



Program Name: Clinical Research Scholars Program (CRSP) Award 2020

Brief Program Overview/Description: The Cystic Fibrosis Foundation (CFF) and the Therapeutics Development Network (TDN) announce the Cystic Fibrosis Clinical Research Scholars Program (CRSP) Award. The CRSP Award will enable outstanding early-career pediatricians and internists to enhance their clinical research proficiency and develop the necessary clinical research capabilities to become independent investigators who formulate and lead multi-center, clinical research studies.

Funding Amount: Individual Salary support requested may not exceed 20% of the NIH salary cap (currently \$197,300) and is limited to \$39,460 per year, for up to three years. In addition, the award will cover institutional fringe benefits for the salary, as well as travel for each year as outlined in Section III below.

Eligibility:

- Candidates must be U.S. citizens or U.S. permanent residents (must have obtained permanent residency prior to the time of application). Applicants must be an investigator at a domestic academic institution.
- Mentor – each applicant must identify a primary Academic Mentor from their home institution who is recognized as a physician-scientist with experience in training independent investigators, and who will provide guidance for the awardee's clinical and research development. The primary Academic Mentor must be committed to continue this involvement through the individual's total period of training
- Awardees are expected to submit informal progress reports to their Academic Mentor throughout the project period. Reports are required monthly during Year 1 and at a mutually agreed upon frequency for years 2 and 3.

Key Dates:

Published	January 31, 2020 – Updated May 13, 2020
LOI Submission Deadline	February 28, 2020
LOI Applicant Notified	Late-March 2020
Full Application Deadline	May 21, 2020
Committee Review Date	Mid-June 2020
Notification to Applicants	Early-July 2020
Project Start Date	November 1, 2020

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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.

II. Program and Award Overview

The Cystic Fibrosis Foundation (CFF) and the Therapeutics Development Network (TDN) announce the Cystic Fibrosis Clinical Research Scholars Program (CRSP) Award. The CRSP Award will enable outstanding early-career pediatricians and internists to enhance their clinical research proficiency and develop the necessary clinical research capabilities to become independent investigators who formulate and lead multi-center, clinical research studies.

Awards will provide early-career faculty the opportunity to undertake up to three years of support (up to 20% FTE per year) for their clinical research training. This dedicated time will be used for career development with a focus on the initiation and management of multi-center clinical investigations, including observational, translational and interventional clinical research.

- **Year 1** – The first year of the program will consist of hands-on, in-person clinical research training at the TDN Coordinating Center in Seattle, Washington, as well as an interactive, distance-training period at the applicant's home institution with mentorship by a program mentor and an academic institution mentor from the investigator's home institution. Components of the program may include serving as a member of the TDN Protocol Review Committee, writing or rewriting the applicant's research proposal to meet TDN protocol standards and developing study materials, conducting a secondary data analysis project (optional), participating in monthly calls with the mentorship team, and presenting the applicant's work at a research seminar during the first week in Seattle.
- **Years 2 and 3** – The second and third years of the program will provide the opportunity to further develop skills in multi-center clinical research by continuing the work started in year 1 along with continued mentorship by program and academic institution mentors. Additionally, in the second and third years, applicants may have a continued role on the TDN Protocol Review Committee, continue to participate in monthly calls with mentor team, and have exposure to other facets of TDN multi-center clinical research such as the CFF DSMB and consulting with industry partners. Additionally, in years two or three, applicants may have the opportunity to participate as a reviewer on the CFF Clinical Research Committee or Physician Training Committee.

Program Learning Objectives:

- Provide early career investigator applicants with rigorous training in the operational aspects of conducting multi-center CF clinical trials.
- Provide mentorship for project development in conjunction with the applicant's home institution.
- Give applicants training in regulatory aspects of drug development and clinical trial conduct.
- Give applicants experience in developing a formal protocol and study materials for a multi-center CF clinical trial.
- Provide applicants with insight regarding common statistical issues and clinical trial design components critical to successful multi-center CF clinical trials.
- Give each applicant the opportunity to do secondary analysis of data held in the CFF TDN Coordinating Center data repository in support of their research goals.
- Provide support to translate the applicant's project into a presentation, publication, or multi-center grant application.
- Provide applicants with the opportunity to serve on the Protocol Review Committee (PRC) during the program.

