CYSTIC FIBROSIS FOUNDATION

For application technical support, please contact ewarnke@cff.org

Program Name: 2025 Clinical Research Scholars Program (CRSP) Award

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 is designed to enable promising early/mid-career physician scientists to enhance their clinical research proficiency and support their development of the necessary leadership and clinical research capabilities to become independent investigators who formulate and lead multi-center, clinical research studies. Awardees are expected to submit informal progress reports to their Academic Mentor and the CRSP mentors throughout the project period.

Funding Amount: Individual Salary support requested may not exceed 20% of the NIH salary cap (currently $225,700 in FY 2025) and is limited to $45,140 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:

- U.S. citizens, U.S. permanent residents (must have obtained permanent residency prior to the time of application), and Canadian Citizens are welcome to apply.
- 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.
- Successful applicants have funded clinical research that have promise to extend to multi-center clinical investigations

Key Dates:

Published	January 27, 2025
LOI Submission Deadline	March 19, 2025
LOI Applicant Notified	April 2025
Full Application Deadline	June 18, 2025
Committee Review Date	July 2025
Notification to Applicants	Late-July/early-August 2025
Project Start Date	November 1, 2025

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*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 Management and Administration (GCMA) Office Team is able to assist all applicant with any potential system-related queries prior to the Application Deadline.

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.

Cystic fibrosis affects people of all racial and ethnic backgrounds. Diversity, equity, and inclusion (DEI) are core to our ability to make a meaningful difference in the lives of all people with CF. Improving the representation of people of color within the CF community – including those in the CF research workforce – and addressing health disparities that exist within these groups is critical to the Foundation's mission of serving all people with CF. Making clinical trial design and engagement more inclusive of people of color with CF will be critical for improving treatment options and health outcomes for these groups; as Black and Hispanic people with CF account for nearly 40 percent of individuals with rare mutations that are not candidates for available treatments addressing the underlying cause of the disease. As PIs prepare clinical research application materials, we strongly encourage the consideration of how to support inclusion of diverse participants, including plans for building trust with community members and ensure adequate recruitment of people from diverse backgrounds.

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 is designed to enable promising early/mid-career physician scientists to enhance their clinical research proficiency and support their development of the necessary leadership and clinical research capabilities to become independent investigators who formulate and lead multi-center, clinical research studies.

Awards will provide early/mid-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 prospective clinical investigations, including observational, translational and interventional clinical research, with the intention of growing these studies to multi-center efforts by the end of the CRSP award.

- **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 include serving as a member of the TDN Protocol Review Committee, participating in monthly calls with the mentorship team, and presenting the applicant's work at a research seminar while in Seattle. Work with mentors may include writing or revising an applicant's research proposal for a prospective, possibly multi-center study to meet TDN protocol standards and developing study materials. An optional opportunity to conduct a secondary data analysis project may be available.
- **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 and 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 and continue to participate in monthly calls with mentor team. In years two or three, applicants may be invited to participate as a reviewer on the CFF Clinical Research Committee or Physician Training Committee.

Program Learning Objectives:

- Provide early/mid career investigator applicants with rigorous training in the operational aspects of conducting prospective CF clinical studies, preparing them for the potential to participate in, conduct and lead multi-center trials.
- Provide mentorship for larger project development in conjunction with the applicant's home institution.

- Provide career development and leadership training focused on how to lead a team, how to manage conflict, and how to promote and advance a career in academic medicine
- 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 CF clinical study.
- Provide applicants with insight regarding common statistical issues and clinical study design components critical to successful CF clinical research.
- Give applicants (if they choose and resources allow) 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 grant application.
- Provide applicants with the opportunity to serve on the Protocol Review Committee (PRC), the CF Clinical Research Committee, or similar committees and/or workshops during the program.

Requirements:

- Awardees are expected to submit informal progress reports to their Academic Mentor and CRSP Mentors 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. 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, if possible, to the Clinical Research Scholars Program throughout the entire project period[1]. 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. If receiving this CRSP award will put the applicant's current effort over 100%, a statement on how the effort will be adjusted to ensure appropriate involvement in the 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 $225,700 FY 2025) and is limited to $45,140 per year, for up to three years. In addition, the award will cover institutional fringe benefits for the salary.
- If an applicant is a recipient of another career development award that protects at least 70% of their effort for research AND they are unable to commit an additional 20% effort to research for this award, the equivalent amount to 20% of the applicant's calculated base salary may be requested for salary to support staff relevant to the work proposed to this program (e.g. biostatistical support for the clinical study proposed).
  - Minimal Level of Effort required for the PI is 5%.
  - The remaining percentage of the PI's calculated base salary may be distributed among appropriate support staff. The total salary support may not exceed 20% of the PI's salary or $45,140.
  - Fringe may be applied separately in addition to these cost limitations.
- 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*)

[1] For applicants with career development awards at the time of application that demand >70% effort to research, the level of effort expectation for CRSP may be waived at the discretion of the CRSP team and program officer. Should this protected research time end during the CRSP award period, the awardee is expected to ensure at least 20% effort is dedicated to CRSP.

