Program Name: Path to a Cure (PTAC) - Postdoctoral Research Fellowship Award – Spring 2020

Brief Program Overview/Description: 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 $63,100 in the first year, and up to $65,450 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 below.

Key Dates:

Published	March 3, 2020
LOI Submission Deadline	N/A
LOI Applicant Notified	N/A
Full Application Deadline	May 13, 2020
Committee Review Date	Mid-August 2020
Notification to Applicants	Mid-September 2020
Earliest Project Start Date	November 1, 2020

Table of Contents:

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**
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.

III. **Funding Amounts**
Awards may be approved for up to a two (2) year period. Funding of up to $63,100 in the first year, and up to $65,450 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	$58,850	$1,250	$3,000	$63,100
Second-year Fellowship	$61,200	$1,250	$3,000	$65,450

IV. **Eligibility**
- Awards may be approved for up to a two-year period. Funding for Year 2 is contingent upon submission and approval of a renewal progress report and the availability of funds.
- 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.

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

Small molecule CFTR modulators that directly target the mutant protein are powerful therapies that will likely be benefit 90% of people with CF in the near future. 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.

Academic projects supported through the Path to a Cure initiative should focus on foundational concepts, strategies, and methods that have the potential to inform or ultimately translate into novel therapies to restore CFTR protein function or fix/replace the defective CFTR gene.

Emerging areas of interest with high priority to the CF Foundation:
- Molecular characterization of CFTR mutations other than F508del
- CFTR structure/function studies relevant to mechanism of modulator action
- 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 Fellowship Program (https://www.cff.org/Research/Researcher-Resources/Awards-and-Grants/Training-Awards/Postdoctoral-Research-Fellowship-Award/).

VII. Review and Award

All applications are evaluated by CFF's Path to a Cure (PTAC) 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 PTAC 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
• Commitment to, or intent to pursue, a research career related to CF • Potential to develop an independent research career related to CF • Research accomplishments	• 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	• 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	• 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 PTAC 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 discussed (or triaged) in two review meetings will not be accepted for further consideration by CFF. In order to resubmit unfunded applications during future application cycles, applicants must 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
Applicants may only submit one (1) Postdoctoral Research Fellowship Award application per funding cycle in 2020

Applications deadline: Wednesday, May 13, 2020 by 5:00 PM (Eastern)

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

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

General Timeline:
Application Deadline _____ May 13, 2020
Review _____ August 2020
Notification to Applicants _____ September 2020
Earliest Start Date for Awarded Projects _____ November 1, 2020

IX. Letter of Intent Guidelines
Not applicable to this RFA

X. Full Application Guidelines
Applications must be submitted online at proposalCENTRAL: https://proposalcentral.com/

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

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

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

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

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

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

Locate the listing for the **"Postdoctoral Research Fellowship"** program. Click on the "**Apply Now**" button in the column on the far right to open the application form.

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

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

1. **Title Page**: Enter the title of your project, indicate whether the Principal Investigator (PI) is an investigator new to CF, and whether this is a resubmission of an application that was reviewed previously (include date of previous submission in the corresponding field).

2. **Download Templates & Instructions**: Download the available templates applicable to the project, fill them out and upload them when completed in Section #10. Templates available include:
   - Applicant Instructions for Letters of Reference (for reference purposes only)

- Biographical Sketch(es) for Key Personnel
- Mentor's Results of Past and Current CFF/CFFT Support
- Other Support
- Facilities Available
- Budget Detail
- Budget Justification
- Critique Response (if resubmission)
- Research Plan
- Training Plan
- Names and Addresses of References (if applicable)

3. **Enable Other User to Access this Proposal:** Complete this section online if you wish to designate access to another individual, such as an assistant who has registered on proposalCENTRAL. Enter the email address of the individual and in the "**Permissions**" column, use the pulldown menu to select the type of access you wish to give. Please note that only delegates who are granted **"Administrator"** rights can submit applications on behalf of the applicant. Click on **"Accept Changes".**

4. **Applicant/PI:** If a profile was completed upon registration, the fields in this section will already be populated with the information entered in your Professional Profile. If you need to make any changes, click the **"Edit Professional Profile"** button and follow the instructions. If a profile was not completed, enter the required information and click **"Save".**

5. **Institution & Contacts:** If a profile was completed upon registration, the Principal Investigator's (PI) institution will be preloaded as Lead Institution. If a profile was not completed, enter the required information and click **"Save".** Be sure to use the full legal name of the institution.

