care clinics)
- Research to evaluate best practices for care of gender diverse individuals

VII. Review and Award

Applications to the Health Equities Team Science Award will be reviewed by an ad hoc committee composed of established researchers with relevant expertise, community representative reviewers, and the CFF.

Applications undergo scientific peer-review and receive scores based on scientific merit, collaboration, and impact on health equity in the CF population. Applications will also be evaluated on their experimental design and methods, rationale, statistical analysis methodology, and collaboration plan. Applicants should adequately describe how the hypothesis will be tested, demonstrate adequate power for testing the hypothesis, and clearly define all variables in their statistical analysis section. Applicants are required to consult with a biostatistician prior to submitting their proposals. In addition, applicants are required to include a biostatistician with a minimum of 5% effort on their project. Purely qualitative research projects may request a waiver for biostatistical support. The collaboration plan will be a fundamental part of the application; proposals that do not include clear communication plans and adequately describe the importance of each investigator's role will not be successfully funded.

Community representative reviewers evaluate applications based on study design and feasibility from the perspective of people with CF. They also evaluate the project on its relevance to the CF Foundation's mission and the project's potential to impact those living with CF. Community representative reviewers do not review an application for scientific merit. Reviews from the community representative reviewers are used to inform funding decisions.

Funding of awards is approved by the CFF Board of Directors and is based on the availability of funds, priority score assigned to each application, and recommendations of the ad hoc review committee, community representative reviewers, and CFF Program Officers. All awards are subject to compliance with applicable regulations and CFF policies.

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

- Incomplete application: Each PI is responsible for submitting a portion of the full application on https://awards.cff.org. See Section X. Full Application Instructions for more details
- Insufficient information or documentation
- Inadequate statement of hypothesis, inadequate experimental design, inadequate analytic methods, or experimental plan that does not address hypothesis
- Failure of the applicant(s) to describe how the collaboration and sharing of resources between the projects is essential to achieving the goals of the research.
- Failure of the applicant(s) to document the necessary skills, training, or collaborate with individuals with the relevant expertise to accomplish the goals of the proposal
- Failure of the applicant(s) to provide sufficient preliminary data to support the proposed research methods and approach
- Failure of the applicant(s) to demonstrate adequate level of support and appropriate plan for data acquisition, management and statistical analyses
- Failure of the applicant(s) to meet all the criteria described in these guidelines
- Failure to adequately describe the collaboration plan and how separate projects address a common scientific theme

CFF may withdraw applications receiving low scores, and/or those deemed nonresponsive to the program announcement, before the review meeting. In these cases, CFF will notify applicants if their application has been withdrawn without discussion. Applications that have not been discussed in two review meetings will not be accepted for further consideration by CFF. Applicants must address reviewer critiques in order to resubmit their applications during future application cycles.

VIII. Submission Information

A Letter of Intent (LOI) must be submitted and approved prior to submitting a 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. CFF reviews applications electronically, and only documents submitted online at https://awards.cff.org will be reviewed.

Specific requests regarding a deviation from these guidelines must be submitted to the Program Officer Dara Riva (driva@cff.org) for approval prior to submitting their application.

NOTE: After this 2024 cycle of the Health Equity Team Science Awards, anyone who is declined is welcome to apply to the Clinical Research Award with LOI or Multiple Principal Investigator (MPI) Clinical Award with LOI programs as we will always welcome work being done in this sector.

General Timeline:

Published	February 8, 2024
LOI Deadline	April 23, 2024
LOI Applicant Notification	July 2024
Full Application Deadline	September 17, 2024
Committee Review Date	December 2024
Notification to Applicants	Late January 2025
Earliest Project Start Date	March 1, 2025

*We highly encourage that you pre-register your profile, institution, contacts, and Title of your Application by this date. This will confirm that your submission at the Application Deadline, is without any system-related issue. It will also allow us to assist you on system-related queries before the Application Deadline. This pre-registration is for new applicants to the system and will only need to be completed once.

The CF Foundation will host a webinar to walk through the RFA content and submission process with a live question and answer session at 1:00 pm ET February 26, 2024. Register Here: https://cff.zoom.us/webinar/register/WN_-wCV36TZT260ynaxstHuxg

IX. Letter of Intent Guidelines

LOI Submission Deadline: Tuesday, April 23, 2024 at 5:00 PM (EST)

Applications must be submitted online at https://awards.cff.org

Only one Letter of Intent (LOI) needs to be submitted per project. Upon invitation to a full application, each investigator identified at the LOI stage will receive a separate invitation for a full application. Required submission materials for each investigator are indicated below in **Section X. Full Application Instructions.**

Investigators with a previously submitted Full Application, and/or investigators submitting a revised application may request to bypass the LOI stage. These requests must be e-mailed to aminucci@cff.org with "**Health Equity Team Science Bypass Request**" in the subject line. LOI bypasses are granted on a case-by-case basis and the CF Foundation Grants & Contracts Management and Administration (GCMA) Office will send a notification of the final determination.