        - TDNCC Practicum in Seattle, WA
            - Week 1: December 2025
            - Week 2: July 2026
        - 2026 TDN Spring meeting – Gaylord Rockies in Denver, COApril 19-21, 2026
        - 2025 NACFC meeting – October 8-10, 2026, Atlanta, GA
        - TDNCC in-person meeting with TDNCC Mentor in Seattle, WA
    - **Year 2** (*up to $3,000 may be requested*)
    - **Year 3** (*up to $5,000 may be requested*)
        - 2027 NACFC meeting – November 4-6, 2027 San Antonio, TX
        - 2028 TDN Spring meeting – date and location TBA
        - 2028 NACFC meeting – date and location TBA

Due to restrictions on travel resulting from the COVID-19 pandemic, awardees may reallocate these expenses to relevant training costs upon approval by the CF Foundation Program Officer.

Allowable costs include:

- Salary and fringe benefits
- Travel

Indirect Costs are not allowed.

IV. Eligibility

- Applicants must be U.S. citizens or permanent residents (must have obtained permanent residency prior to the time of application). Canadian citizens or permanent residents are also welcome to apply.
- Environment – applications are encouraged from applicants at US or Canadian 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 researchers and clinicians.
- Applicants eligible for the program must have completed subspecialty 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/mid career faculty who are within 7 to 10 years of completing their subspecialty 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 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 is leading an ongoing or upcoming single-center clinical research study or trial that can be directly applied to program objectives and mentoring opportunity.
- Applicants with existing career development awards should assess the compatibility of this program with the stipulations of those awards (e.g. K-awards, others) and reach out to the Program Officer (eyu@cff.org) with questions.
- A very 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.
- Applicants must be from a non-profit or academic institution; for-profit entities are not eligible to apply. For-profit entities should visit Industry Funding Opportunities for more information.

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

Proposed research must be relevant to the CFF's mission and to the health and well-being of CF patients. Applicants are encouraged, but not required, to address a research priority outlined below, and in further detail on https://www.cff.org/key-research-priorities-applicants All applications are reviewed and scored not only on scientific merit but also on relevance to the CFF's mission.

Research Priorities:

- Treat the underlying cause of CF for all people with the disease and drive progress toward a cure. In particular, research related to **evaluating genetic-based therapies** that may have clinical impact for people with CF, developing therapies that address the **underlying cause of CF for individuals with nonsense and rare mutations**, and **improving and better understanding cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapies**.
- Understand the biological mechanisms of, and advance new and improved treatments to address the many complications of CF, including:
    - Mental health;
    - Infections affecting people with CF;
    - Inflammation, impaired airway hydration, and mucus clearance;
    - Serious complications of CF outside the lungs, such as GI complications (including in the liver, the pancreas, and the impact of nutritional deficiencies), endocrine system dysfunction (including CF related diabetes and CF bone disease);
    - Sinus disease;
    - Lung transplant and advanced lung disease;
    - Sexual and reproductive health – applicants with an existing hypothesis and interest in research in this space are encouraged to connect with the Sexual Health, Reproduction, and Gender Research (SHARING) Working Group for additional mentoring: Raksha Jain is the working group chair (Raksha.Jain@UTSouthwestern.edu), and Traci Kazmerski is the co-chair (Traci.Kazmerski@chp.edu).
- Characterize the best CF care and treatment regimens to provide optimal, individualized care as the CF treatment landscape evolves.
- Improve understanding of system-level and societal barriers to optimal CF care and explore opportunities to minimize their effects, including racial disparities and socioeconomic barriers to equitable care.
- Ensure that the CF care model adapts to meet the future needs of people with CF across their lifespan. This includes considerations for the aging CF population and the increasing utilization of remote care.
- Research related to biomarker or outcome measure development in support of research and development of genetic-based therapies

Funding priority will be placed on those projects that will lead to a better understanding of disease mechanisms, pathophysiology, and prevention, and treatment strategies.