Requirements:

- Awardees are expected to submit informal progress reports to their Academic Mentor throughout the project period. Reports are required monthly during Year 1 and at a mutually agreed upon frequency for years 2 and 3.
- Duration and Effort – this is a non-renewable award for up to three years of salary support. All funds must be used on behalf of the original applicant. Support is divided into three distinct years that relate to the individual's progress in becoming an independent investigator. Awardees are required to devote 20% effort to research and the Clinical Research Scholars Program throughout the entire project period. This award does not serve to fund the research project itself, but rather protect the awardee's time for career development in multi-center clinical research. Further, if receiving this CRSP award will put the applicant's current effort over 100%, a statement on how the effort will be adjusted to a maximum of 100%, while meeting the requirements of this program, is required.
- Minimum Requirements - Awardees must agree to inform the CFF annually for a period of five years subsequent to completion of the award about academic status, publications, and research grants or contracts received. In addition, all awardees and institutions must comply with CFF award policies and Terms and Conditions of Award.

III. Funding Amount

- Individual Salary support requested may not exceed 20% of the NIH salary cap (currently \$197,300) and is limited to \$39,460 per year, for up to three years. In addition, the award will cover institutional fringe benefits for the salary.
- Travel Support may be requested for each year as follows (registration costs associated with the below meetings are part of the funding allotments, but should be listed under "Other Expenses" in the Budget Detail template):
 - **Year 1** (*up to \$10,000 may be requested*)
 - TDNCC Practicum in Seattle, WA
 - Week 1: November 16-20, 2020
 - Week 2: July 21-22, 2021
 - 2021 TDN Spring meeting – date and location TBD
 - 2021 NACFC meeting, September 30 – October 2, 2021 San Antonio, TX
 - Additional in-person meeting with TDNCC Mentor in Seattle, WA
 - **Year 2** (*up to \$5,000 may be requested*)
 - 2022 TDN Spring meeting – date and location TBD
 - 2022 NACFC meeting – date and location TBD
 - TDNCC in-person meeting with TDNCC Mentor in Seattle, WA
 - **Year 3** (*up to \$3,000 may be requested*)
 - 2023 TDN Spring meeting – date and location TBD
 - 2023 NACFC meeting – date and location TBD

Allowable costs include:

- Salary and fringe benefits
- Travel

Indirect Costs are not allowed

IV. Eligibility

- Candidates must be U.S. citizens or U.S. permanent residents (must have obtained permanent residency prior to the time of application). Applicants must be an investigator at a domestic academic institution.
- Environment – applications will be accepted from applicants at domestic academic institutions with:
 - A strong, established CF-related research and clinical training program.

- A commitment from senior faculty at the applicant's home institution with the capability to provide guidance and mentorship to applicants in the development of independent careers as cystic fibrosis researchers and clinicians.
- Awardees are expected to submit informal progress reports to their Academic Mentor throughout the project period. Reports are required monthly during Year 1 and at a mutually agreed upon frequency for Years 2 and 3.
- Applicants eligible for the program must have completed specialty fellowship training (as an MD or DO) and have an academic faculty appointment at their home institution at the time of application. Priority will be given to early career faculty who are within 7 to 10 years of completing their fellowship training. In some cases, consideration will be given to mid-career faculty who are making a transition in their career/research focus and for which this program would provide the training necessary to lead multi-center clinical research studies.
- Prospective applicants will need to demonstrate sufficient commitment to and experience in CF clinical research to support the rationale for participating in this program at this time in their career. The optimal applicant will be one who has an ongoing or upcoming single-center clinical research study or trial that can be directly applied to program objectives.
- Applicants with other career development awards should assess the compatibility of this program with the stipulations of those awards (e.g. K-awards, others). Current recipients of other CFF Fellowship awards (e.g., Shwachman or Leroy Matthews) may submit an LOI and will be considered on a case by case basis.
- A limited number of scholars are accepted each year. The scholars will begin the program at the same time and will together attend two one-week sessions based at the CFF TDNCC (in Seattle, WA).
- Prospective applicants will be required to outline a mentorship plan and identify mentor(s) at their home institution who will continue in this role after they complete the program. Ideally, a mentor (or mentors) along with a mentorship plan will have been in place before applicants apply and program participation begins.

