



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

Program Name: 2024 Clinical Research Award Plus Concept Proposal and Planning Grant: Therapy Initiation and Modification on ETI (TIME)

Brief Program Overview/Description: This Request for Application is intended to support a Planning Grant as part of the CRA+ program. The CRA+ program is a collaborative funding mechanism between the Cystic Fibrosis Foundation and academic clinical researchers with the goal to develop and execute large, clinical studies that address high priority research questions. The CRA+ program is a two-step process that involves the submission of a Planning Grant prior to full application submission of the full study. The purpose of the Planning Grant is to provide the CF Foundation with sufficient detail to determine if the proposal addresses a CF Foundation TIME research area and to determine if the application is appropriate for the CRA+ funding mechanism. Planning Grants may provide support for activities required to develop a full study protocol, (i.e., salary, meeting planning, travel, consultant fees, etc.).

Funding Amount:

- Each applicant may request funding of up to \$125,000 per year for one (1) year, plus an additional twelve (12) percent indirect costs per year. Indirect costs are allowable for this program. Requested support for services provided by the Therapeutic Development Network (TDN) Coordinating Center are not required to be included in the budget or budget justification.

Eligibility:

- Applicants must be independent investigators (CFF defines an independent investigator as an individual who may apply for funding on behalf of an organization, institution, or the government)
- United States residents and applicants from outside the United States are welcome to apply.
- Must be a M.D., D.O., Ph.D. or dual M.D./D.O., Ph.D.
- Collaborations that include junior investigators or mentorship are particularly encouraged to apply.
- Additional eligibility requirements are outlined below in Section IV.

Key Dates:

Published	December 12, 2023
Full Application Deadline	January 30, 2024
Committee Review Date	April 2024
Notification to Applicants	April 2024
Earliest Project Start Date	June 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](#)
- VIII. [Submission Information](#)
- IX. Letter of Intent Guidelines
- X. [Application Guidelines](#)
- XI. Other Information
- XII. [Contact Information](#)
- XIII. [Electronic Application Checklist](#)

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.

CF Foundation Resources

The Cystic Fibrosis Foundation supports the development of a number of helpful tools and resources to assist the research community in accelerating the progress toward new scientific knowledge of and new therapies for cystic fibrosis. Some of the resources available for use are listed below.

For more information on Tools and Resources for the CFF research community, please visit: <https://www.cff.org/for-researchers>

- CFF Patient Registry Data
- CFF Biorepository
- Community Voice – Getting Community Input
- National Resource Centers

II. Program and Award Overview

TIME CRA+ Planning Grant

The intent of the TIME CRA+ Planning Grant is to support the planning of a large, multi-center, investigator-initiated clinical research study that addresses a TIME RFA Area of Interest listed in **Section IV**. Proposed studies must be a randomized controlled trial. The planning of an observational study is not allowed under this funding mechanism. Please visit CFF.org to learn about other funding mechanisms.

Recipients of the TIME CRA+ Planning Grant are required to participate in an ongoing, constructive dialogue with CF Foundation and the Therapeutic Development Network (TDN) throughout the project.

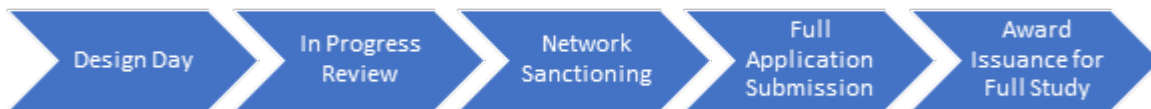
PLEASE READ THE CRA+ PROGRAM OVERVIEW PRIOR TO APPLYING. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT DARA RIVA (driva@cff.org)

TIME CRA+ Concept Proposal & Planning Grant Program Overview

The purpose of the Concept Proposal is to provide the CF Foundation with sufficient detail to determine if the proposed randomized controlled trial addresses TIME Areas of Interest in which we need good evidence and to determine the feasibility and likelihood of success of the proposed study resulting in meaningful results and changes in the treatment paradigm. Concept Proposals may include requests for planning support to develop a full application, the use of CF Foundation network resources, and/or assistance in identifying potential collaborators to successfully execute a large, multi-center clinical study. Concept proposals requesting TDNCC services and collaboration will undergo additional review to evaluate the capacity of the network to provide any requested resources. This may affect proposed study timelines. The Policy and Guidelines for the CRA+ full application is available only to those who have an accepted concept proposal. **The Policy and Guidelines for the CRA+ full application is not found in this document.**

CRA+ Process and Project Development

If the planning grant is funded, awardees will follow the process below throughout the planning period until full application submission and award to support the multicenter study.



