



CYSTIC FIBROSIS FOUNDATION

CF Statistical Expertise and Network (CF StatNet) Award

POLICIES AND GUIDELINES

Published: June 1, 2018

Full Application Deadline: July 6, 2018

I. ABOUT THE CYSTIC FIBROSIS FOUNDATION

The mission of the Cystic Fibrosis Foundation (CFF) is to cure cystic fibrosis (CF) and to provide all people with the disease the opportunity to lead full, productive lives by funding research and drug development, promoting individualized treatment, and ensuring access to high-quality, specialized care.

II. STATISTICAL EXPERTISE AND NETWORK (CF StatNet) 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) each year, and quarterly 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.

General Guidelines and Eligibility

- Applications will be accepted from individuals at domestic academic institutions that are CF accredited Therapeutic Development Centers (TDCs).
- All 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).
- This program provides salary support at a maximum of 35% effort, and travel for meetings. Indirect costs are not allowed on this award.
 - 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 \$189,600. Salaries may be supplemented by the applicant institution.

Institutional Awardee (Principal Investigator or PI) should:

- Have a faculty appointment at a domestic academic institution affiliated with an accredited CF Therapeutics Development Center (TDC)
- Be engaged in CF clinical research
- 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. If naming a Statistician-Awardee, the PI must commit a minimum of 0.5% effort, with a \$0 salary request to support the statistician on the award.

Statistician-Awardee should:

- Have a master's degree or higher in statistics, 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
- Be able to attend the North American Cystic Fibrosis Conference (NACFC) and an additional two-day meeting of biostatisticians and epidemiologists in Seattle, WA each year of the award.
 - NACFC for each year awarded
 - October 18-20, 2018 in Denver, CO
 - October 31, 2019 to November 2, 2019 in Nashville, TN
 - October 22-24, 2020 in Phoenix, AZ
 - TDNCC/University of Washington Biostatistical and Epidemiology Meeting for each year awarded
 - July 25-26, 2019 in Seattle, WA
 - July 23-24, 2020 in Seattle, WA
 - 2021 dates - TBD

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 original candidate. 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 does not fund effort of the Institutional-Awardee (unless the applicant/PI is also serving as the Statistician-Awardee).

Minimum Requirements

Statistician-Awardees must provide quarterly one-page progress reports to the CF StatNet Director and make every effort to participate in quarterly teleconferences/webinars throughout the funding period. 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. 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

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.

IV. SUBMISSION INFORMATION AND GENERAL TIMELINE

Submit application online at proposalCENTRAL: <https://proposalcentral.altum.com/>
(Refer to Section V and Section VI of these guidelines for specific submission instructions)

An application will be considered incomplete if it fails to comply with the instructions, or if the submitted material is insufficient to permit adequate review. CFF reviews applications electronically, and only documents submitted online at proposalCENTRAL will be reviewed. Late applications will not be accepted, and the deadline will not be waived.

General Timeline

Application Submission Deadline	_____	July 6, 2018
Review by CF StatNet Committee	_____	August 2018
Notification to Applicants	_____	August 2018
Earliest Award Start Date	_____	September 1, 2018

V. APPLICATION SUBMISSION GUIDELINES

Application Submission Deadline: Friday, July 6, 2018 at 5:00 PM (ET)

Applications must be submitted online at proposalCENTRAL: <http://proposalcentral.altum.com/>

Documents should be typed using:

- Times New Roman or Arial 11 font
- Margins: No less than a half inch on each side
- Numbering: Each section should be numbered individually

Note: When all the documents have been uploaded to proposalCENTRAL, the system will compile them into a single PDF file in the correct sequence as shown in Section VI. ELECTRONIC APPLICATION CHECKLIST. Page numbering is not necessary for all uploaded templates except as noted in the instructions for specific templates in this section.