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 https://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 well before the date you plan to submit 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 "**2024 Health Equity Team Science Award with LOI**" 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, IACUC, and/or IBC/rDNA 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

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 selecting their Employer Identification Number (EIN) or Tax Identification Number (TIN) that will be pre-loaded based on the institution linked to your CONTACT PROFILE. 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 GCMA Office must have a copy of the applicant institution's current W-9 and 501(c)3 letter, or other documentation verifying its Federal tax status and will not issue Award Letters to Awardees if these documents are not received and on file.

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

International Applicants (if applicable):

For international applicants, you will need to answer an eligibility question specifying if you are an independent investigator. If answering yes, CFF may require an additional letter of support to be added to the application to verify eligibility.

Applicants whose institution is not a United States based-entity will be required to provide additional information and complete the CFF International Institution Form as part of the Full Application stage. Refer to **International Institution Form** section on page 23.

CONTACTS

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

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

Additional contacts not associated with the applicant institution may also be added. These contacts are considered additional contributors involved in the proposed research plan. These may include consultants, collaborators, or subcontractors. In order to add contacts external to the applicant institution, please select the appropriate "Add Subcontractors" or "Add Consultants/Collaborators" button(s) and add the contacts in the table, then click "Save".

ABSTRACTS/RELEVANCE

In the spaces provided online, 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 "**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 (Period 1, 2, 3). All Health Equity Team Science Awards are awarded for a maximum of four (4) years, up to:

- $200,000 per year plus an additional twelve (12) percent indirect costs per year. The lead institution may request up to $50,000 in additional direct costs per year to support an administrative core.
- Applicants may request up to $25,000 in additional direct costs over the course of the entire project to support the translation of validated PROMs. Only one application per study team may request this supplement.
- **The estimated total project budget (for all PIs) should be provided in the LOI.**

Please refer to Section III. Funding Amounts for detailed funding allotments

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

LOI 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:

- Biographical Sketch(es) of Key Personnel
- Response to Prior LOI Critique (if resubmission)

- Budget Justification
- LOI Project Description
- LOI Collaboration Details
- Health Equity - Translation Supplement Request (if applicable)
- CFF Patient Registry Data Request (if applicable)
- CFF Biorepository Clinical Specimen Confirmation Letter (if applicable)

Biographical Sketch(es) of Key Personnel (NIH template available for download)
CFF defines "key project personnel" as any individual with an advanced degree who will play an instrumental role in the research project. An NIH Biographical Sketch form should be completed for each key project personnel and uploaded as PDF. The maximum length for each biosketch is five (5) pages. Personnel must include a biostatistician with a minimum of 5% effort during the entire project period.

Response to Prior Critique (template available for download, if applicable)
Resubmissions of applications that were previously not approved are required to make a point-by-point response to the limitations noted in the critique of the earlier submission (Maximum of three (3) pages)

LOI Budget Justification (template available for download)
Describe the estimated costs listed in the Budget Detail. Use major categories, such as Salary & Benefits, Consultant Costs, Major Equipment, etc. In this justification clearly define what estimates apply to each investigator**. LOI Budget Justification will need to include the budget summary for all potential PI's.**

LOI Project Description (template available for download)
Upload a PDF copy of the completed document. Maximum of five (5) pages (not including the literature cited). Components should include:

- **Statement of Hypothesis and Specific Aims**: State concisely and realistically the intent of the proposed research and the hypothesis to be tested. The specific aims should both test this stated hypothesis and be relevant to the mission of the Cystic Fibrosis Foundation.
- **Brief Study Design**: Briefly describe the research design and methods for achieving the specific aims. Include any pertinent preliminary data to support the rationale and feasibility of the proposed study, the hypothesis being tested, and the selection of outcome measures and timepoints. Briefly describe the eligibility criteria, recruitment and retention processes, study procedures (including participant and study timeline), and study outcomes and other measures. Include a brief statistical section describing methodologies and any confounders or demographic variables that will be considered during analysis.
- **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).

LOI Collaboration Details (template available for download)
List all project PIs and institutions, as well as their overall role in the study. Discuss in detail the advantages of addressing this problem through the combined expertise of the PIs and how this contributes to the synergy of the application. Describe how the proposed partnership involves a substantial contribution by each investigator and the reciprocal flow of ideas and information. Describe how the combined efforts of the PIs will result in a level of productivity that is greater than that achievable by each PI working independently.

Health Equity - Translation Supplement (template available for download, if applicable)
Provide a brief description of no more than 1,500 characters of the proposed process of translating the PROM OR details related to utilizing interpreter services. This should include, but not limited to, the process of translating and reconciling translated versions into the target language, and the process for testing and obtaining feedback from the patient population and subject matter experts. Clearly describe how the

translation of the specific PROM or interpreter services are essential to the success of the research study. Provide support from the PROM developer expressing permission for the translation of the PROM.