V. Mentorship Requirements

- Mentor – each applicant must identify a primary Academic Mentor from their home institution who is recognized as a physician-scientist with experience in training independent investigators, and who will provide guidance for the awardee's clinical and research development. The primary Academic Mentor must be committed to continue this involvement through the individual's total period of training (Years 1-3) under the award.

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

Areas of Encouragement

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 are particularly encouraged:

1. Respiratory Microorganism Detection and Treatment
2. Gastrointestinal symptoms (including, but not limited to, GERD, DIOS, and Pancreatitis)
3. Reducing Treatment Burden
4. CF-related Diabetes
5. Diet and Nutrition
6. Mental Health
7. CF-related Liver Disease (including cirrhosis and non-cirrhosis, gall stones, hepatic steatosis, and other clinical manifestations of portal hypertension)
8. Exercise

9. Sinus Disease
10. Allergies and Asthma in CF
11. Alternative/Holistic Treatments and Therapies
12. Sexual Reproductive Health
13. Bone/Joint Health
14. Pain Management

VII. Review and Award

The CRSP Application Review Committee will evaluate all application 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 each application, and the committee recommendations when determining awards. The below review criteria are utilized for the CRSP proposal:

CRSP Proposal Review Criteria

- The Applicant
 - Competence in clinical activities and potential for a career in multi-center clinical research
 - Commitment to a research career related to CF
- The Mentor
 - Accomplishments in clinical research related to CF
 - Commitment of the primary Academic Mentor for the duration of the applicant's development and research plan
 - Experience of the Academic Mentor in training individuals for multi-center clinical research
- The Environment
 - Presence in the institution of highly trained faculty in clinical research related to CF
 - Institution's CF research and research training programs
 - Institution's commitment and ability to provide the opportunities necessary for the clinical and research career development related to CF
 - Institution's commitment to the applicant's overall career development
- Applicant Project Proposal
 - Feasibility and value of the proposed plan
 - Clinical research merit of the proposed research
 - Ability of the proposed plan to develop the applicant into a multi-center clinical research investigator
 - Relationship to the applicant's career development

Payments

Payments for successful proposals are made quarterly in arrears to the Awardee Institution and not to the individual Awardee. Payments are subject to various contingencies, such as a Signed Assurances, Progress Report and Financial Reporting.

VIII. Submission Information

A Letter of Intent (LOI) must be submitted and approved prior to submitting a Full Application

Submit online through proposalCENTRAL: <https://proposalcentral.com/>
(Refer to Section X of these guidelines for specific submission instructions)

An application will be considered incomplete if it fails to comply with the instructions, or if the submitted material is insufficient to permit adequate review. CFF reviews applications electronically, and only documents submitted online at proposalCENTRAL will be reviewed.

General Timeline:

LOI Submission Deadline _____	February 28, 2020
LOI Review by CRSP Committee _____	Late-March 2020
LOI Applicant Notified _____	Late-March 2020
Full Application Deadline _____	May 21, 2020
Review by CRSP Committee _____	Late-June 2020
Notification to Applicants _____	Early-July 2020
Award Start Date _____	November 1, 2020
Face-to-Face Meetings at TDNCC in Seattle, WA _____	November 16-20, 2020 and July 19-22, 2021

IX. Letter of Intent Guidelines

LOIs Submission Deadline: Friday, February 28, 2020 at 5:00 PM (EST)

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

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 proposalCENTRAL 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

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

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

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

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

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

Locate the listing for the **“Clinical Research Scholars Program with LOI”** program. Click on the **“Apply Now”** button in the column on the far right to open the application form.

