



Program Name: 2023 Postdoc-to-Faculty Transition Award

Brief Program Overview/Description: The Postdoc-to-Faculty Transition Award is designed to support postdoctoral research fellows during their CF fellowship and aid in their transition to an independent research faculty position. Candidates for this award can be identified any time during the first four years of their postdoctoral fellowship. ***Applicants seeking to submit proposals focused on topics such as the restoration of CFTR protein function or approaches to fix/replace the defective CFTR gene should apply through the Path to a Cure Postdoc-to-Faculty Transition Award Program.***

Funding Amount: Awards can provide individuals up to five (5) years of combined support for their research training (maximum of 3 years, known as “Phase I”) and the initiation of their independent research career (2 years, known as “Phase II”). Refer to the Funding Level table on Page 3 for allowable amounts.

Eligibility:

- Candidates must be U.S. citizens, permanent residents, or non-residents working in a U.S.-based laboratory.
- Postdoctoral applicants (Ph.D., M.D., D.V.M. or equivalent) in their first four years of fellowship who are engaged in or planning CF-related basic science research projects are eligible. Preference will be given to recent graduates and those just beginning their research careers and those with a clear commitment to CF research. Candidates who are clinical fellows should apply to the [CFF Clinical Fellowship](#) Program for the appropriate year, or for the [LeRoy Matthews Physician-Scientist Award Program](#).

Key Dates:

	2023 Cycle
Published	October 17, 2023
Full Application Deadline	December 7, 2023
Committee Review Date	March 2024
Notification to Applicants	April 2024
Earliest Project Start Date	May 1, 2024

Table of Contents:

- I. [About the Cystic Fibrosis Foundation](#)
- II. [Program and Award Overview](#)
- III. [Funding Amounts](#)
- IV. [Eligibility](#)
- V. [Mentorship Requirements](#)
- VI. [Goals of Research Currently of Interest to CFF/Priority Areas](#)
- VII. [Review and Award](#)
- VIII. [Submission Information](#)
- IX. Letter of Intent Guidelines
- X. [Full Application Guidelines](#)
- XI. Other Information
- XII. [Contact Information](#)

*We strongly 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.

I. About the Cystic Fibrosis Foundation

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

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

II. Program and Award Overview

The Postdoc-to-Faculty Transition Award is designed to support postdoctoral research fellows during their CF fellowship and aid in their transition to an independent research faculty position. Candidates for this award can be identified any time during the first four years of their postdoctoral fellowship.

These awards are intended to enable research training in new research areas and methods to advance the scientific knowledge of the applicant and to collect data to enable their transition into an independent research career. Research projects proposed through this program should seek to improve our understanding of disease pathogenesis or development of novel treatment approaches on topics such as defects in airway defense, microbial adaption to the CF lung, mucociliary clearance and airway hydration, and extrapulmonary manifestations of the disease. ***Applicants seeking to submit proposals focused on topics such as the restoration of CFTR protein function or approaches to fix/replace the defective CFTR gene should apply through the Path to a Cure Postdoc-to-Faculty Transition Award Program.***

Awards can provide individuals up to five (5) years of combined support for their research training (maximum of 3 years, known as "Phase I") and the initiation of their independent research career (2 years, known as "Phase II"). It is anticipated that the award will provide the opportunity for awardees to hone research skills, develop into independent investigators, and initiate an independent CF research program.

Phases:

The program and individual award application is designed in two phases, as follows:

- **Phase I:** Research training to occur during the fellowship: This phase of the award is intended to provide support for up to three (3) years to develop research and professional development skills and undertake research training in an area of priority to CFF. As part of this application, applicants are only required to submit a Research Plan for Phase I. Awardees and their mentors will be required to submit additional materials prior to the initiation of Phase II.
- **Phase II:** Independent Research Investigation (first independent application): This phase is intended to provide support for up to two (2) years for independent research studies. This support need not occur at the institution where Phase I took place. The outline for this work should be submitted for consideration by CFF near the end of Phase I, coinciding with the first academic appointment. In addition to scientific merit, CFF will assess the institution's commitment to the research career development of the recipient in his/her first academic appointment. **At least 75% of the candidate's time must be devoted to CF-related research during Phase II.**

The award will not be made for Phase II independently. Awardees who transition to an independent faculty position before the start of their third year of training support (at an institution other than where they received their Phase I training) may add a maximum of one (1) additional year onto Phase II of the award. Transition early into Phase II of the award must be approved by the CFF Program Director.