6. **Letters of Support/Reference:** Letters of Support and/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.

   Invite Referees to submit Letters of Support/Reference through proposalCENTRAL
   Letters of Support/Reference must be submitted electronically ONLY. To "invite" Referees, go to the "Letters of Reference" section of the online application, and enter the email addresses of the individuals you have asked to submit letters. This will generate automated emails (with instructions) sent to each Referee through the proposalCENTRAL website. 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 proposalCENTRAL should not be password protected or otherwise encrypted. Such encryption will cause errors in assembling a single-print PDF of the application. The applicant should inform the individuals writing letters to not include password protection on their documents.

Additionally, applicants must complete the "Names and Addresses of References" template and upload it in Section #10.

7. **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 2,000 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.

8. **Budget Summary:** Fill in the start and end date and applicable amounts for each year of support requested by completing the online fields (Period 1, 2). The total requested salary and benefits must not exceed $58,850 for Year 1 and $61,200 for Year 2. The total budget requested cannot exceed $63,100 for Year 1 and $65,450 for Year 2. *Note: The Budget Detail and Budget Justification templates downloaded in Section #2 need to be completed and uploaded in Section #10 for each year of the award. The amounts included in the uploaded Budget Detail must match the amounts entered in the Budget Summary online.*

9. **Organization Assurances:** Select the type of assurances that are applicable to the project and provide all required information (i.e. IRB, IACUC, and/or IBC/rDNA approval letter and status at the time of submitting the application). Refer to Section K. ORGANIZATION ASSURANCES & CERTIFICATIONS in these guidelines for details.

10. **Research Plan & Supporting Documents:** In this section, upload the completed templates downloaded in Section #2 above in PDF format. Fill out the fields describing the attachment, select the attachment type from the pulldown menu, enter a description for the attachment in the corresponding field, choose the file to be uploaded, and click the "Upload Attachment" button to upload the file. Do this for each attachment.

    A. **Biographical Sketch(es) of Key Personnel (template available online)**
       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.

B. **Mentor's Results of Past and Current CFF/CFFT Support (template available online)**
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

C. **Other Support (template available online)**
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.

D. **Facilities Available (template available online)**
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.

E. **Budget Detail and Budget Justification (separate templates available online)**
Fill out the Budget Detail and Budget Justification templates for each and all years of support requested. In the space provided on the templates, indicate the year or period as well as start and end dates for the proposed budget period. (Be sure the amounts entered in the Budget Detail(s) match the amounts entered in the online budget summary in Section #8).

Budget Detail – Direct Costs
Salary & 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 **$197,300**. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all funding agencies and foundations.

Travel - 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 $1,500 per person per year**. Registration fees associated with conferences are in addition to this allowance should be listed under "Other Expenses".

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. Tuition costs may be requested for personnel supported through this study but may not exceed **$10,000** per person per year.

Budget Detail – Indirect Costs
Indirect costs are not allowable

Budget Justification
Describe costs listed in the Budget Detail. Use major categories, such as Salary & Benefits, Supplies, etc. Justify all items and make sure amounts and figures listed in the narrative are consistent with those listed in the Budget Detail(s).

F. **Critique Response (template available online, if applicable)**
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.

G. **Research Plan (template available online)**
   - *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 Postdoctoral Research Fellowships are reviewed by CFF's Research and Research Training Committee (RRT), 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).