Log-in at proposalCENTRAL: <https://proposalcentral.altum.com/>

First-time applicants must register to create a user name and password for proposalCENTRAL and will need to complete a profile online before applying. If you are already registered and cannot remember your password, click on the **“Forgot Your Username/Password?”** link below the **“Application Login”** fields. *Note: Use the Customer Service link on the top right of each screen as needed.*

Grant and award opportunities, including this program, are listed on the opening screen, but you must be logged in to see them.

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

Click on the light blue **“Filter by Grant Maker”** button to the left and scroll down to locate **Cystic Fibrosis Foundation Therapeutics** in the list.

Locate the listing for the **“Statistical Expertise and Network (CF StatNet) Award”** program. Click on the **“Apply Now”** button in the column on the far right to open the application.

Applicants may stop at any point but must click the **“Save”** button before exiting in order to save their work. When logging in to continue, click on the blue tab, **“Manage Proposals”**, and then the **“Edit”** button.

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

1. **Title Page:** Enter the title of your project and click **“Save”**.
2. **Download Templates & Instructions:** Download the available template(s), complete and upload as PDF documents in Section #8. Templates available include: Proposed Plan, Budget

Detail, Budget Justification, Biographical Sketch(es) of Key Personnel, Other Support, and Names and Addresses of References.

3. **Enable Other User to Access this Proposal:** Complete this section online if you wish to designate access to another individual, such as an assistant who has registered on proposalCENTRAL. Enter the email address of the individual and in the “**Permissions**” column, use the pulldown menu to select the type of access you wish to give. Please note that only delegates who are granted “**Administrator**” rights can submit applications on behalf of the applicant. Check the “**Auto Notify**” box and then “**Save**”.
4. **Applicant/PI:** If a profile was completed upon registration, the fields in this section will already be populated with the information entered in your Professional Profile. If you need to make any changes, click the “**Edit Professional Profile**” button and follow the instructions. If a profile was not completed, enter the information in the required fields and click “**Save**”.
5. **Institution:** If a profile was completed upon registration, the Principal Investigator’s (PI) institution will be preloaded as Lead Institution. If a profile was not completed, enter the required information and click “**Save**”. Be sure to use the full legal name of the institution.
6. **Letters of Reference/Support:** Letters of Reference and/or Support are weighted heavily during the review. At least two (2) letters are required. Letters must be submitted by the following individuals:
 - **Supervisor or senior colleague:** describes the applicant’s qualifications/expertise and the environment that would support the applicant’s collaboration with the CF Clinical Research individual(s).
 - **Local CF clinical investigator(s):** describe the proposed projects that the applicant would work on and the collaboration.

Enter the email addresses of the individuals who will be asked to submit Letters of Reference for the applicant. Automated emails (with instructions) will be sent to each Referee through the proposalCENTRAL website. **The letters must be uploaded by the referees prior to submitting the application, preferably one (1) week before the application deadline.** Additionally, applicants must complete the “Names and Addresses of References” template and upload it in Section #8.

Note: Detailed Instructions on how to invite referees to submit the letters of reference are also available in a downloadable document found in Section #2. Letters uploaded to proposalCENTRAL 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.

7. **Budget Summary:** Fill in the start and end date and applicable amounts for the support requested by completing the applicable online fields (Period 1, Period 2, Period 3). The total budget requested cannot exceed 35% effort of the NIH salary cap \$189,600 plus fringe benefits, plus an additional \$3,000 stipend travel expenditures per person per year.
Note: The Budget Detail template and Budget Justification template downloaded in Section #2 must be completed and uploaded in Section #8 for each year of funding being requested.

- 8. Proposed Plan & Supporting Documents:** In this section, upload the completed templates downloaded in Section #2 above. Fill out the fields describing the attachment, select the attachment type from the pull-down menu, choose the file to be uploaded, and click the **“Upload Attachment”** button to upload the file. Do this for each attachment.

Below are instructions specific to each template as well as additional information regarding other application components.

A. Proposed 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 candidate statistician apply as the institutional awardee for the grant.