The candidate's progress and career goals will be subject to annual evaluation by CFF throughout Phase I. Transition to Phase II will be subject to an additional review by CFF, with the scientific merit of the

proposed research project evaluated, as well as the institutional commitment to the career development of the candidate.

It is desirable for individuals to complete both phases of the program without interruption. It may be permissible, however, to interrupt the award and delay the start of Phase II, such as to receive additional training, or if a tenure-track faculty position is not obtained. In the event such a contingency arises, the grantee and the Mentor must notify CFF of the interruption and receive approval to assure that funds will be available to resume the award so that the candidate may complete the program.

Guidance:

- Successful candidates for this award will demonstrate outstanding research potential and provide evidence of serious intent for an academic research career related to CF. Please note that the review process for this award is highly selective.
- Postdoc-to-Faculty Transition Awards are awarded based on individual merit, program relevance, and institutional environment. Therefore, **Phase I awards are not transferable** to other individuals or institutions, unless previously approved by the CFF Program Director.
- Individuals entering Phase II are encouraged to apply for additional external research support to fund their program. Program overlap of external funds is allowed.
- Awardees are required to inform 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 grantees and institutions must comply with CFF grant policies.

III. Funding Amounts

Awards can provide individuals up to five (5) years of combined support for their research training (maximum of 3 years, known as "Phase I") and the initiation of their independent research career (2 years, known as "Phase II").

Funding levels:

The first year of funding requested should coincide with the year of postdoctoral experience as outlined in the following table:

Phase I: Postdoctoral Year	Stipend (salary + fringe)	Research*	Total
First-year Postdoc	\$66,000	\$15,000	\$81,000
Second-year Postdoc	\$67,000	\$15,000	\$82,000
Third-year Postdoc	\$68,000	\$15,000	\$83,000
Fourth-year Postdoc	\$69,000	\$15,000	\$84,000
Fifth-year Postdoc	\$70,000	\$15,000	\$85,000
Sixth-year Postdoc	\$71,000	\$15,000	\$86,000

Phase I stipends may only be used to support the postdoctoral fellow. During Phase II, salary support may be used to support the PI or research staff.

*Research support may include funds for technical costs, i.e., supplies, minor equipment, candidate travel to a national scientific meeting.

The maximum level of support available under this program during Phase I is \$86,000. *Note that applicants may not request a Phase I salary above a 4th year postdoc since applicants should be in their first four years of fellowship.

The faculty phase of the award (Phase II) includes \$80,000 for salary support and \$30,000 for research support, for a maximum level of support of \$110,000 per year.

Note: Salaries should be in compliance with institutional guidelines and can be supplemented by the Grantee Institution.

IV. Eligibility

- Candidates must be U.S. citizens, permanent residents, or non-residents working in a U.S.-based laboratory.
- Postdoctoral applicants (Ph.D., M.D., D.V.M. or equivalent) engaged in or planning CF-related basic science research projects are eligible. Preference will be given to recent graduates and those just beginning their research careers and those with a clear commitment to CF research. Candidates who are clinical fellows should apply to the CFF Clinical Fellowship Program for the appropriate year, or for the LeRoy Matthews Physician-Scientist Award Program

V. Mentorship Requirements

- Each candidate must identify a primary Mentor with substantial experience in training, and who will provide primary guidance for the awardee's research and professional career development. The Mentor is encouraged to form an advisory committee to develop and monitor the Phase I program and should include course work, seminars, research experience, and other educational experience deemed necessary for the development of an independent research career in Phase II.
- The Mentor(s) must be able to provide the mentorship needed to guide the project if awarded.
- The Mentor(s) must be at the institution where the applicant will be carrying out the work for the project.

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

The landscape of CF has changed significantly over the past 30+ years since the identification of the CFTR gene. The introduction of CFTR modulators, small molecule drugs that target the basic CFTR defect, has led to unprecedented improvement in health for many people with CF. However, there is still a significant unmet need for people with CFTR mutations that either do not respond to modulators, do not generate sufficient quantities of protein for correction, or block protein synthesis (i.e., premature stop codon mutations, splice mutations, insertion/deletion mutations etc.). In addition to correcting the basic defect, CFF realizes the needs of the community and places a high priority on supporting efforts that improve our understanding of disease pathogenesis, such as defects in airway defense, microbial adaption to the CF lung, mucociliary clearance and airway hydration, and extrapulmonary manifestations of the disease that may not be completely corrected by CFTR modulators. We therefore encourage investigators to review the list below for basic and translational science areas of interest to the CFF.