Design Day

Upon the approval of the Concept Proposal, a design day will be scheduled to kick-off study design and collaboration with the CF Foundation team. The goals of design day are to develop a high-level protocol design and provide the awardee with a strong foundation to continue planning and refining their study. Awardees will work with CFF and the TDN to plan design day.

In Progress Review (IPR)

Towards the end of your planning period, you will be requested to present your progress and work-in-progress study plan to members of CFF and TDN network leadership. During the IPR, there will be an opportunity for Q&A and you will receive feedback regarding your progress. The result of the IPR will be either an approval to continue with your study protocol as planned or a recommendation that your protocol design be revisited to address concerns raised during the IPR before proceeding.

Network Sanctioning

Once your protocol is fully developed, you will submit your protocol to be scientifically reviewed by TDN Protocol Review Committee. Once the protocol is reviewed, your project will either be approved to move forward with a full application submission or deferred. A response to reviewer critiques will be required.

Full Application Submission

After receiving network sanctioning, you will work with members of the TDNCC to develop a budget and budget justification for your multicenter study to be included in your full application submission to the CF Foundation. Other components of your full application to CFF include network sanctioning approval letter, response to PRC and/or reviewer critiques, along with other typical application components (e.g., research plan, biosketches, etc.). Your full application submission to the CFF will not undergo an additional scientific review. However, CFF will evaluate the budget and budget justification and your responses to the scientific review critiques. Once CFF approves your full application and budget, you will receive notification and an award letter will be issued.

III. Funding Amount

- Each applicant may request funding of up to \$125,000 per year for one (1) year, plus an additional twelve (12) percent indirect costs per year. Indirect costs are allowable for this program. Requested support for services provided by the Therapeutic Development Network (TDN) Coordinating Center are not required to be included in the budget or budget justification.

IV. Eligibility

- Applicants must be independent investigators (CFF defines an independent investigator as an individual who may apply for funding on behalf of an organization, institution, or the government)
- United States residents and applicants from outside the United States are welcome to apply.
- International applicants and institutions are required to submit additional information in accordance with USA Patriot Act and the U.S. Department of Treasury Anti-Terrorist Financing Guidelines.
- Must be a M.D., D.O., Ph.D. or dual M.D./D.O., Ph.D.

- Collaborations that include junior investigators or mentorship are particularly encouraged to apply.
- CFF defines “junior investigator” as any individual who has not received a CFF/CFF Research Grant or NIH equivalent (e.g. R01, R21, R23) as a Principal Investigator AND is within their first five years of their first academic appointment at the level of Assistant Professor or equivalent.
- Industry-sponsored research projects are not eligible to apply through this program and instead should consider applying to the Therapeutics Development Awards program. For additional information, please contact grants@cff.org.

V. Mentorship Requirements

Not applicable to this RFA.

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

Applicants are required to address an Area of Interest in response to this RFA.

The Cystic Fibrosis Foundation regularly assesses its key research priorities to ensure we are on track to accomplish our mission to cure CF and to provide people with CF the opportunity to lead long lives. Since the uptake of elexacaftor/tezacaftor/ivacaftor (Trikafta® or ETI), there is significant ongoing interest in whether daily, supportive therapies should be used differently in people with cystic fibrosis responding well to ETI. Particularly, there is a need for randomized controlled trials to provide clinicians and patients the evidence they need to make treatment plan decisions. The Cystic Fibrosis Foundation, in conjunction with the TDN and external advisors, conducted surveys with clinical providers and other care team members and conducted numerous focus groups with people with CF and their family members. Using the information gathered from clinicians, people with CF, and their families, the following Areas of Interest were developed:

- Studies to inform **the initiation of supportive pulmonary therapies** in children <5 years of age who have or will start ETI therapy.
- Studies evaluating or standardizing **supportive pulmonary therapies on an as-needed bases** in people with CF who have had a robust response to ETI therapy and have already reduced or withdrawn standard of care therapies.
- Studies evaluating the impact of **withdrawing or re-introducing chronic anti-microbial therapies** in the presence of positive cultures in those with CF who are characterized as having advanced lung disease and a robust response to ETI therapy, including significant decrease in sputum production, time in hospital, and/or time on IV therapies.
- Studies evaluating the **effectiveness of alternative non-pharmacological airway clearance techniques**, including exercise duration/intensity, organized sport/extracurricular activities, compared to standard of care.
- Studies evaluating novel methods or outcome measures to elucidate small functional and/or structural changes in the lung of those with FEVpp >90 in response to pulmonary therapy changes.