CFF Patient Registry Data Request (if applicable)
CF Foundation Patient Registry. Applicants whose project will include requesting data from the CF Foundation Patient Registry should check the appropriate box. It is not necessary to check the box for single site studies or studies acquiring Registry data from the biorepository. Please note: if the LOI is approved for full submission, the applicant will need to submit the project for review by the Registry / Comparative Effectiveness Research (CER) committee prior to grant submission. Instruction regarding submission for review are located at: https://www.cff.org/Research/Researcher-Resources/Tools-and-Resources/Patient-Registry-Data-Requests/

CFF Biorepository Clinical Specimen Confirmation Letter (if applicable)
To request clinical samples from the CFF Biorepository to use in the proposed study, please follow the following steps:

1. Visit https://www.cff.org/researchers/cf-foundation-biorepository#biobanked-samples-available to identify potential sample fit and download request form.
2. Submit clinical specimen inquiry form to ezagnit@cff.org at least six weeks prior to LOI submission. You will receive documentation confirming receipt of your request and that the sample request is feasible from the Sr. Clinical Research Development Specialist. This should be submitted with your LOI.
3. Should you be invited to submit a full application, you must connect with the Sr. Clinical Research Development Specialist and finalize your sample request no less than 6 weeks prior to the Full Application deadline (2 January 2024, 2 July 2024). ***Late requests may not be processed in time for submission of materials to the CRC.***
4. A letter documenting available sample counts and other pertinent biorepository details, and confirming access to samples pending CFF funding will be provided by the Sr. Clinical Research Development Specialist for submission with the Full Application. ***Applications without this documentation may have funding held OR may be downgraded during review due to lack of CFF Biorepository support.***

Note: *Applicants must upload the confirmation letter provided by the CFF Sr. Clinical Research Development Specialist to the application. Funding is contingent upon approval and availability to access clinical specimens.*

Submission

Prior to selecting "**Sign & Submit**", please complete a thorough review of the entire LOI. The "Sign & Submit" button will trigger validation on all required fields and identify any errors. Only the Principle Investigator will need to sign off on the application at the LOI stage.

X. Full Application Guidelines

Application Deadline: September 17, 2024 at 5:00 PM (EST)

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 https://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 for each of the pre-identified PIs. Log in with your existing credentials to access the application.

Your draft application will be 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 "**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.

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.

Note: The project title should start with the last name of the PI and the title (i.e., if the PI submitting is John Smith, the project title should be "Smith – XYZ"). All related applications should ensure that the titles of their application are identical to other members of their team.

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

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 CFF Grants & Contracts Management and Administration (GCMA) Office must have a copy of the applicant institution's current W-9 and 501(c)3 letter, or other documentation verifying its Federal tax status and will not issue Award Letters to Awardees 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 GCMA Office.
- Non-U.S. applicants must provide a copy of the W-8BEN-E form (required). In addition, a tax equivalency letter should be uploaded, if available. If a tax equivalency letter is not available, applicants must upload a letter stating this documentation is not available.

International Applicants (if applicable):
For international applicants, you will need to answer an eligibility question specifying if you are an independent investigator. If answering yes, CFF may require an additional letter of support to be added to the application to verify eligibility.

Applicants whose institution is not a United States based-entity must complete the CFF International Institution Form. Refer to **International Institution Form** section on page 24.

CONTACTS

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

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

Additional contacts not associated with the applicant institution may also be added. These contacts are considered additional contributors involved in the proposed research plan. These may include consultants, collaborators, or subcontractors. In order to add contacts external to the applicant institution, please select the appropriate "Add Subcontractors" or "Add Consultants/Collaborators" button(s) and add the contacts in the table, then click "Save".

REFERENCES

This section will appear if you have selected "**Yes**" for the question on the **GENERAL** tab "**Are you a junior investigator?**"

Letters of Reference for Junior Investigators*: CFF defines "junior investigator" as any individual who has not received a CFF Research Grant or NIH equivalent (e.g. R01, R21, R23) as a Principal Investigator OR is within their first five (5) years of their first academic appointment at the level of Assistant Professor or equivalent.

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

- **The Chair of the applicant's department at the applicant Institution** – The letter of reference from the Department Chair should indicate the release of sufficient space and facilities for the work described, as well as guarantee the time commitment of the investigator to the project. If the applicant is currently a fellow, the letter of reference should include confirmation of the pending faculty-level appointment.
- **At least two (2) other individuals** familiar with the applicant's scientific interests and abilities.

Letters of Reference must be submitted prior to submission of the application. To invite Referees, go to the "**REFERENCES**" tab of the online application, then select the blue button to open a pop-up window in order to add the referees in the table. You must click "Invite" in order to trigger the e-mail to the referee. The

referee(s) will be sent an e-mail asking them to Accept or Decline the invitation to submit a letter of reference and will be provided instructions to submit the letter. **The applicant will be alerted if a referee Declines the invitation; please make sure to check this tab regularly to see the status of the references.** The applicant should inform Referees to submit the letters at least one (1) week prior to the application deadline. This helps to ensure that the letters have been uploaded before the application is submitted. Once the application has been submitted, no documents can be added.

Letters uploaded to http://awards.cff.org should not be password protected or otherwise encrypted. Such encryption will cause errors in assembling a single-print PDF of the application. The applicant should inform the individuals writing letters to not include password protection on their documents.