Investigators working in the following areas are particularly encouraged to submit an application for consideration:

- Understanding of how modulators impact disease pathogenesis across all stages of life as well as the cellular and molecular changes that cannot be reversed by modulators, which may include direct and indirect influences of CFTR modulation on the airway milieu, including resident pathogens, inflammation and inflammatory cell function, mucus structure (tethered and secreted), airway surface liquid (ASL), and mucociliary clearance (MCC), as well as extrapulmonary manifestations.
- Biological mechanisms involved in chronic lung allograft dysfunction (CLAD), rejection and transplant immunology.

- Improved understanding of acquisition, detection, pathogenesis, host-pathogen interactions, and treatment approaches for difficult to treat CF infections (i.e., NTM, MDR Pseudomonas, MRSA, Aspergillus, Burkholderia, Stenotrophomonas). *
- Approaches to understand and treat nutritional deficiencies and CF-related GI complications, including intestinal, pancreatic, and hepatobiliary disease across the lifespan.
- Effects of endocrine system dysfunction in CF, especially projects focused on biological underpinnings of Cystic Fibrosis Related Diabetes (CFRD), CF bone disease, and sexual & reproductive health.

Projects that will lead to a better understanding of disease mechanisms and pathophysiology or will focus on strategies and methods with the potential to develop new prevention and treatment strategies may be prioritized for funding.

**Projects focused on individual pathogens not listed above or that solely explore basic biology of pathogens that will not have direct applicability to the development of new treatment strategies or improve outcomes for people with CF may be deprioritized for funding.* Infection/microbiology-focused applications should utilize clinically relevant strains and specimens or address host responses to the organism as part of the application.

Note: Applicants seeking to submit proposals focused on topics such as the restoration of CFTR protein function or approaches to fix/replace the defective CFTR gene should apply through the Path to a Cure Postdoc-to-Faculty Transition Award Program (<https://www.cff.org/path-cure-academic-programs>). Topics for the PTAC program include but are not limited to characterization of rare CFTR mutations, nonsense modulation, gene editing/replacement strategies, and characterizing cellular targets for CFTR correction.

VII. Review and Award

All applications are evaluated by an external review committee, whose recommendations are reviewed by the Medical Advisory Council (MAC) and/or the Board of Trustees. Funding of awards is based on the priority score awarded to each application and the recommendations of the committee. Funding decisions are based on the relevance of the proposed study to the goals of the Foundation, alignment with specific research priorities, and enhancement to the existing CFF project portfolio. All awards are subject to compliance with applicable regulations and CFF policies and are contingent upon the availability of CFF funds.

In addition to scientific merit and relevance to the CFF mission, applications will be evaluated in the following areas:

Applicant	Mentor(s)	Environment	Training & Research Development Plan
<ul style="list-style-type: none"> • Commitment to, or intent to pursue, a research career related to CF • Potential to develop an independent research career related to CF • Research accomplishments 	<ul style="list-style-type: none"> • Established expertise in CF-related basic research or related research areas of high priority to CFF • Commitment of the primary Mentor for the duration of the applicant's development and research plan 	<ul style="list-style-type: none"> • Quality (breadth and depth) of faculty in basic and/or clinical sciences related to CF at applicant institution • Quality of institution's CF research and training programs • Demonstrated interaction between basic and clinical investigators 	<ul style="list-style-type: none"> • Feasibility and impact of the proposed plan • Didactic course work required by the applicant (if indicated) • Scientific and technical merit of the proposed research

	<ul style="list-style-type: none"> • Track record of the Mentor training individuals for basic biomedical research 	<ul style="list-style-type: none"> • Institution's commitment and ability to provide opportunities and facilities necessary for research career development related to CF 	<ul style="list-style-type: none"> • Ability of the proposed plan to develop research skills of the applicant needed for independence • Relationship to applicant's career development
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All applications will be reviewed and scored by the committee. CFF may withdraw applications receiving low scores, and/or those deemed nonresponsive to the program announcement before the review meeting. In these cases, CFF will notify applicants if their application has been withdrawn without discussion. Applications that have not been funded in two review cycles will not be accepted for further consideration by CFF. In order to resubmit unfunded applications during future application cycles, applicants must indicate that this is a resubmission and address reviewer critiques.