VII. Review

Planning Grants considered appropriate for the CRA+ mechanism will be reviewed by an ad hoc committee and CFF. Study proposals that do not fully meet the intent of the CRA+ award may be re-directed to other CFF funding mechanisms. The Planning Grant will be evaluated on its scientific merit, TIME Areas of Interest relevance, and likelihood of success. Planning Grant requesting CFF network (e.g., TDNCC, STRC) collaboration will undergo additional review to evaluate the capacity of the network to provide any requested resources.

Awards are approved by the CFF Board of Directors based on the priority score assigned to each application and recommendations of the CRC and CFF Program Officers. All awards are subject to compliance with applicable regulations and CFF policies.

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

- Insufficient information or documentation
- Inadequate statement of hypothesis
- Failure of the applicant to describe potential relevance of the proposed study to TIME Areas of Interest
- 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 the criteria described in these guidelines
- Failure of the applicant to demonstrate likelihood of success

CFF may withdraw Concept Proposals deemed not appropriate for the CRA+ funding mechanism. In these cases, CFF will notify applicants if their application has been withdrawn and may recommend application to a different CFF funding mechanism.

VIII. Submission Information

Application Deadline: January 30, 2024 at 5:00 PM (EST)

Applicants may only submit one (1) application per funding cycle.

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 documents should be submitted online at <http://awards.cff.org> for review.

General Timeline:

Application Deadline	January 30, 2024
Review	April 2024
Notification to Applicants	April 2024
Earliest Project Start Date	June 1, 2024

****We highly encourage that you pre-register your profile, institution, contacts, and Title of your Application by this date. This will confirm that your submission at the Application Deadline, is without any system-related issue. It will also allow us to assist you on system-related queries before the Application Deadline. This pre-registration is for new applicants to the system and will only need to be completed once.***

IX. Letter of Intent Guidelines

Not applicable to this RFA

X. 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 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.

Locate the listing for the “**2024 Clinical Research Award Plus Concept Proposal and Planning Grant: Therapy Initiation and Modification on ETI**” 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.

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 (maximum 1 year), and complete any additional questions. As applicable, 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 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 your W-9 or equivalent documentation. 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 Grants and Contracts Office must have a copy of the applicant institution's current W-9 and 501(c)3 letter, or other documentation verifying its Federal tax status and will not issue Award Letters to Awardees if these documents are not received and on file.

- Applicants from for-profit organizations must submit a copy of the applicant institution's W-9 and IRS documentation verifying the organization's Federal tax status. Awards are not issued prior to having these documents on file with the CFF Grants and Contracts Office.
- 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.*

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"**.

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. Awards funded through this RFA are for a maximum of one (1) year for \$125,000 plus 12 percent indirect costs.

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 (FY2023) 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.

Consultant Costs - Give the name and institutional affiliation (if applicable) of any consultant who has agreed to serve in this capacity, including patient partners, statisticians and physicians in connection with the project if they are not listed under personnel. In the budget justification, briefly describe services to be performed, the number of days, rate of compensation, per diem and any other associated costs. Qualifying consultants are individuals that are generally not employed at the applicant institution and/or are consulting independently to the project.

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 Grants and Contracts Office. **Travel expenses may not exceed \$2,000 per person per year**. Registration fees associated with conferences are not allowable cost.

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 community engagement costs, duplication costs, publication costs, minor equipment (under \$5,000), computer charges, etc. Tuition costs are not allowable.

Subcontractors Summary - If applicable, detailed budgets and budget justifications for each subcontract, including indirects, must be provided for each year of support. Subcontractors are added in the prior section entitled **CONTACTS**. The lead/prime applicant (PI) and/or Grants Officer can initiate/complete the subcontract budget. After adding Subcontractor(s), in order to access the subcontract budget activity, please select the “**BUDGET**” tab of the application and click the “Open” button next to each listed subcontractor. After completing the subcontract budget activity, please select “**Pending PI Acceptance**”, as well as “**Submit**” to ensure the subcontractor budget is included as part of the main application budget.

