



Program Name: CF Statistical Expertise and Network (CF StatNet) Award with LOI 2022

Brief Program Overview/Description: This award will promote greater collaborative integration of statisticians and CF clinical investigators at TDN institutions by funding local statisticians and integrating them into the CF Statistical Research Network (CF StatNet).

Funding Amount: Funding for up to three (3) years may be requested for salary support for the named statistician-awardee (non-student). The amount of funding offered is per a tapered structure (Year 1 funding at a maximum of 35% Full-Time Effort (FTE); Year 2 funding at a maximum of 25% FTE, and Year 3 funding at a maximum of 20% FTE. Travel for the statistician-awardee of up to \$3,000 per year may also be requested. This program provides optional salary support for the non-statistician Principal Investigator (PI) from 1% up to a maximum of 5% FTE each year. Indirect costs are not allowed for this award.

Eligibility:

- Applications will be accepted from individuals at domestic academic institutions that are CF accredited Therapeutic Development Centers (TDCs).
- PI applicants must be U.S. citizens or U.S. permanent residents (i.e. applicants must have obtained permanent residency prior to the time of the application).
- *Additional eligibility requirements can be found in Section IV below.*

Key Dates:

Published	February 16, 2022
LOI Submission Deadline	March 15, 2022
LOI Applicant Notified	Late-April 2022
Full Application Deadline	June 9, 2022
Committee Review Date	July 2022
Notification to Applicants	July/August 2022
Project Start Date	September 1, 2022

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I. About the Cystic Fibrosis Foundation

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

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

II. Program and Award Overview

This award will promote greater collaborative integration of statisticians and CF clinical investigators at TDN institutions by funding local statisticians and integrating them into the CF Statistical Research Network (CF StatNet).

Dedicated statistical expertise is increasingly important to conducting rigorous clinical research in CF. Most clinical investigators, regardless of experience level, lack adequate training to conduct studies without the assistance of a dedicated biostatistician to assist with the design, implementation, and analysis of results. This program is intended to attract existing statisticians into the local CF research communities by providing funded effort specific to CF clinical research at those sites. This activity may include analyses of existing data, assisting in the preparation of applications, designing and assisting with the conduction of prospective clinical studies, or data analysis and publication of new results.

Applications are encouraged from either CF clinical investigators who identify a faculty or staff statistician at their home institution or faculty statisticians who already have an existing relationship with the local CF Therapeutics Development Center (TDC).

The biostatistical faculty and staff at the CF Foundation's TDN Coordinating Center (TDNCC) will engage recipients of this award to develop and expand the academic community of likeminded biostatistical researchers across the United States. This will include an annual CF biostatistics and epidemiology meeting in Seattle, Washington, dedicated meetings during the North American Cystic Fibrosis Conference (NACFC), and monthly webinars to share works-in-progress and research methods specific to biostatistics, study design, and outcomes in CF. This broader integration will help to develop a national network of experts capable of more effectively meeting the statistical needs in CF clinical research. This group will be poised to establish consensus and innovate methods applicable to a variety of CF clinical research outcomes in the years ahead.

Environment

TDCs that have pediatric and adult programs may apply separately for the award or may apply jointly if the intent is to share the Statistician-Awardee and collaborate on projects. If the adult and pediatric programs are applying separately, both programs should submit a separate application, budget, and budget justification. Their respective offices of research management should separately process the applications. For those centers where both programs apply, there is not guarantee that if one program receives the award that the other will be granted the award as well.

Duration and Effort

This is a non-renewable award for up to three (3) years. All funds must be used on behalf of the Statistician-Awardee. Support is divided into three distinct years that relate to the Statistician-Awardee's progress in becoming an independent CF biostatistician. It is required that a minimum of 20% effort during the award be devoted to the research and collaboration with the CF Community. This award does not serve to fund research projects themselves. This award is not intended to fund more than one named Statistician-Awardee at each applying institution. This award does not fund students.