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

- Insufficient information or documentation
- Inadequate statement of hypothesis, experimental design or methods
- Failure of the applicant to demonstrate awareness of and plans for coping with key problems and pitfalls associated with the proposed research
- Insufficient or improper controls
- Failure of the applicant to describe potential relevance of the proposed study to issues in CF
- Failure of the applicant to document the necessary skills or training to accomplish the goals of the proposal
- Failure of the applicant to meet all of the criteria described in the policy statement for a given award

VIII. Submission Information

Application deadline: Thursday, December 7, 2023 by 5:00 PM (Eastern)

Submit online through <http://awards.cff.org>

(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:

	2023 Cycle
Application Deadline	December 7, 2023*
Committee Review Date	March, 2024
Notification to Applicants	April, 2024
Earliest Project Start Date	May 1, 2024

*We strongly 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

Not applicable to this RFA

X. Full Application Guidelines

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>

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 prior to submitting 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 "**2023 Postdoc-to-Faculty Transition Award**" 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 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 below Organizational Assurances and Certifications as cited at the end of 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 preloaded 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. If the EIN/TIN is not located, you may 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.

International Applicants (if applicable):

Not applicable

CONTACTS

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

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

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

REFERENCES

Letters of Support and/or Reference are weighted heavily in the review. At least four (4) letters are required as follows:

- **The Mentor(s) for this award** – A Letter of Support from the current Mentor(s) should clearly identify the merits of the applicant and must include a description of CF-specific and other training the applicant will receive while working under the Mentor's direction (i.e., seminars, new techniques, professional development, etc.).
- **Additional referees** – Letters of Reference from at least three (3) other individuals familiar with the applicant's scientific interests and abilities (with no more than two [2] from the same institution) should attest to the candidate's academic qualifications, motivation, and research potential.

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 abstracts, provide a statement of no more than 2,000 characters (including spaces) explaining the subject of the research proposal and its relationship to CFF. 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. Please refer to the Funding Levels table on Page 3 for allowable amounts. Indirect costs are not allowed.

Salaries & Benefits - List the names, positions, and percent effort of all professional and non-professional personnel involved in the project, whether or not salaries are requested. For each individual, be sure to complete all fields on the Budget Detail in full on the template provided. In accordance with National Institutes of Health (NIH) policy, salary requests may not use an institutional base salary in excess of the current federal salary cap of **\$212,000**. 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 - Describe the purpose of any CF-relevant travel. Please note: expenses for travel outside the North American Continent, including travel to Hawaii, Puerto Rico, and other U.S. territories are not allowable expenses without prior written approval from the CFF GCMA Office. **Travel expenses may not exceed \$1,500 per person per year.** Registration fees associated with conferences are in addition to this allowance should be listed under “Other Expenses”. Applicants are encouraged to attend the North American CF Conference each year to present their work.

Consumable Supplies - Itemize supplies e.g., glassware, chemicals, animals, in separate categories and give the estimated cost of each category. If animals are involved, state the number, unit purchase cost, and unit care cost.

Other Expenses - Itemize other expenses by major categories, such as duplication costs, publication costs, minor equipment (under \$5,000), computer charges, conference registration fees, etc.

Budget Detail – Indirect Costs

Indirect costs are not allowable

FULL APPLICATION UPLOADS

Download the available templates applicable to the project, upload the completed templates to the corresponding attachment types within this section. Templates available for download include:

- Budget Justification
- Research Plan
- Training Plan
- Biographical Sketches for Key Personnel
- Other Support
- Facilities Available
- Mentor's Results of Past and Current CFF/CFFT Support
- Critique Response (if resubmission)

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. ***Budget Justification upload(s) should be provided individually for each year of funding support being requested. These can be uploaded as a single PDF or separate PDF uploads for each year.**

RESEARCH PLAN

Page limit: Seven (7) single-sided pages, not including the Literature Cited. Applications exceeding this page limit will not be reviewed. Type the PI's name in the space available in the header of the document. The template available will track page numbers at the bottom.