B. Budget Detail and Budget Justification (separate templates available for download)

Fill out the Budget Detail and Budget Justification templates individually for each year of support requested. In the space provided on the templates, indicate the year as well as start and end dates for the proposed budget period. (Be sure the amounts entered in the Budget Detail(s) match the amounts in the online budget summary in Section #7).

- **Budget Detail – Direct Costs Only**
Personnel - List the name and position of the person involved in the project. 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, the institutional base salary of an individual may not exceed the current federal salary cap of \$189,600. The total budget requested cannot exceed 35% effort of the \$189,600 salary cap plus fringe benefits and \$3,000 for travel expenditures per year. 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 – Funds may be requested for award-related travel costs for the following:

- NACFC for each year awarded
 - October 18-20, 2018 in Denver, CO
 - October 31st to November 2, 2019 in Nashville, TN
 - October 22-24, 2020 in Phoenix, AZ
- TDNCC/University of Washington Biostatistical and Epidemiology Meeting for each year awarded
 - July 25-26, 2019 in Seattle, WA
 - July 23-24, 2020 in Seattle, WA

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.”

Note: expenses for travel outside the North American continent, including travel to Hawaii, Puerto Rico, and other U.S. territories are not allowable expenses without prior written approval from the CFF Grants and Contracts Office.

Other Expenses – Other expenses may include NACFC conference registration fees. *Indirect costs are not an allowable cost for this award.*

• **Budget Justification**

Describe costs listed in the Budget Detail. Use major categories, such as Personnel, Travel, etc. Justify all items and make sure amounts and figures listed in the narrative are consistent with those listed in the Budget Detail(s).

C. Biographical Sketches of Key Personnel (template available for download)

Complete and upload an NIH Biographical Sketch for all key project personnel, beginning with the Principal Investigator. (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.

D. Other Support (template available for download)

Complete and upload an “Other Support” form, for the statistician awardee. There is no page limitation.

E. Names and Addresses of References and/or Letters of Support (template available for download)

List the names, titles, and contact information of the individuals who have been asked to

submit Letters of Reference on the applicant's behalf. A PDF copy of the completed form should be uploaded. Though not required to submit Letters of Reference, Senior investigators should still check the box in the template that identifies them as Senior investigators and upload the form to proposalCENTRAL.

F. Verification of Applicant's Tax Status (upload as PDF document)


The 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 Form 147C, or other documentation verifying the organization's Federal tax status. Awards are not issued prior to having these documents on file with the Grants and Contracts Office.

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

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

13. Print Face Pages: Follow the prompts on the screen to generate and print a face page. The Face Page will be populated automatically with data entered in the online application (applicant's name, institution, title of application, etc.). The Face Page must be signed by the Principal Investigator and Authorized Institutional Official. Co-Principal Investigators, if any, are not expected to sign the Face Page. **Scan and email the signed Face Page to grants@cff.org in conjunction with the application submission on proposalCENTRAL.** No hardcopy is required.

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

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

For technical support with the online application:

proposalCENTRAL at pcsupport@altum.com or
800-875-2562 on weekdays, 8:00 a.m. to 5:00 p.m. (Eastern)

For program/content information:

CFF Grants and Contracts at grants@cff.org or 301-841-2614

VI. ELECTRONIC APPLICATION CHECKLIST

Application Submission Deadline: Friday, July 6, 2018 at 5:00 PM (ET)

Applications must be submitted online at proposalCENTRAL: <http://proposalcentral.altum.com/>

A PDF copy of the signed Face Page should be emailed to CFF (grants@cff.org) by the same date. The complete application must be submitted online, and no other documents will be reviewed.

Face Page which includes:

- Principal Investigator (Co-PI's are not required to sign)
 - 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)

Proposed Plan & Supporting Documents:

- Abstracts/Relevance – (complete online)
- 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, NIH format – (upload)
- Names and Addresses of References – (referees will upload)
- Verification of Applicant Institution's Tax Status – (upload)
 - W-9 (signed and dated within the last three years)
 - 501c(3) or equivalent IRS tax status letter