***Senior investigators, or those who have received a prior CFF/CFFT Research Grant or NIH equivalent, are not required to submit Letters of Reference; however, if they are new to CF research, Letters of Support and/or Collaboration should be provided and uploaded as Appendices.**

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 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 Health Equity Areas of Emphasis**: All applications are reviewed and scored not only on scientific merit but also on impact on health equity in the CF population:

  Provide a statement of no more than 3,000 characters (including spaces) summarizing the relevance of the proposed research to the health equity of the CF community. Provide discussion on how your project may address one or more of the Areas of Emphasis 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 four (4) years.

- For each PI, the budget **may not exceed $200,000 in direct costs per year (plus 12% indirect costs) for a maximum of four (4) years.** This amount is inclusive of the cost of any subcontracts. The lead institution may request up to $50,000 in additional direct costs per year to support an administrative core (see Other Expenses).
- One application per study team may request up to $25,000 in additional direct costs over the entire project period to support the translation of a validated PROM essential to the aims of the research project. (see Other Expenses)
- Each PI must submit a budget and justification specific to their own portion of the effort as part of their separate https://awards.cff.org application packages. The Budget for the initiating PI should not include budget information for the partnering PIs, even if they are at the same organization.
- Applicants are required to include a biostatistician with a minimum of 5% effort per year of their project. Projects that are purely qualitative research may request a waiver for the biostatistician requirement.
- 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.
- Under most circumstances, hospitalization costs of study subjects cannot be included in this budget.

The following budget categories are offered under this program:

Salaries & Benefits - List the names, positions, and percent effort of all professional and non-professional personnel involved in the project, whether or not salaries are 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 (FY24) of **$221,900**. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all funding agencies and foundations.

Consultant Costs - Give the name and institutional affiliation of any consultant who has agreed to serve in this capacity, including statisticians and physicians in connection with the project if they are not listed under personnel. In the budget justification, briefly describe services to be performed, the number of days, rate of compensation, per diem and any other associated costs. Qualifying consultants are individuals that are generally not employed at the applicant institution and/or are consulting independently to the project.

Travel – Describe the purpose of any CF-relevant travel. Please note: expenses for travel outside the North American Continent, including travel to Hawaii, Puerto Rico, and other U.S. territories are not allowable expenses without prior written approval from the CFF GCMA Office with the exception of travel for speaking engagements at the European Cystic Fibrosis Conference to present data obtained through a CFF funding opportunity. 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. glassware, chemicals, animals, in separate categories and give the estimated cost of each category. If animals are involved, state the number, unit purchase cost, and unit care cost.

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

Other Expenses - Itemize other expenses by major categories, such as duplication costs, publication costs, minor equipment (under $5,000), computer charges, conference registration fees, other research costs (e.g., recruitment flyers, brochures, patient travel cost reimbursement, translation of patient facing materials, and reasonable patient stipends for participation), etc. Tuition costs may be requested for personnel supported through this study but may not exceed **$10,000** per person per year. The lead institution may request up to **$50,000** in additional direct costs per year to support an administrative core. Administrative core duties should include activities to facilitate communication and data sharing between individual PIs. One application per study team can request up to $25,000 in additional support over the entire project period for the translation of a validated PROM. Please justify all items listed.

Patient Research Costs – Funds may be requested for patient research costs specifically related to the proposed research. 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. **Please note costs**

associated with patient recruitment and/or reimbursement for study participation should be included in "Other Expenses" section.

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)).

Subcontractor Summary

Partnering investigators may be included as subcontractors on a fellow investigator's budget IF their work on this project is distinct/non-overlapping with the work on their own project. All costs associated with an individual project/application should be listed on that grant.

If applicable, detailed budgets and budget justifications for each subcontract, including indirects, must be provided for each year of support. Subcontractors are added in the prior section entitled CONTACTS. The lead/prime applicant (PI) and/or Grants Officer can initiate/complete the subcontract budget. After adding Subcontractor(s), in order to access the subcontract budget activity, please select the "BUDGET" tab of the application and click the "Open" button next to each listed subcontractor. After completing the subcontract budget activity, please select "Pending PI Acceptance", as well as "Submit" to ensure the subcontractor budget is included as part of the main application budget.

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 (12) percent may be requested from CFF. Indirect costs may be requested for all expenses except for the following:

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

Applicants may request indirect costs on the first $25,000 of each subcontract for the project period.

LOI UPLOADS

This section will allow access to the documentation uploaded at the LOI stage. If you were invited directly to the full application, this section will not include LOI uploads from the original LOI submission.