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

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

1. **Title Page:** Enter the title of your project and indicate whether this is a new LOI or a resubmission of an earlier version.
2. **Download Templates & Instructions:** Download the available templates applicable to the project, fill them out and upload them when completed in Section #6. Templates available include:
 - LOI Cover Sheet
 - LOI Project Description
 - Biographical Sketch(es) of Key Personnel.
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 applicant’s/PI’s 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. **Attachments:** Complete the templates downloaded from Section #2 and upload them here as PDF documents. Below are instructions specific to each template.
 - A. **LOI Cover Sheet (template available for download)**

The Principal Investigator and Academic Mentor are required to sign where indicated. The Awardee Institution’s Authorized Institutional Official’s signature is not required for the LOI.
 - B. **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 CRSP Award, and how this award will help the applicant meet his/her career goals.
 2. A description of the applicant’s and mentor’s working relationship, and the applicant’s qualifications to conduct the proposed project.
 3. A brief description of the proposed study or research plan.
 - C. **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.
7. **Validate:** Upon completing your LOI, click on the “Validate” button on the main screen. Attend to any omissions/errors as prompted onscreen, and then click “Validate” again.
8. **Submit:** Click on the blue button with white lettering. CFF will not receive your application unless the “Submit” button is clicked.

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

X. Full Application Guidelines

Full Application Deadline: Thursday, May 21, 2020 at 5:00 PM (EST)

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

Documents should be typed using:

- Font: Times New Roman 12 or Arial 11
- Margins: No less than a half inch on each side

Note: *When all the documents have been uploaded to proposalCENTRAL, the system will compile them into a single PDF file in the correct sequence as shown in Section XIII. ELECTRONIC APPLICATION CHECKLIST.*

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

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

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

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

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

Locate the listing for the “**Clinical Research Scholars Program with LOI**” program. Click on the “**Apply Now**” button in the column on the far right to open the application form.

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

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

1. **Title Page:** Enter the title of your project, indicate whether this is a new LOI or a resubmission of an earlier version, and respond to the additional questions listed.
2. **Download Templates & Instructions:** Download the templates applicable to the project, fill them out and upload them in Section #9. Templates available include:
 - Project Proposal/Research Plan
 - Budget Detail
 - Budget Justification
 - Biographical Sketches of Key Personnel
 - Other Support
 - Names and Addresses of References

- CF-Related Activities of the Academic Mentor and Applicant Institution
 - Previous Training and Future Plans
 - Future Career Goals
3. **Enable Other User to Access this Proposal:** Complete this section online if you wish to designate access to another individual, such as an assistant who has registered on proposalCENTRAL. Enter the email address of the individual and in the “Permissions” column, use the pulldown menu to select the type of access you wish to give. Please note that only delegates who are granted “Administrator” rights can submit applications on behalf of the applicant. Click on “Accept Changes”.
 4. **Applicant/PI:** If a profile was completed upon registration, the fields in this section will already be populated with the information entered in your Professional Profile. If you need to make any changes, click the “Edit Professional Profile” button and follow the instructions. If a profile was not completed, enter the required information and click “Save”.
 5. **Institution & Contacts:** If a profile was completed upon registration, the Principal Investigator’s (PI) institution will be preloaded as Lead Institution. If a profile was not completed, enter the required information and click “Save”. Be sure to use the full legal name of the institution.
 6. **Letters of Support/Reference:** Letters of Support and Reference are weighted heavily in the review. At least four (4) letters are required. Letters must be submitted by the following individuals:
 - **Academic Mentor(s) for this applicant**
 - **The Chair of the applicant’s department at the applicant institution.**
Letters from the Academic Mentor and the Department Chair should clearly describe the Institution’s commitment to the professional growth of the applicant. The Chair’s letter must affirm a commitment to protect the applicant’s time for program activities, including travel to meetings required for this award.
 - **CF Center Director**
The CF Center Director at the applicant institution (or nearby) institution (if the same person as the Academic Mentor, there is no need to submit duplicates).
 - **At least one (1) other individual familiar with the applicant’s scientific interests and abilities**
These individuals must be familiar with the applicant’s CF-related research and care; consider including previous preceptors and mentors. The letter of recommendation should attest to the applicant’s academic qualifications, motivation, research potential and commitment to CF related research and care.

