



Program Name: 2023 Spring Path to a Cure (PTAC) Postdoctoral Research Fellowship Award

Brief Program Overview/Description: Path to a Cure: Postdoctoral Research Fellowships are offered for support of postdoctoral research training related to CF. 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 develop new information that contributes to the development of new therapies for CF, especially projects focused on advancing CFTR repair and replacement strategies.

Funding Amount: Awards may be approved for up to a two (2) year period. Funding of up to \$75,000 in the first year, and up to \$76,000 in the second year may be requested. Indirect costs are not allowable.

Eligibility:

- Candidates must be U.S. citizens, permanent residents, or non-residents working in a U.S.-based laboratory.
- Postdoctoral applicants engaged in or planning CF-related research 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.
- Applicants can apply for this fellowship anytime during their postdoctoral period. However, funding levels are based on the year when the award is made, not the year of the applicant's fellowship.
- Additional eligibility requirements can be found in Section IV and Section VI (Goals of Research) below.

Key Dates:

	Spring 2023 Cycle
Published	February 16, 2023
Full Application Deadline	May 11, 2023
Committee Review Date	August 2023
Notification to Applicants	September 2023
Earliest Project Start Date	November 1, 2023

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*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

Path to a Cure: Postdoctoral research fellowships are offered for support of postdoctoral research training related to CF. 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 develop new information that contributes to the development of new therapies for CF, especially projects focused on advancing CFTR repair and replacement strategies. **Applicants seeking to submit proposals focused on topics such as mucociliary clearance and airway hydration, infection and inflammation, or non-lung manifestations of disease should apply through the General Postdoctoral Research Fellowships Award mechanism.**

III. Funding Amounts

Awards may be approved for up to a two (2) year period. Funding of up to \$75,000 in the first year, and up to \$76,000 in the second year may be requested. Indirect costs are not allowable.

Funding levels:

Fellowship Year	Stipend (salary + fringe)	Travel	Research	Total
First-year Fellowship	\$66,000	\$1,500	\$7,500	\$75,000
Second-year Fellowship	\$67,000	\$1,500	\$7,500	\$76,000

***Note: funding cannot be moved between budget categories**

IV. Eligibility

- Candidates must be U.S. citizens, permanent residents, or non-residents working in a U.S.-based laboratory.
- Postdoctoral applicants engaged in or planning CF-related research 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.
- Applicants can apply for this fellowship anytime during their postdoctoral period. However, funding levels are based on the year when the award is made, not the year of the applicant's fellowship.
- Candidates who are clinical fellows should apply to the CFF Clinical Fellowship program for the appropriate year. Please refer to the Policies and Guidelines of the Clinical Fellowship programs on the CFF website at www.cff.org.
- Fellowships are awarded on the basis of individual and institutional merit. Awards are not transferable to other individuals or institutions unless previously approved by the CFF Program Director.
- Applications must focus on one or more of the research areas of interest outlined in Section VI below.
- Fellowships are intended to support mentored training to enable awardees to be competitive for independent, faculty positions. For awardees who obtain a faculty position before the end of their 2-year, please contact the CFF Program Director to determine if part of your award may be eligible to be converted to a P&F for the remainder of the funding period.

V. Mentorship Requirements

- Each fellow must have a Mentor who will be responsible for the fellow's training and research activities.
- 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. In 2012, Kalydeco™ (VX-770), the first drug to target the basic *CFTR* defect, was approved for a small subset of people with CF and clearly demonstrated that *CFTR* modulating drugs can improve clinical parameters such as sweat chloride, lung function, and body weight. Since that time, additional *CFTR* modulating drugs have been approved that continue to change the course of disease for the nearly 90% of people who will benefit from them. 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.). To ensure all people with CF have access to effective *CFTR*-directed therapies, the CF Foundation announced the Path to a Cure Initiative in 2019.