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. Please note that some uploads may be created as a single document and uploaded to each full application. Templates available for download include:

- **Collaboration Details** - Partnership Statement and Communication Plan-Only one collaboration detail needs to be developed per team. This document should be uploaded to each full application.
- **Research Plan**
- **Statement of Work**
- **Protocol Synopsis, Schedule of Events, and Study Participant**
- **Statement of Community Engagement**
- **Health Equity - Translation Supplement (if applicable)**

- **Training Plan**
- **Budget Justification**
- **Biographical Sketches of Key Personnel**
- **Other Support**
- **Facilities Available**
- **Data Safety Monitoring Plan**
- **International Institution Form (if applicable)**

Collaboration Details - Partnership Statement and Communication Plan (template available for download)

- At the top of each page, type the PI's name. Each page must be sequentially numbered at the bottom. Partnership Statement and Communication Plans are limited to three (3) single-sided pages. Applications exceeding this page limit will not be reviewed. **Only one Collaboration Details needs to be developed per team. This document should be uploaded to each full application.** Do not provide different content for each PI, as only one Collaboration Details upload will be reviewed per team.
- Discuss in detail the advantages of addressing the team's over-arching theme through the combined expertise of the PIs and how this contributes to the synergy of the application. Describe how the proposed partnership involves a substantial contribution by each investigator and the reciprocal flow of ideas and information. Considering the team's over-arching theme, describe how the combined efforts of the PIs will result in a level of productivity that is greater than that achievable by each PI working independently.
- In regard to the planned communication for the project, this document should clearly outline:
  a. How research activities will be coordinated among investigators.
  b. How data will be integrated and shared among investigators.
  c. How the collaborative nature of the program will be maintained.
  d. How reagents, equipment, resources and data will be shared within the program.
  e. How conflict and scientific disagreements will be managed and resolved.

Research Plan (template available for download)

- At the top of each page, type the PI's name. Each page must be sequentially numbered at the bottom.
- The lead PI for each project should submit a unique research plan. Each Health Equity Team Science Award project should have a collaboration with at least two (2) projects but no more than four (4) that **share a well-defined theme and overall objective.**
- Research Plans are limited to twelve (12) 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 necessitating reference to previous applications, or to the cited literature. Information should be presented in a clear and concise manner, while being specific and informative.
- **Key figures and legends must be included in the Research Plan. If uploaded as Appendices, they will NOT be reviewed.**
  a. **Hypothesis and Specific Aims:** State concisely and realistically the intent of the proposed research and the hypothesis to be tested. The specific aims should test this hypothesis and be relevant to the health equity of the CF population.
  b. **Background and Significance:** Briefly describe the background. Critically evaluate existing knowledge and specifically identify the gaps that the project is intended to fill, including considerations of strengths/weaknesses or gaps in published research. Concisely state the importance and rationale of this research by relating the specific aims to longer-term objectives. This section should show the potential importance of the proposed work to CF and clearly describe the team's over-all theme or objectives and how the collaboration with the other projects advances the researcher further than if done alone.
  c. **Approach:** Describe in detail the proposed research. This section should address the following areas, but the order of presentation can vary to enhance readability and presentation.

i. **Preliminary Results:** Discuss preliminary studies, data, and/or experience of the study team pertinent to the proposed research plan. Provide any preliminary data that supports and informs the study hypothesis, experimental design and feasibility of the proposed aims. Information in this section should demonstrate the study team's expertise and ability to complete the study aims, including attaining recruitment goals. Figures and tables should be provided when possible and sufficiently annotated.

ii. **Experimental Design and Methods:** Provide a detailed discussion of the experimental design and methods to be used to accomplish the specific aims and test the stated hypothesis. Please discuss (if applicable): primary and secondary outcome measures; study sample-inclusion and exclusion criteria; subject enrollment including age range; sex distribution; randomization scheme; description of experimental procedures and schedule including a study timeline; measures of protocol compliance or treatment fidelity; follow-up schedule including a study timeline for full project up to four years; efficacy and safety evaluation, and data monitoring and quality control. If proposed implementation science research, please provide discussion on specific implementation science methods/approaches used to address project aims. A study timeline and schedule of events table is highly recommended.

iii. **Recruitment and Retention Plan:** Describe the recruitment plan for the proposed study, including discussion of the availability of potential participants meeting inclusion and exclusion criteria for the proposed study and anticipated yield from recruitment and screening efforts. Describe the purpose of collecting and using race and ethnicity and other social constructs data, including supportive data or documentation for the research study's use of social constructs as proxy variables. If there is more than one recruitment site, please provide a table showing the expected number and demographics of the population to be recruited at each site and overall. The plan should also include a discussion of experience in recruiting and retaining similar populations, expected challenges to recruitment and retention, and possible contingency plans. Applicants enrolling subjects are required to provide a demographic table of anticipated study participants, including race and ethnicity information, and a description of their plans for including a diverse population including individuals historically underrepresented in research (sex/gender, race, ethnicity, socioeconomic status, etc.). Such a plan should include discussion of recruitment of historically underrepresented subjects in research, including those whose primary language is not English.

iv. **Statistical Analysis and Power:** Clearly describe the statistical methodologies, including software, to be used for each aim of the proposed study. Clearly describe analytic strategies for each endpoint or outcome measure being collected. Describe any potential confounders or demographic variables that will be considered during analysis. Provide discussion on how the statistical methods are appropriate for the proposed sample size. Provide a rationale for the number of participants who will be studied. If a full power calculation is provided, the sample size and statistical power calculations should contain sufficient detail, including assumptions made, such that a reviewer can readily duplicate the sample size. A discussion of how missing data will be handled should be included. Any planned interim analyses should also be described.

v. **Limitations and Potential Pitfalls:** Discuss potential difficulties and/or limitations of the proposed procedures and alternative approaches to achieve aims. Point out any procedures, situations or materials that may be hazardous to personnel or patients and the precautions to be exercised. Include any possible limitations due to the way patient registry data is collected, including sex assigned at birth vs gender, race, and/or ethnicity.

d. **Consultant Arrangements:** If the proposed project includes consultant arrangements and/or collaboration with other individuals outside the applicant's group, describe the working relationships and support this description with letter(s) of support signed by collaborating individual(s).