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 becoming a leader in CF clinical research
  - Commitment to research related to CF and a career focused on clinical research
  - Existence of funded clinical research that has promise to extend to multi-center clinical investigations
- 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 clinical research or relevant translational science
- 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, including funding to conduct the work
  - Clinical research merit of the proposed research and an ability to use this to facilitate the training and mentoring goals of this program
  - Ability of the proposed plan to develop the applicant into a 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. 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:

Published	January 27, 2025
LOI Submission Deadline	March 19, 2025
LOI Applicant Notified	Mid-April 2025
Full Application Deadline	June 18, 2025
Committee Review Date	July 2025
Notification to Applicants	Late-July/Early August 2025
Project Start Date	November 1, 2025

*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 Management and Administration (GCMA) Office is able to assist all applicant with any potential system-related queries prior to the Application Deadline.

IX. Letter of Intent Guidelines

LOIs Submission Deadline: Wednesday, March 19, 2025 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 "**2025 Clinical Research Scholars Program with LOI**" program. Click on the "Apply" button in the column on the far right to open the application form.

Applicants may stop at any point but must click the **"Save"** button at the bottom of each page *before exiting* in order to save their progress. When you wish to return to your draft application, please do not go through the "Funding Opportunities" tab. Instead, go to the "My Applications" tab in the right corner of the main page. When you are in the "My Applications" tab you will be able to find all your draft applications by clicking on the "Draft Applications" module.

The following sections are displayed as tabs across the application screen. Click on each section and follow the directions. Click "**Save**" as you complete each section.

GENERAL

Enter the title of your project, enter the project start and end dates, select the number of periods being requested, and complete any additional questions. Also, please complete the organizational assurances

indications (i.e. IRB, IACUC, and/or IBC/rDNA approval letter and status at the time of submitting the application) in this section.

CONTACT PROFILE

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

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

INSTITUTION

If a profile was completed upon registration, the applicant's/principal investigator's institution will be pre-loaded as the Lead Institution. Domestic applicants must verify their institution by 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 GCMA Office must have a copy of the applicant institution's current W-9 and 501(c)3 letter, or other documentation verifying its Federal tax status and will not issue Award Letters to Awardees if these documents are not received and on file.

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

International Applicants

Applicants whose institution is not a United States based entity are required to provide additional information and complete a CFF International Institution Form as part of the Full Application stage if the LOI is approved. The completion of this form also includes submission of additional documentation.

CONTACTS

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

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

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

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
- Response to Prior LOI Critique (if resubmission)

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 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

Response to Prior LOI Critique (template available for download, if applicable)

Resubmissions of LOI applications that were previously not approved are required to make a point-by-point response to the limitations noted in the critique of the earlier submission (Maximum of three (3) pages).

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: Wednesday, June 18, 2025 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 by listed under "**My Applications**", then within the "**Draft Applications**" section. Upon locating the draft application, you may select it to begin your submission.

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

The following sections are displayed as tabs across the application screen. Click on each section and follow the directions. Click "**Save**" as you complete each section.

Please note: Only select the "**Submit to AIO**" button after the application has been fully completed. This will trigger validation on all required fields and send the application to your Authorized Institutional Official "AIO" for review and signature.

GENERAL

Enter the title of your project, enter the project start and end dates, select the number of periods being requested, and complete any additional questions. Also, please complete the organizational assurances indications (i.e. IRB, 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 below.**

CONTACT PROFILE

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

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

INSTITUTION

If a profile was completed upon registration, the applicant's/principal investigator's institution will be pre-loaded as the Lead Institution. Domestic applicants must verify their institution by entering the Employer Identification Number (EIN) or Tax Identification Number (TIN) to search the system for the correct institution. You may find your EIN by referencing the Institutional W-9 or equivalent documentation. If the EIN/TIN is not located in our system, you have the option to add the legal institution. Please also confirm if the project site is the same as the legal institution.

Verification of Applicant Institution's Tax Status (upload as PDF documents):

The CFF GCMA Office must have a copy of the applicant institution's current W-9 and 501(c)3 letter, or other documentation verifying its Federal tax status and will not issue Award Letters to Awardees if these documents are not received and on file.

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

International Applicants (if applicable):

Applicants whose institution is not a United States based entity are required to provide additional information and complete a CFF International Institution Form. The completion of this form also includes submission of additional documentation.