Minimum Requirements

Statistician-Awardees must provide quarterly one-page progress reports to the CF StatNet Director and make every effort to participate in monthly teleconferences/webinars throughout the funding period and attend NACFC and TDNCC/University of Washington Biostatistical and Epidemiology Meeting in Year 1. Institutional Awardees must provide a two-page annual progress report each year for renewal. In addition, all awardees and institutions must comply with CFF award policies and Terms and Conditions.

III. Funding Amount

This program provides salary support for the named statistician-awardee in a tapered structure in addition to travel for meetings. Indirect costs are not allowed on this award. Students are not supported on this award.

- Year 1 funding is at a maximum of 35% FTE
- Year 2 funding is at a maximum of 25% FTE
- Year 3 funding is at a maximum of 20% FTE

The award will cover standard institutional fringe benefits for that salary. In accordance with NIH policy, salary requests may not use an institutional base salary in excess of the current federal salary cap of \$203,700. Salaries may be supplemented by the applicant institution.

This program provides optional salary support for the non-statistician Principal Investigator (PI) from 1% up to a maximum of 5% FTE each year. Regardless of salary support requested, the PI is expected to regularly interact with the statistician-awardee in an effort to fully integrate her or him into the local CF research community and transition to additional external grant support during the award. PIs requesting salary support are expected to attend the majority of monthly conference calls, individually meet with the statistician-awardee regularly to review active projects, and work to ensure local faculty support. They are not expected to attend the in-person meetings in Seattle, WA.

(Allowable) Direct costs may be requested for:

- Salary and Benefits
- Travel

Indirect costs are not an allowable cost for this award.

IV. Eligibility

- Applications will be accepted from individuals at domestic academic institutions that are CF accredited Therapeutic Development Centers (TDCs).
- PI applicants must be U.S. citizens or U.S. permanent residents (i.e. applicants must have obtained permanent residency prior to the time of the application).
- Students are not supported by this program.

Statistician-Awardee should:

- Have a master's degree or higher in statistics, epidemiology, biostatistics or a closely related area of study
- Have a staff or faculty appointment at the same institution as the CF clinical research investigators associated with the application
- Be employed at an institution that is a CFF accredited Therapeutic Development Center (TDC).
- Be able to devote at least 20% additional effort to their existing collaboration with the local and national CF clinical research community
- Aim to attend the North American Cystic Fibrosis Conference (NACFC) each year of the award and an additional two-day meeting of biostatisticians and epidemiologists in Seattle, WA in Year 1 (Years 2-3 optional).

- NACFC for each year awarded
 - Year 1 - November 3-5, 2022 Philadelphia, PA (highly recommended)
 - Year 2 - November 1-4, 2023 Phoenix, AZ (highly recommended)
 - Year 3– September 26-28, 2024 Boston, MA (highly recommended)
- TDNCC/University of Washington Biostatistical and Epidemiology Meeting for each year awarded
 - Year 1 - July 27-28, 2023 in Seattle, WA (mandatory)
 - Year 2 - July 25-26, 2024 in Seattle, WA (optional)
 - Year 3 – TBD (optional)

Institutional Awardee (PI) should:

- Have a faculty appointment at a domestic academic institution affiliated with an accredited CF Therapeutics Development Center (TDC)

AND

- Be engaged in CF clinical research

AND

- Have a master’s degree or higher in statistics, biostatistics or a closely related area of study

OR

- Name a Statistician-Awardee meeting the requirements below.