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

Statement of Work (SOW, template available for download)
The SOW is an outline of specific aims of the proposed research project that establishes the project milestones during the performance period of the award. The SOW should contain sufficient detail to be informative as a standalone document.

Protocol Synopsis, Schedule of Events, and Study Participants (template available for download, if applicable)
Complete the information required in the available template for each aspect of the study protocol.

Provide a Schedule of Events (SOE) in a form of a table listing the study visit timelines and procedures/events associated with each visit over the entire period of the project. Include information on which study visits must occur in person and which may be done remotely. Provide information related to recruitment incentives or payment for study participation for participants, this should include proposed method and timing of disbursement. Discuss any identified potential unintended harm(s) of the proposed research and plans to mitigate unintended harm. Describe plans for translating research findings to study participants, including reporting clinically pertinent results, and connecting participants to relevant and available resources if need is identified during the research study.

Statement of Community Engagement (template available for download)
Provide a statement of no more than 500 words (including spaces) summarizing patient engagement activities that occurred throughout the study design and any future patient engagement activities related to the implementation of the study aims. Specifically, please provide descriptions about what type of support you are requesting from the CFF's Community Partnerships department, including survey development and dissemination, focus groups, or patient partnership identification. **It is highly encouraged that each team include at least one member of the CF community as a consultant, patient partner, or as an advisor.** To learn more about Community Engagement and CFF's Community Voice, visit **https://www.cff.org/Research/Researcher-Resources/Community-Input-into-Research/**

Health Equity - Translation Supplement (template available for download, if applicable)
Provide a brief description of no more than 3,000 characters of the proposed process of translating the PROM OR details related to utilizing interpreter services. This should include, but not limited to, the process of translating and reconciling translated versions into the target language, and the process for testing and obtaining feedback from the patient population and subject matter experts. Clearly describe how the translation of the specific PROM or use of interpreter services are essential to the success of the research study. Provide support from the PROM developer expressing permission for the translation of the PROM.

Training Plan (template available for download)
Provide a summary of previous research and/or completed trainings related to diversity, equity, and inclusion, including courses and certifications, in no more than 3,000 characters that clearly demonstrate the applicant's experience and knowledge of health equity research. Provide a description of any planned equity training that will take place during the award should be included.

Budget Justification (template available for download)
Budget Justification should only be provided from the PI who is listed on the application, do not include justifications from the team unless they are listed as a subcontract. Describe costs listed in the Budget Detail. This document should be unique and describe the costs associated with the work for each collaborating

investigator. 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.

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. (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.

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. **Make sure all other support is listed and not only CF Foundation funded projects (pending, current, and previous support).** 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.

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, 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.

Data Safety Monitoring Plan (template available for download, if applicable)
In compliance with Federal regulations, all applicants must submit a general description of the Data Safety Monitoring Plan (DSMP) for any proposed study that places human subjects at more than minimal risk. A DSMP helps to ensure subject safety, as well the validity and integrity of the data. Furthermore, a DSMP allows for the monitoring of study data to assess whether or not an early termination is necessary for safety or efficacy reasons.

The extent of monitoring required for a study is dependent on the level of risk involved for the subjects, as well as the size and complexity of the study. Large, multi-center CFF-funded interventional clinical trials may be required to utilize a Data Safety and Monitoring Board (DSMB). In addition, because its members are CF clinicians and clinical trial experts, CFF strongly encourages and may require that investigators utilize the CFF DSMB for any other interventional CF clinical trial that meets one or more of the following criteria:

- Multi-center;
- Randomized;
- Conducted in an emergency setting;
- Use high-risk interventions, such as gene therapy, gene transfer, or bronchoscopy; or Include particularly vulnerable study populations, such as pediatric patients.

***Note**: On the available template, please check whether a DSMP is required and upload the template regardless of the response.*

Address the following areas in the DSMP:

Assessment of Risk – Describe the level of risk the proposed research presents to subject participants and provide a detailed justification for the level of risk. Discuss who will monitor the study.

Level of Risk

- Minimal Risk
  - Study poses no more risk than expected in daily life (blood draw, physical exam, etc.)
  - Observational studies
  - Survey or questionnaire studies
- Low Risk
  - Post-marketing study Phase IV drug or device, as defined by FDA
- Moderate Risk
  - Substantial risk (>5%) of a Serious Adverse Event (SAE) originating from the underlying condition of the enrolled subject
  - Phase I or II study with available safety data in humans
- High Risk
  - Involves an intervention or invasive procedure with substantial risk
  - Involves the use of a new chemical or drug for which there is little or no toxicology data in humans
  - A gene therapy study or research involving recombinant DNA or RNA molecules (gene transfer)
  - Involves vulnerable populations (pediatric, pregnant, etc.)