- 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.
 - Key figures and legends must be included in the Research Plan and should be of sufficient quality and size to be evaluated by the reviewer. If uploaded as Appendices, they will NOT be reviewed.
 - If the application is a resubmission of an earlier one, revisions must be clearly indicated by a change in font, bolded or underlined. **CFF will not review resubmissions that have not been revised.**
- 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. 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 particular those areas listed as areas of special interest to CFF. In addition, describe the relationship of the proposed work to your long-term career goals. Preference will be given to applicants who express an interest in a long-term career in CF-related research.
 - c. **Preliminary Results:** If applicable, provide a detailed discussion of any preliminary results.
 - d. **Experimental Design and Methods:** Provide a detailed discussion of the experimental 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. Discuss the data

expected to be obtained and the means by which data will be analyzed and interpreted. If clinical samples are included in the Research Plan, provide details of the methods for patient selection. Discuss potential pitfalls and/or limitations of the proposed procedures and alternative approaches to achieve aims. Point out any procedures, situation or materials that may be hazardous to personnel or patients and the precautions to be exercised. Since PTAC Postdoctoral Research Fellowships are reviewed by CFF's PTAC Committee, applications that include methodologies requiring sampling of materials from human subjects will only be considered under this mechanism if the sampling method constitutes minimal patient risk (e.g., venipuncture, nasal cell brushing) and patient samples or data are anonymous.

Describe the level of risk and measures taken to assure patient anonymity to the PI and other professional personnel unless the PI or other professional personnel are care providers. Note: Interventional studies involving human subjects cannot be supported through this program.

- e. **Literature Cited:** References should be numbered in the sequence that they appear in the text 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).

TRAINING PLAN

The applicant, in conjunction with the Mentor(s), should develop a training plan that outlines skills and techniques that will be learned during this fellowship period as well as CF-specific training that will be available to the applicant. This plan should also address the applicant's long-term career goals and include training and professional development activities that will facilitate the applicant's transition to the next phase of their career. Do not exceed four (4) pages.

BIOGRAPHICAL SKETCH(ES) OF KEY PERSONNEL

Complete and upload an NIH Biographical Sketch for all the Applicant/Principal Investigator and the Mentor(s). Do not exceed five (5) pages per person.

OTHER SUPPORT

Complete and upload an NIH Biographical Sketch for all the Applicant/Principal Investigator and the Mentor(s). There is no page limitation. Information on other support assists CFF in the identification and resolution of potential sources of overlap. Scientific and budgetary overlap should be minimized. Commitment of an individual's effort greater than 100 percent, is not permitted.

FACILITIES AVAILABLE

Describe the facilities and equipment available at the applicant's institution that will be used for this project, such as laboratory, clinical, animal, computer, office, etc. Provide any additional information about the environment, including any support services available that will be utilized. Describe their pertinent capabilities, proximity, and anticipated extent of use. If facilities or equipment at a consultant's or collaborative site will be used, they should be identified and clearly described. There is no page limit. Use continuation pages, if necessary.

MENTOR'S RESULTS OF PAST AND CURRENT CFF/CFFT SUPPORT

Mentor(s) are requested to Identify the results of past and current CFF/CFFT support (e.g., subsequent funding from other sources, journal articles, and invited presentations) and the CFF/CFFT grant/award from which they resulted for the past three to five years. Please note that the following information must be included with each research project identified:

- CFF/CFFT Award Number
- Principal Investigator (PI)
- CFF/CFFT Project Title
- Applicant's Title on Project

- Project Start/End Dates
- Total CFF/CFFT Award Amount
- Results of Support

CRITIQUE RESPONSE (IF RESUBMISSION)

If the application is a resubmission of a previously declined application, please provide a point-by-point response to the prior reviews. There is no page limit to your responses, but please be concise and succinct.

APPENDICES (UPLOAD MATERIALS AS PDF DOCUMENTS, IF APPLICABLE)

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

- Certification of organization assurances (i.e., IRB, IACUC and IBC approvals), if applicable.
- Up to three (3) reprints of the applicant's work relating to the general area of research in the proposal may be uploaded in PDF format.

***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. Other Information

Not applicable to this RFA

XII. Contact Information

For technical support and content information:

Primary CFF GCMA Office contact Edwin Gregorian at egregorian@cff.org or 301-841-2614

Secondary CFF GCMA Office contact grants@cff.org or 301-841-2614

For scientific and programmatic questions:

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