For applications that include a subcontract with a third party, the applicant may request indirect costs on the first \$25,000 of each subcontract per project period. Negotiations of subcontracts are between the applicant institution and the subcontractor.

Budget Detail – Indirect Costs

Indirect costs of up to twelve percent (12%) may be requested from CFF. Indirect costs may be requested for all expenses except for the following:

- Major equipment (items over \$5,000 in value)- not allowed
- Computer software
- Software licenses
- Tuition – not allowed

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
- Concept Proposal
- Planning Period Statement of Work (SOW)
- Statement of Community Engagement (if applicable)
- Biographical Sketches for Key Personnel
- Other Support
- International Institution Form (If applicable)

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.

Concept Proposal

Upload a PDF copy of the completed document. Maximum of seven (7) pages (not including the literature cited). At the top of each page, type the PI's name. Each page must be sequentially numbered at the bottom. Components should include:

- **General Questions:** Please respond to the following question below:
 - a. Funding for this mechanism will support planning activities only. Application for funding for the full-scale research study may be submitted to an NIH funding opportunity, submitted to the CFF CRA+ Full Application Program, or submitted for joint funding. Do you plan on applying for funding or joint funding with another funding agency? If so, please describe the other funding mechanisms and the general timeline of review in your application.
- **Project Description**

The proposed study addressing a TIME Area of Interest should be clear, concise, specific, and informative. However, full study protocol and/or study design details, (e.g., details on recruitment, statistical analysis plans, participating sites, etc.) are not expected to be included in this application. Activities and goals for the planning of the study should be clearly described in this application.

 - 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 test this hypothesis and be relevant to the mission of the CFF as well as the Areas of Interest of this RFA. **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. This section should clearly describe how the proposal addresses a TIME Area of Interest.

- c. **Approach:** Describe in brief detail the proposed research concept and the activities of the planning grant. **Full details about the methods, experimental design, and recruitment, etc. are not expected at the time of the planning grant submission.** This section should address the following areas, but the order of presentation can vary to enhance readability and presentation.
- a. **Preliminary Efforts and Studies:** Summarize any preliminary work pertinent to this application that has been undertaken by the Principal Investigator(s) and/or information that will establish the competence and/or experience of the investigator(s) to pursue the proposed study. Include any preliminary community engagement/partnership work conducted to gather information for the proposed study. Titles, complete references and supplemental charts, graphs, etc., may be submitted in the Appendix (see Section H).
 - b. **Planning grant activities and goals:** Describe the activities to be conducted that are related to planning, design, and preparation of a study protocol. Briefly describe the anticipated results of the planning period. Activities and goals listed here should be consistent with those of the Planning Period Statement of Work upload.
 - c. **Study design concept:** Briefly describe the study design concept and the research idea, the goals and outcomes of the proposed study, and how the planning period will prepare you to conduct the future full scale CRA+ study. Specify the purpose of the proposed research, the research question(s), and research hypothesis. Feasibility assessment for subject recruitment should also be included. Please include a brief statistical analysis section highlighting key endpoints and a preliminary power or sample size justification for scope and size of study proposed.
 - d. **Limitations and Potential Pitfalls:** Discuss potential challenges that may be encountered during the planning period. Discuss any potential difficulties and/or limitations of the proposed study, including recruitment challenges, study participant adherence, etc.
 - e. **Coordinating Center and Operational Plan.** State whether you are seeking resources from the CF Foundation TDN to execute the proposed study. If you are working with a coordinating center other than the TDN, briefly describe their responsibilities and operational capacities for supporting the study.
 - f. **Literature Cited:** References should be numbered in the sequence that they appear in the text and listed at the end of the Concept Proposal. 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).

Planning Period Statement of Work

The SOW is an outline of the activities and milestones to be completed during the performance period of the award. The SOW should contain sufficient detail to be informative as a standalone document; however, should be consistent with activities and goals listed in the Concept Proposal section of the application. In table format, provide details on the tasks that will be performed during the planning period. Include details on who will be responsible to complete the task and the general timeline to complete each task. Indicate milestones to concisely identify the goals and expectations that will be accomplished during this planning period.