V. Mentorship Requirements

Not Applicable to this RFA

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

Areas of Interest

The CF Foundation seeks applications for the Clinical Pilot and Feasibility Award from all areas of clinical research that will have an impact on the lives of people with CF. However, the following research areas are of particular interest to the CF Foundation as they will address critical needs of people with CF:

- Studies that investigate CF disease complications (lung, GI tract, liver, pancreas, reproduction, mental health, endocrine etc.)
- Strategies to improve care and quality of life of people with CF
- Assessment and validation of biomarkers, clinical trial tools, outcome measures and efficacy endpoints
- Translational or clinical studies in lung transplant¹ research
- Characterization of CF disease manifestations and management in the era of highly effective modulator therapy
- Novel interventions that improve CF patient care and outcomes
- Studies designed to translate laboratory findings of disease pathogenesis/treatment to clinical evaluation
- Studies that identify and characterize racial, ethnic, and/or societal contributors to CF disease expression and management

Areas of Encouragement

In addition to CF Foundation Areas of Interest, extensive survey input from the CF community (people with CF, family members and caregivers) have identified key research Areas of Encouragement that are most important to them. The areas selected by the CF community are listed below in order of prioritization.

Applications may address any topic area advancing CF care, treatment, or research. However, applications addressing the following areas in CF are particularly encouraged:

¹ In 2017, the CF Foundation created the Lung Transplant Initiative to address the unmet needs of people living with cystic fibrosis with advanced lung disease. The mission of this initiative is to improve the care and long-term outcomes of individuals with CF and advanced lung disease. For more information about this initiative, or the CF Foundation’s research priorities in lung transplant research, please email Carmen Ufret (cufret@cff.org).

- [Respiratory Microorganism Detection and Treatment](#)
- Gastrointestinal symptoms (including, but not limited to, GERD, DIOS, and Pancreatitis)
- Reducing Treatment Burden
- CF-related Diabetes
- Diet and Nutrition
- Mental Health
- CF-related Liver Disease (including cirrhosis and non-cirrhosis, gall stones, hepatic steatosis, and other clinical manifestations of portal hypertension)
- Exercise
- Sinus Disease
- Allergies and Asthma
- Alternative/Holistic Treatments and Therapies
- [Sexual Reproductive Health](#)
- Bone/Joint Health
- Pain Management

More information regarding the research priorities of the CF Foundation can be found [here](#).

VII. Review and Award

A limited number of awards will be granted each year. Priority will be given to applications that support teams of CF clinical investigators.

The CF StatNet Review Committee will evaluate all applications and make recommendations to CFF and the Board of Trustees for final approval and funding. CFF considers the availability of funds, the priority score awarded to each application, and the committee recommendations when determining awards.

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 CF StatNet review committee, and CFF Program Officers. All awards are subject to compliance with applicable regulations and CFF policies.

Payments for successful applications are made quarterly in arrears to the Awardee Institution and not to the individual applicant. Payments are subject to various contingencies, such as signed assurances, progress reports, and financial reports. Brief annual reports of productivity will be used to determine award renewals for the three (3) year period of funding.

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

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 per cycle.

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.

General Timeline:

*LOI Submission Deadline	_____	March 15, 2022
LOI Applicant Notified	_____	Late-April 2022
Full Application Deadline	_____	June 9, 2022
Committee Review	_____	July 2022
Notification to Applicants	_____	July/August 2022
Award Start Date	_____	September 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 CFF Grants & Contracts Team is able to assist all applicant with any potential system-related queries prior to the Application Deadline.

IX. Letter of Intent (LOI) Guidelines

LOIs Submission Deadline: Tuesday, March 15, 2022 at 5:00 PM (EST)

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

An LOI will be considered incomplete if it fails to comply with these instructions, or if the submitted material is insufficient to permit adequate review. CFF reviews LOIs electronically, and only documents submitted online at <https://awards.cff.org> will be reviewed. Late applications will not be accepted, and the deadline will not be waived.

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 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 “**CF Statistical Expertise and Network Award 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, 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 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.

International Applicants

Not Applicable to this Program

APPLICATION CONTACTS

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

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

Additional contacts not associated with the applicant institution may also be added. These contacts are considered additional contributors involved in the proposed research plan. These may include co-mentors, consultants, collaborators, or subcontractors. If the desired external contact is not available in the system,

you may select “**Add External Contact**” to create a basic contact profile in order to add the individual to your application.