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 #9 in proposalCENTRAL.

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. **Abstracts/Relevance:** In the space provided online for abstracts, provide a statement of no more than 250 words (up to 2,000 characters max, 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:** Provide a statement of no more than 250 words (up to 2,000 characters max, 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. 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 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.

8. **Budget Summary:** Fill in the start and end date and applicable amounts for each year of support requested by completing the online fields (Period 1, 2, 3). A separate budget must be completed for each year of funding requested. All Clinical Research Scholars Program awards are for a maximum of three (3) years. **Note: The Budget Detail template and Budget Justification template downloaded in Section #2 must be completed and uploaded in Section #9 in proposalCENTRAL for each year of the award. The amounts included in this uploaded Budget Detail must match the amounts entered in the Budget Summary online.**
9. **Research Plan & Supporting Documents:** In this section, upload the completed templates downloaded in Section #2 above in PDF format. Fill out the fields describing the attachment, select the attachment type from the pulldown menu, 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. Project Proposal/Research Plan (template available for download)

- Key figures and legends must be included in the Research Plan. If uploaded as Appendices, they will NOT be reviewed.
 - At the top of each page, type the applicant’s/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. **Hypothesis and Specific Aims:** State concisely and realistically the intent of the proposed research and the hypothesis to be tested. The specific aims should be relevant to the mission of the Cystic Fibrosis Foundation. Do not exceed one page.
- b. **Background and Significance:** Briefly describe the background of the present proposal. Critically evaluate existing knowledge and specifically identify the gaps that the project is intended to fill. Concisely state the importance and rationale of this research by relating the specific aims to longer-term objectives. This section should also show the potential

importance of the proposed work to CF. In addition, the applicant should describe the relationship of the proposed work to his/her long-term career goals. Description of how the CRSP participation builds off of on-going research efforts is encouraged. Note: This award does not include support for research costs. Preference will be given to those applicants who have expressed an interest in a long-term career in leading CF multi-center clinical research.

- c. **Preliminary Results:** If applicable, provide a detailed discussion of any preliminary results.
- d. **Experimental Design and Methods:** As described in the introduction, the optimal applicant will be one who has an ongoing or upcoming single-center clinical research study or trial that can be directly applied to program objectives. Provide a detailed discussion of the ongoing or proposed clinical research study design, and methods to be used to accomplish the specific aims. Describe the protocols, including methods for new techniques, and explain potential advantages over existing methodologies. If applicable, discuss the data expected to be obtained and the means by which data will be analyzed and interpreted. Provide details of the methods for patient selection and care, as applicable. Discuss potential difficulties and/or limitations of the proposed procedures and alternative approaches to achieve aims. As applicable, please specify facets of the project that are clearly defined and those that need further development.
- e. **Benefit of this training award toward successful completion of the planned research:** As noted above, it is important to explain how this unique support and training opportunity will directly advance the research project of the applicant. This is separate from considerations of career development in CF. Please address this consideration either as a separate section or as part of sections above when discussing the experimental hypothesis, specific aims, design and methods. Note that the protected effort provided by the CRSP award is not intended to provide enough time to complete a research project but rather is designed to allow protected effort for *additional* training and program participation to enhance the project and career success of the scholar. For example, the CRSP award may critically support a research project by helping the investigator to: refine a study hypothesis, identify appropriate outcome measures, better understand and defend study inclusion and exclusion criteria, refine sample randomization scheme, study time-line, or procedures, improve measures of compliance, ascertainment of response variables, data collection and monitoring, and/or refine data analysis and statistical procedures for your hypothesis testing.
- f. **Literature Cited** (not included in the five (5) page limit): 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).

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

Fill out a separate Budget Detail and Budget Justification for each year of support requested. In the space provided on each page, indicate the year or period as well as start and end dates for the proposed budget period.