Statement of Community Engagement (template available for download, if applicable)

Provide a statement of no more than 500 characters (including spaces) summarizing the proposed work completed under this planning grant that will involve patient engagement. Specifically, please provide

descriptions about what type of support you are requesting from the CFF's Community Partnerships department, including survey development and dissemination, focus groups, or patient partnership identification. Please provide a timeline on when patient engagement will occur during this planning grant. To learn more about Community Engagement and CFF's Community Voice, visit <https://www.cff.org/Research/Researcher-Resources/CommunityInput-into-Research/>

Biographical Sketch(es) of Key Personnel

Complete and upload an NIH Biographical Sketch for all key project personnel, beginning with the Applicant/Principal Investigator. International applicants can upload a biosketch that is equivalent in content to the NIH template provided. (CFF defines "key 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

Complete and upload the Other Support form for all key project personnel, beginning with the Applicant/Principal Investigator. 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.

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. The completion of this form also includes submission of the following documentation:

- Institution's mission statement
- If the Institution is a nonprofit organization, provide government-issued documentation of the Institution's nonprofit status, if available, as well as governing documents (such as a Charter, Statute, or By-Laws) detailing the funding and expenditures related to activities outlined in the Mission Statement of the Institution compared to activities outside of the mission of the Institution
- If the Institution is a for-profit organization, provide a complete list of key employees, members of the governing board, and/or other senior management as well as any governing documents (such as an Articles of Association or Organization) detailing the funding and expenditures of the Institution
- A complete and accurate Form W-8 signed by the institutional official within the last three years. While CFF issues grant funding to 501(c)(3) and nonprofit institutions, CFF also issues contract award funding to other kinds of institutions.
- A description of external sources of support, including the names of individuals and organizations providing the Institution with major donations, official awards, private endowments, and/or commercial activities
- Standard Operating Procedure(s) or relevant policy to ensure that all awarded funds, including but not limited to CFF funds, are used in compliance with all applicable U.S. anti-terrorist financing, privacy and asset control statutes, regulations and executive orders, resulting in the Institution neither distributing awarded funds to terrorists nor supporting their networks, organizations, or activities (*If your institution does not have a relevant policy, please provide a statement 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. In the alternative, if the institution does not have this policy, CFF can provide an Anti-Terrorism Certification Form to be signed by the institutional official*).

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.**

Appendices (upload as PDF documents)

Up to five (5) appendices within the following (2) categories may be uploaded:

- Supporting documentation (e.g., reprints of the applicant’s work, pertinent survey(s), discussion guide(s), interview questions, etc.) relating to the proposal may be uploaded in PDF format.
- Signed Letters of Collaboration
 - If there are Co-Investigators, a letter of collaboration is required from each.

***Organization Assurances & Certifications (If applicable)**

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 Grants and Contracts 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 Grants and Contracts 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 Grants and Contracts 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 deadline.

XI. Other Information

Not applicable to this RFA

XII. Contact Information

For technical support and program/content information:

Primary CFF Grants and Contracts contact Angela Minucci at aminucci@cff.org or 301-841-2614

For scientific questions:

Dara Riva, M.S. at driva@cff.org

XIII. Electronic Application Checklist

Application Deadline: January 30, 2024 at 5:00 PM (EST)

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

Project Description & Supporting Documents:

- ☐ Budget Justification (download template, upload as PDF document)
- ☐ Concept Proposal Proposal (Download template, upload as PDF)
- ☐ Planning Period Statement of Work (SOW) (Download template, upload as PDF)
- ☐ Statement of Community Engagement (download template, if applicable)
- ☐ Biographical Sketches for Key Personnel (download template, upload as PDF document)
- ☐ Other Support (Download template, upload as PDF)
- ☐ Appendices (Up to five (5) appendices within the following (2) categories may be uploaded:
 - Supporting documentation (e.g., reprints of the applicant's work, pertinent survey(s), discussion guide(s), interview questions, etc.) relating to the proposal may be uploaded in PDF format.
 - Signed Letters of Collaboration
 - If there are Co-Investigators, a letter of collaboration is required from each.
- ☐ International Institution Form (if applicable, download template and upload as PDF documents)
 - ☐ Institution's most recent Mission Statement
 - ☐ Applicant institution's tax status documentation or equivalent, or a letter stating it is not available
 - ☐ Description of other sources of support, such as official awards, private endowments, and commercial activities, received by institution
 - ☐ Institution's Standard Operating Procedure(s) or relevant policy to ensure that funds provided are neither distributed to terrorists or their support networks, nor used for activities that support terrorism or terrorist organizations
 - ☐ For-profit institution must submit a complete list of key employees, members of the governing board, and/or other senior management