H. **Training Plan (template available online)**
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.

I. **Names and Addresses of References for Junior Investigators (template available online)**
List the names, titles, and contact information of the individuals who have been asked to submit Letters of Reference on the applicant's behalf. A PDF copy of the completed form should be uploaded. Though not required to submit Letters of Reference, Senior investigators should still check the box in the template that identifies them as Senior investigators and upload the form to proposalCENTRAL.

J. **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.

K. **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 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.

L. **International Institution Form (template available online, if applicable)**
    Applicants whose institution is not a United States based-entity must complete the International Institution Form. **Upload a PDF version of the completed and signed form, together with the following documents*:**
    - A copy of the institution's most recent Mission Statement.
    - A copy of the institution's tax status documentation or equivalent, or a letter stating it is not available.
    - A brief description of other sources of support, such as official awards, private endowments, and commercial activities, received by the institution.
    - A copy of the institution's Standard Operating Procedure(s) or relevant policy to ensure that funds provided are neither distributed to terrorists or their support networks, nor are funds used for activities that support terrorism or terrorist organizations.
    - For-profit institutions must submit a complete list of key employees, members of the governing board, and/or other senior management.

    Applicants who have provided these documents within the past three (3) years are 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 CFF Grants and Contracts 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.

M. Appendices (upload materials as PDF documents, if applicable)
Appendices are restricted to the following three (3) 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.

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

12. Print Face Pages: Follow the prompts on the screen to generate and print a Face Page. The Face Page will be populated automatically with data entered in the online application (applicant's name, institution, title of application, etc.). The Face Page must be signed by the Principal Investigator and Authorized Institutional Official and uploaded in Section #10. Co-Principal Investigators, if any, are not expected to sign the Face Page.

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

14. Submit: Click on the gray button with blue lettering. **Submit** CFF will not receive your application unless the "Submit" button is clicked.

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

XI. Other Information
Not applicable to this RFA

XII. Contact Information

For technical support with the online application:
proposalCENTRAL at pcsupport@altum.com or
800-875-2562 on weekdays, 8:00 a.m. to 5:00 p.m. (Eastern)

For program/content information:
CFF Grants and Contracts at grants@cff.org or 301-841-2614

XIII. Electronic Application Checklist

Applications deadline: Wednesday, May 13, 2020 by 5:00 PM (Eastern)

Submit online through proposalCENTRAL: https://proposalcentral.com/

Face Page which includes:
- ☐ Signatures
- ☐ Principal Investigator (Co-PI's are not required to sign)
- ☐ The Official authorized to sign on behalf of the Awardee Institution
- ☐ Applicant/PI information (online)
- ☐ Complete Institution and PI Contact Information, including correct mailing address (online)
- ☐ Organization Assurances (check those that apply online/complete the required information)
  - ☐ Human Subjects Certification
  - ☐ Recombinant or Synthetic Nucleic Acid Molecules/Biosafety Information
  - ☐ Research Involving Animals Approvals

Research Plan, Supporting Documents and Appendices:
- ☐ Abstracts ~ Summary of Relevance - (complete online)
- ☐ Biographical Sketches for Key Personnel - (upload)
- ☐ Mentor's results of Past and Current CFF/CFFT Support - (upload)
- ☐ Other Support (NIH Format) - (upload)
- ☐ Facilities Available - (upload)
- ☐ Budget Detail for each year - (upload)
- ☐ Budget Justification for each year - (upload)
- ☐ Critique Response - (upload, if applicable)
- ☐ Research Plan - (upload)
  - ☐ Hypothesis and Specific Aims
  - ☐ Background and Significance
  - ☐ Preliminary Results
  - ☐ Experimental Design and Methods
  - ☐ Literature Cited (not included in Research Plan page limitation)
- ☐ Training Plan – (upload)
- ☐ Names and Addresses of References for Junior Investigators (upload, if applicable)
- ☐ Verification of Applicant Institution's Tax Status - (upload)
  - ☐ W-9 form
  - ☐ Federal (IRS) tax status letter
- ☐ Appendices (upload as PDF, if applicable)
  - ☐ 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