Anticipated Adverse Events and Grading Scale – Describe anticipated adverse events (AEs), including expected frequency and the grading scale to be used. Discuss plans for addressing AEs.

Reporting of AEs – Detail the plan for reporting AEs, including who shall be notified in the event an AE should occur.

Safety Monitoring Plan – Describe all tests, evaluations, and exclusion criteria that will be implemented to ensure and monitor the safety of human subjects. Discuss stopping rules for the study subjects or for the overall study if necessary.

Safety Reviews – Describe the process for monitoring and reviewing subject safety data, including the frequency of such reviews. Include details as to who will perform the monitoring and plans for reporting. If utilizing the CFF DSMB, provide the frequency of meetings, the reporting requirements, including AEs and SAEs, and the procedure for interim reporting as necessary. If this information is not available at the time of submission of the application, note that CFF will not release awarded payments until it is provided.

Registrations for Investigator-Initiated Clinical Trials:

- Clinicaltrials.gov (United States): Applicants are required to register all non-exempt human subject studies in the ClinicalTrials.gov database to ensure information is freely available on CFF-funded trials within the community. The registration should be no later than twenty-one (21) days after the first subject is enrolled. CFF requires copies of documentation confirming this registration, when applicable.
- EudraCT Registration (European Union): For interventional clinical trials with medicinal products conducted in the European Union, the Institution must provide documentation to CFF confirming registration of the clinical trial when applicable.

CFF Patient Registry Data Request (if applicable)

Researchers who wish to request Registry data for their proposed clinical research study must complete and submit the "Application for CFFPR Data and Confidentiality Agreement" application to datarequests@cff.org prior to submitting their full application to CFF. The formal application for CFF Patient Registry Data Requests

can be found at https://www.cff.org/Research/Researcher-Resources/Tools-and-Resources/Patient-Registry-Data-Requests/

Note: *The application must be submitted using the online system available from the link above and the email from the system indicating receipt of the application must be uploaded to the submission. Funding is contingent upon approval to access registry data.*

CFF Biorepository Clinical Specimen Confirmation Letter (if applicable)
Since 2006, the Cystic Fibrosis Foundation has collected and stored samples from a variety of clinical trials. The CF Foundation has developed a database that combines information from these samples with data from CF clinical trials and the CF Foundation Patient Registry to create a unique and specific sample profile. To request clinical samples to use in the proposed study, download and complete the template from https://www.cff.org/Research/Researcher-Resources/Tools-and-Resources/CFFT-Biorepository/. Applicants **must** supply a letter from the clinical research program manager confirming samples are available before funding will be approved. For more information, contact JP Clancy, MD, senior vice president of clinical research at the CF Foundation, at jpclancy@cff.org.

Note: *Applicants must upload the confirmation letter provided by the CFF Clinical Research Program Manager to the application. Funding is contingent upon approval and availability to access clinical specimens.*

International Institution Form (template available for download, if applicable)
Applicants whose institution is not a United States based-entity must complete the CFF International Institution Form. The completion of this form also includes submission of the following documentation:

- Institution's mission statement
- If the Institution is a nonprofit organization, provide government-issued documentation of the Institution's nonprofit status, if available, as well as governing documents (such as a Charter, Statute, or By-Laws) detailing the funding and expenditures related to activities outlined in the Mission Statement of the Institution compared to activities outside of the mission of the Institution
- If the Institution is a for-profit organization, provide a complete list of key employees, members of the governing board, and/or other senior management as well as any governing documents (such as an Articles of Association or Organization) detailing the funding and expenditures of the Institution
- A complete and accurate Form W-8 signed by the institutional official within the last three years. While CFF issues grant funding to 501(c)(3) and nonprofit institutions, CFF also issues contract award funding to other kinds of institutions.
- A description of external sources of support, including the names of individuals and organizations providing the Institution with major donations, official awards, private endowments, and/or commercial activities
- Standard Operating Procedure(s) or relevant policy to ensure that all awarded funds, including but not limited to CFF funds, are used in compliance with all applicable U.S. anti-terrorist financing, privacy and asset control statutes, regulations and executive orders, resulting in the Institution neither distributing awarded funds to terrorists nor supporting their networks , organizations, or activities (*If your institution does not have a relevant policy, please provide a statement signed by an institutional official indicating that all award funds, including but not limited to CFF funds, will be used in compliance with applicable U.S. anti-terrorist financing, privacy and asset control statutes, regulations and executive orders, resulting in funds never being used to support terrorist networks, organizations and/or activities. In the alternative, if the institution does not have this policy, CFF can provide an Anti-Terrorism Certification Form to be signed by the institutional official).*

Applicants who have provided these documents within the past one (1) year is not required to resubmit them. However, if any of the above documents have been updated since they were previously submitted,

please upload any updated documents. The CF Foundation GCMA Office will contact applicants if documents are outdated or missing.