Be sure the Budget Detail matches the online budget summary in Section #8.

- **Budget Detail – Direct Costs**
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 \$197,300. 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 – Funds may be requested for award-related travel costs. Awardees are required to attend CRSP face-to-face meetings in Seattle, WA, the annual North American CF Conference (NACFC), and the TDN Spring Meeting (see Section III. above for the schedule of required meetings). Registration fees associated with conferences should be listed under “Other Expenses” and are part of the per year travel support allotment.

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

- **Budget Detail – Indirect Costs**

Indirect costs are not allowable.

- **Budget Justification**

Describe costs listed in the Budget Detail. Use major categories, such as Personnel, Consultant Costs, Equipment, etc.

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 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.

D. 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.

E. Names and Addresses of References (template available for download)

List the names, titles, and contact information of the individuals who have been asked to submit Letters of Reference/Support on the applicant’s behalf. A PDF copy of the completed form should be uploaded.

F. CF-Related Activities of the Academic Mentor and Applicant Institution (template available for download)

Describe fully the CF related clinical and research activities of the applicant institution. The Academic Mentor and the applicant institution should also include a list of their previous trainees (past 10 years) and the current affiliations of these trainees.

G. Previous Training and Future Plans (template available for download)

Prepare a brief summary of the applicant’s previous research and/or clinical fellowship training, including the reasons for entering fields related to CF research and care. In conjunction with the Academic Mentor, a future training plan should be completed in and should outline the general plan for training the applicant in CF-related research. Participation in supplemental course work and special seminars should be included. Further, this section should clearly indicate plans for introducing the applicant to leading multi-center clinical research. Do not exceed two (2) pages.

H. Future Career Goals (template available for download)

Prepare a brief summary of the applicant’s intended future career goals. This section should specifically describe how this training award will help the applicant meet their career goal of becoming an independent multi-center clinical research investigator. Do not exceed one (1) page.

I. Verification of the 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 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 CFF Grants and Contracts Office.

J. Appendices (upload materials as PDF documents)

Appendices are restricted to the following three (3) categories:


- Proposed Protocol (if applicable)
- 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**

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

11. Print Face Pages: Follow the prompts on the screen to generate and print a Face Page. The Face Page will be populated automatically with data entered in the online application (applicant’s name, institution, title of application, etc.). The Face Page must be signed by the Principal Investigator and Authorized Institutional Official and uploaded in Section #7. Co-Principal Investigators, if any, are not expected to sign the Face Page.

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

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

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

XI. Other Information

Not applicable to this RFA

XII. Contact Information

For technical support with the online application:

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

For program/content information:

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

XIII. Electronic Application Checklist

LOI Submission Deadline: Friday, February 28, 2020 at 5:00 PM (EST)

Full Application Deadline: Thursday, May 21, 2020 at 5:00 PM (EST)

Application must be submitted online at proposalCENTRAL: <https://proposalcentral.com/>

LETTER OF INTENT

- Signed LOI Cover Sheet (upload)
- 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)

Project Proposal/Research Plan & Supporting Documents

- Project Proposal/Research Plan (upload)
 - Hypothesis and Specific Aims
 - Background and Significance
 - Preliminary Results
 - Experimental Design and Methods
 - Benefit of this training award toward successful completion of the planned research
 - Literature Cited (not included in Research Plan page limitation)
- Budget Detail individually for each year requested (upload)
- Budget Justification individually for each year requested (upload)
- NIH Biographical Sketch of Key Personnel (upload)
- Other Support for all key personnel (upload)
- Names and Address of References (upload)
- CF-Related Activities of the Mentor and Applicant Institution (upload)
- Previous Training and Future Plans (upload)
- Future Career Goals (upload)
- Verification of the Applicant Institution's Tax Status (upload)
 - W-9 (US applicants) or W-8BEN-E (non-US applicants)
 - 501(c)3, IRS Form 147C or equivalent tax status letter
- Appendices (upload as PDF documents, if applicable)
 - Proposed Protocol
 - 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