Projects supported through the Path to a Cure initiative should focus on foundational concepts and strategies, novel tools and methods, and/or technologies that have the potential to inform or ultimately translate into novel therapies to restore *CFTR* protein function or fix/replace the defective *CFTR* gene. The CF Foundation will continue to support research programs focused on characterizing *CFTR* mutations other than F508del, structural studies of *CFTR*, and mechanisms of action of *CFTR* modulators. However, the following emerging areas of interest represent the highest priority to the CF Foundation:

- Identifying, characterizing, and validating potential targets to promote nonsense mutation suppression, which includes understanding the pathways and mechanisms that regulate translation termination and nonsense mediated decay (NMD)
- Developing novel means of repairing and/or replacing the mutant *CFTR* gene
- Characterization of cellular targets for *CFTR* correction, including airway progenitor cells and other affected epithelial tissues (biliary tract, GI tract, pancreas)
- Developing and optimizing the chemistry and formulation of nucleic acid delivery vehicles, both viral and non-viral, that can target disease relevant cells and tissues
- Comprehensive evaluation of the role of various pulmonary cell types in CF disease pathogenesis (i.e. ciliated cells, club cells, ionocytes, etc.) and the region of the lung that is necessary to target with a genetic-based therapy to prevent, halt, or reverse disease
- Methods to overcome barriers that limit delivery of genetic therapies to disease relevant cells and tissues
- Cell, tissue, and animal models to discover and develop nucleic acid delivery vehicles and/or methods of restoring or repairing *CFTR*
- Tools and assays to pre-clinically evaluate the efficacy and safety of restoring functional *CFTR* through gene repair, gene replacement, small molecules, or any other novel method

Note: Applicants seeking to submit proposals focused on other CF relevant topics, including but not limited to mucociliary clearance and airway hydration, infection and host-pathogen interactions, lung allograft dysfunction/rejection, CF-related GI complications, CFRD and other endocrine abnormalities should apply through the general Postdoctoral Research Fellowship Award mechanism (<https://www.cff.org/postdoctoral-research-fellowship-award>).

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 • Track record of the Mentor training individuals for basic biomedical research 	<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 • Institution's commitment and ability to provide opportunities and facilities necessary for research career development related to CF 	<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 • Ability of the proposed plan to develop research skills of the applicant needed for independence • Relationship to applicant's career development

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, May 11, 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 <http://awards.cff.org> will be reviewed.

General Timeline:

	Spring 2023 Cycle
Application Deadline	May 11, 2023*
Committee Review Date	August, 2023
Notification to Applicants	September, 2023
Earliest Project Start Date	November 1, 2023

*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. **Please note:** Applicants should register their profile using the “Domestic Institution” or “International Institution” options to ensure that your profile aligns properly with the institution where the project will be conducted. 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 Spring Path to a Cure (PTAC) Postdoctoral Research Fellowship 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 on page 11.*

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. **Please be sure to use the dash formatting when entering your EIN/TIN (XX-XXXXXXX).** 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.
- Non-U.S. applicants must provide a copy of the W-8BEN-E form (required). In addition, a tax equivalency letter should be uploaded, if available. If a tax equivalency letter is not available, applicants must upload a letter stating this documentation is not available.

International Applicants (if applicable):

Not applicable

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 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 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. Postdoctoral Research Fellowships funded through this RFA are for a maximum of two (2) years. The total budget request cannot exceed \$75,000 for Year 1 and \$76,000 for Year 2 (please refer to the funding table in Section III above). 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 **\$212,100**. 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 travel being requested. Please note: For North American applicants, 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. Requests for computer hardware maybe considered if the need is well justified and the Trainee’s Mentor agrees to share the costs.

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/CFRT 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.

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.**
- 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.
 - 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.
 - Preliminary Results:** If applicable, provide a detailed discussion of any preliminary results.
 - 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.
 - 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 all authors, title, 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 personalized training plan that outlines skills and techniques that will be learned during this fellowship period as well as CF-specific training and mentorship that will be available to the applicant. The training plan should also include a description of seminars and conferences the applicant will attend. Applicants are encouraged to attend NACFC and submit an abstract each year of their award. 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 an independent research 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. If an applicant has a current source of funding (i.e. training grant or other fellowship) that will be relinquished if this award is received, please note that in the Other Support document.

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 (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 Face Page electronically using Adobe Sign. Once signed by the PI, the Face Page 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 program/content information:

Primary CFF GCMA Office contact Aimee Lee Russell at arussell@cff.org or 301-841-2614

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

For scientific questions:

John Sheridan, Ph.D. at jsheridan@cff.org