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 consultants, collaborators, or subcontractors. In order to add contacts external to the applicant institution, please select the appropriate "Add Subcontractors" or "Add Consultants/Collaborators" button(s) and add the contacts in the table, then click "Save".

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 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.

Letters of Reference must be submitted prior to submission of the application. To invite Referees, go to the "**REFERENCES**" tab of the online application, then select the blue button to open a pop-up window in order to add the referees in the table. You must click "Invite" in order to trigger the e-mail to the referee. The referee(s) will be sent an e-mail asking them to Accept or Decline the invitation to submit a letter of reference and will be provided instructions to submit the letter. **The applicant will be alerted if a referee Declines the invitation; please make sure to check this tab regularly to see the status of the references.** The applicant should inform Referees to submit the letters at least one (1) week prior to the application deadline. This helps to ensure that the letters have been uploaded before the application is submitted. Once the application has been submitted, no documents can be added.

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

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. All Clinical Research Scholars Program awards are for a maximum of three (3) years.

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 $225,700. 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 counted as 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.

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
- CF-Related Activities of the Academic Mentor and Applicant Institution
- Previous Training and Future Plans
- Future Career Goals
- International Institution Form
- Critique Response (LOI or resubmission)

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, itis 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)

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.

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.

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.

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.

International Institution Form (template available for download, if applicable)
- Applicants whose institution is not a United States based-entity must complete the CFF International Institution Form. Please attach a current copy of the following documents to your completed form and cite to the relevant page(s) or paragraph(s) in the supporting documentation:
- A Form W-BEN-E or W-8EXP signed by the authorized institutional official within the last three years.
- An anti-terrorism certification signed by an institutional official indicating that all award funds, including but not limited to CFF funds, will be used in compliance with applicable U.S. anti-terrorist financing, privacy and asset control statutes, regulations and executive orders, resulting in funds never being used to support terrorist networks, organizations and/or activities. Please see the CFF template provided in Appendix A;
- Names and Addresses of all Institutional Officers and Directors (Appendix B);
- Institution's Current Sources of Support, including grants, private endowments, commercial activities, etc. (Appendix C).

Applicants who have provided these documents within the past one (1) year is not required to resubmit them. However, if any of the above documents have been updated since they were previously submitted, please upload any updated documents. The CF Foundation GCMA Office will contact applicants if documents are outdated or missing.

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

Critique Response (template available for download, if applicable)
For new applications: Provide a point-by-point response to the limitations noted in the critiques of the LOI, using the template provided. Maximum three (3) pages

For resubmissions: Provide a point-by-point response to the prior reviews.
Beginning in 2018, applicant's will only be allowed to revise and resubmit their full application for a specific project one time unless granted permission from the CFF Program Officer.

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**

***Organization Assurances & Certifications**
CFF requires, as applicable, that all U.S.-based awardees obtain Institutional Review Board (IRB) approvals for human subject research, Institutional Biosafety Committee (IBC) approval for recombinant or synthetic nucleic acid research, and Institutional Animal Care and Use Committee (IACUC) approval for animal research, (see additional information regarding these approvals below). Copies of these approvals, if available at the time the application is submitted, must be uploaded with the application as appendices. CFF will not release payments to awardee institutions until these documents are received and on file with the CFF GCMA Office.

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

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

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

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

Validation and Submission

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

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

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

XI. Resources and Other Information

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

XII. Contact Information

The CFF Grants and Contracts Office Hours of Support: Monday through Friday, 9:00AM – 5:00PM EST

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

For scientific questions:
Elizabeth Yu, Ph.D. at eyu@cff.org

XIII. Electronic Application Checklist

LOI Submission Deadline: Wednesday, March 19, 2025 at 5:00 PM (EST)
Full Application Deadline: Wednesday, June 18, 2025 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)
- ☐ Response to Prior LOI Critique (upload, if applicable)

FULL APPLICATION

Face Page (upload) which includes:

- ☐ Signatures
  - ☐ Principal Investigator (Co-PI's are not required to sign)
  - ☐ The Official authorized to sign on behalf of the Applicant Institution
- ☐ Applicant/PI information (online)
- ☐ Complete Institution and PI Contact information, including correct mailing address (online)

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)
- ☐ CF-Related Activities of the Mentor and Applicant Institution (upload)
- ☐ Previous Training and Future Plans (upload)
- ☐ Future Career Goals (upload)
- ☐ Critique Response (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
- ☐ International Institution Form (upload, if applicable)
- ☐ 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