See a How-To Guide Here: <https://www.cff.org/sites/default/files/2021-10/GMS-Guide-Applicants.pdf>

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 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 (Periods 1,2, and 3). An entire budget detail does not need to be completed for LOI Stage but rather potential total amounts for each field that will calculate to a potential grant total.

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
- LOI Project Description

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.

LOI Project Description

Maximum one (1) page. The project description should include the following information:

1. A description of the applicant’s interest in the CF StatNet Award, and how this award will enrich the TDC’s clinical research profile.
2. A description of the Statistician-Awardee’s qualifications and existing or planned working relationship with the applicant/TDC research team.
3. A brief description of the clinical researchers and studies proposed to benefit from this award.

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.

X. Full Application Guidelines

Full Application Deadline: Thursday, June 9, 2022 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 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 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 “**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.

***Please ensure that you review and comply with the Organizational Assurances and Certifications as cited on page 13.**

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.

International Applicants (if applicable):

Not Applicable for this Program

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.

See a How-To Guide Here: <https://www.cff.org/sites/default/files/2021-10/GMS-Guide-Applicants.pdf>

REFERENCES

Letters of Support and Reference are weighted heavily in the review. At least two (2) letters are required. Letters must be submitted by the following individuals:

- **Statistician-Awardee Personal Statement:** describes their qualifications/expertise and the environment that would support the application and collaboration with the local CF investigators and also the national CF StatNet Network.

- **Local CF clinical investigator(s) Letter of Reference/Support:** describe the proposed projects that the Institutional Awardee and Statistician-Awardee would work on and the collaboration with themselves and other local CF investigators

Letters of Reference must be submitted prior to submission of the application. To invite Referees, go to the “**REFERENCES**” tab of the online application, and first search for the referee using the lookup field. If the referee is not located in the system, you may select “**Add Referee**” to create a basic contact profile in order to add the individual to the application. Once added, this will generate automated emails (with instructions) that will be sent to each Referee. **The applicant will not be alerted when a reference is completed or declined; 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.

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 CFF mission:** All applications are reviewed and scored not only on scientific merit but also on relevance to CFF’s mission:

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

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

BUDGET

Select the “**Edit Budget**” button under Application Budget, to enter and begin completion of the application’s budget detail for each year of funding being requested. The total budget requested cannot exceed the percent effort as noted in the tapered salary structure (Year 1 - 35% FTE, Year 2 - 25% FTE, and Year 3 - 20% FTE) of the NIH salary cap \$203,700 plus fringe benefits, plus an additional \$3,000 stipend travel expenditures per Statistician-Awardee per year. The PI must commit a minimum of 1% effort and may request up to 5% salary request (limited to NIH salary cap of \$203,700) to support the statistician on the award with the expectation that the PI will:

- Attend the majority of calls
- Meet with the Statistician-Awardee regularly to review projects
- Ensure the Statistician-Awardee has local faculty support

The following budget categories are offered under this program:

Salaries & Benefits - List the names and positions of all professional and non-professional personnel involved in the project, whether or not salaries are requested. Indicate the percent effort on the project for all personnel. For each individual, be sure to complete all fields on the Budget Detail in full on the template provided. In accordance with National Institutes of Health (NIH) policy, salary requests may not use an institutional base salary in excess of the current federal salary cap of \$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.

Travel – Travel funds may be requested for award-related travel costs for the following:

- Year 1
 - NACFC November 3-5, 2022 in Philadelphia, PA (highly recommended but not mandatory)
 - TDNCC/University of Washington Biostatistical & Epidemiology July 27-28, 2023 in Seattle, WA (mandatory)
- Year 2
 - NACFC November 1-4, 2023 in Phoenix, AZ (recommended)
 - TDNCC/UW Biostatistical & Epidemiology July 25-26, 2024 in Seattle, WA (optional)
 - Other statistical conference of choice if not traveling to UW Biostat/Epi conference
- Year 3
 - NACFC September 26-28, 2024 in Boston, MA (recommended)
 - TDNCC/UW Biostatistical & Epidemiology July TBD 2025 in Seattle, WA (optional)
 - Other statistical conference of choice if not traveling to UW Biostat/Epi conference