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

Appendices (upload as PDF documents)
Appendices are restricted to the following two (2) categories*:

- Signed Letters of Support and/or Collaboration: A Letters of Support/Collaboration from individuals **other than Co-PIs submitted individual applications**, if any, should be uploaded and included in the application. Investigators new to CF research are required to consult/collaborate with an established CF investigator/clinician either at their own institution or another. The letter from the collaborator/consultant should be explicit as to how the proposed work is relevant to CF and how he/she will assist the investigator new to CF research.
  Note: Junior investigators must provide such letters by contacting referees via section #6 of the navigation bar.
- 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.

***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 GCMA Office.

Awardees based outside of the U.S. must comply with the applicable equivalent regulations in their respective countries and provide copies of approvals as soon as they are available. CFF will not release payments until these documents are received and on file with the CFF GCMA Office.

Research Involving Human Subjects: CFF policy pertaining to the protection of individuals as research subjects requires that for each proposal awarded, the awardee institution certify in writing that an Institutional Review Board (IRB) has reviewed and approved the procedures for the use of human subjects, or human organs, tissues and body fluids, in the proposed research, in accordance with the Department of Health and Human Services policies found at https://www.hhs.gov/ohrp/regulations-and-policy/index.html. In the event the IRB has determined a study is exempt, documentation demonstrating the exempt status must also be submitted to the CFF GCMA Office.

Research Involving Recombinant or Synthetic Nucleic Acid Molecules: All research involving recombinant 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 as "Submitted" once fully signed, to indicate that your application has been received by CFF.

XI. Resources and Other Information

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

XII. Contact Information

For technical support and program/content information:
Primary CFF GCMA Office contact Angela Minucci at aminucci@cff.org or 301-841-2614

For scientific questions:
Dara Riva, M.S. at driva@cff.org

XIII. Electronic Application Checklist

LOI Application Deadline: Tuesday, April 23, 2024 at 5:00 PM (EST)
Full Application Deadline: Tuesday, September 17, 2024 at 5:00 PM (EST)

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

LETTER OF INTENT

- ☐ Biographical Sketch(es) of Key Personnel - (upload)
- ☐ Response to Prior LOI Critique (if resubmission) – (upload)
- ☐ LOI Project Description - (upload)
- ☐ Protocol Synopsis – (upload)
- ☐ Health Equity - Translation Supplement– (upload, if applicable)
- ☐ CFF Patient Registry Data Request (if applicable)
- ☐ CFF Biorepository Clinical Specimen Request Confirmation letter (if applicable)

FULL APPLICATION

Face Page (upload) which includes:

- ☐ Signatures
  - ☐ 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 Involving recombinant or synthetic nucleic acid molecules information
  - ☐ Research Involving Animals information

Research Plan, Supporting Documents and Appendix:

- ☐ Abstracts ~ Summary of Relevance ~ Keywords - (complete online)
- ☐ Partnership Statement and Communication Plan - (upload)
- ☐ Research Plan - (upload)
  - ☐ Hypothesis and Specific Aims
  - ☐ Innovation Statement
  - ☐ Background and Significance
  - ☐ Preliminary Results
  - ☐ Experimental Design and Methods
  - ☐ Limitations and Potential Pitfalls
  - ☐ Consultants/Collaborative Arrangements
  - ☐ Literature Cited (not included in Research Plan page limitation)
- ☐ Statement of Work (SOW) – (upload)
- ☐ Protocol Synopsis – (upload)
- ☐ Statement of Community Engagement
- ☐ Budget Detail for each year and for each subcontract, when applicable - (upload)
- ☐ 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)
- ☐ Training Plan (upload)
- ☐ Health Equity Translation Supplement (upload)
- ☐ Facilities Available - (upload)
- ☐ Letters of Reference for Junior Investigators - (invite referees to submit via awards.cff.org –*Note: applicant will not be able to see the letters)*

- ☐ Data Safety Monitoring Plan – (upload, if applicable)
- ☐ CFF Biorepository Clinical Specimen Request Confirmation letter – (upload, if applicable)
- ☐ CFF Patient Registry Data
    - ☐ Application for CFFPR Data and Confidentiality Agreement – (upload, if applicable)
- ☐ Verification of Applicant Institution's Tax Status - (upload)
    - ☐ W-9 (U.S. applicants) or W-8BEN-E (non-U.S. applicants)
    - ☐ 501(c)3, IRS Form 147C or equivalent tax status letter
- ☐ International Institution Form (non-U.S. based entities only) - (upload, if applicable)
    - ☐ Institution's most recent Mission Statement
    - ☐ Institution's Tax Exemption Letter, if institution is not-for-profit
    - ☐ Description of other sources of support
    - ☐ Institution's Standard Operating Procedure(s) or relevant policy to ensure that funds provided are neither distributed to terrorists or their support networks nor 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
- ☐ Appendices - (upload as PDF documents, if applicable)
    - ☐ Signed Letter(s) of Support and/or Collaboration
    - ☐ Up to three (3) reprints of the applicant's work relating to the general area of research in the proposal