Note: *Travel expenses may not exceed \$3,000 per year for the statistician’s travel to the above meetings. Registration fees associated with attending NACFC and the TDNCC/UW Biostatistical and Epidemiology Meeting are in addition to this allowance and should be listed under “Other Expenses.” Additionally, expenses for travel outside the North American continent, including travel to Hawaii, Puerto Rico, and other U.S. territories are not allowable expenses without prior written approval from the CFF Grants and Contracts Office.*

Other Expenses – Itemize meeting/conference registration fees related to above required meetings.

Budget Detail – Indirect Costs

Indirect costs are not allowable.

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:

- Project Proposal/Research Plan
- Budget Justification
- Biographical Sketches of Key Personnel
- Other Support

Project 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.
- Page limit: Five (5) 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) Statistician-Awardee Applicant: Review background, position and any previous collaborative work in CF clinical research. Biostatistical and clinical research expertise outside of, or complementary to CF that would enrich the CF team may also be highlighted. Applications should include a description of the candidate and how his or her additional protected effort will be used to directly integrate with the local CF clinical research team.
- b) Significance of Award: Specifically describe how this award would bolster the local research community and enhance or extend existing research capabilities and productivity.
- c) Plan for Sustainability: Describe plans to incorporate the Statistician-Awardee into future research projects, grant support, and any other local or regional/national CF research activities.
- d) The Local CF Clinical Research Environment: Review the local CF investigators and ongoing or planned clinical research projects. Highlight areas of need or opportunity for additional biostatistical support. This information should be provided regardless of whether the CF clinical investigator or Statistician-Awardee apply as the Institutional Awardee for the grant.

Budget Justification

Describe costs listed in the Budget Detail. Use major categories, such as Salary & Benefits, Consultant Costs, Major Equipment, etc. Justify all items and make sure amounts and figures listed in the narrative are consistent with those listed in the Budget Detail. For Salary and Benefits, if choosing to allocate 20% of the applicant's salary to support staff relevant to the work proposed to this program, clearly explain why this is being requested.

Biographical Sketches of Key Personnel (template available for download)

Complete and upload an NIH Biographical Sketch for all key project personnel, beginning with the applicant/PI (CFF defines "key project 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 an "Other Support" form, for all key project personnel, beginning with the applicant/PI. There is no page limitation.

Appendices (upload materials as PDF documents)

Appendices are restricted to the following two (2) categories:

- Up to three (3) reprints of the applicant's work relating to the general area of research in the proposal
- Other materials pertinent to the proposal, not already described

***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.

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

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

Validation and Submission

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

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

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

XI. Other Information

Not applicable to this RFA

XII. Contact Information

The CFF Grants and Contracts Office Hours of Support: Monday through Friday, 8:30AM – 5:00PM EST

For technical support and program/content information:

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

For scientific questions:

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

XIII. Electronic Application Checklist

LOI Submission Deadline: Tuesday, March 15, 2022 at 5:00 PM (EST)

Full Application Deadline: Thursday, June 9, 2022 at 5:00 PM (EST)

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

LETTER OF INTENT

- LOI Project Description - (upload)
- Biographical Sketch(es) of Key Personnel – (upload)

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)

Research Plan, Supporting Documents and Appendix:

- Proposed Plan - (upload)
 - Statistician-Awardee Applicant
 - Significance of Award
 - Plan for Sustainability
 - The Local CF Clinical Research Environment
- Budget Detail for each year - (upload)
- Budget Justification for each year - (upload)
- Biographical Sketch(es) of Key Personnel - (upload)
- Other Support for all key personnel (NIH Format) - (upload)
- Verification of Applicant Institution's Tax Status - (upload)
 - W-9
 - 501(c)3, IRS Form 147C or equivalent tax status letter