CYSTIC FIBROSIS FOUNDATION

CFF/NIH-Unfunded Grant Award

POLICIES AND GUIDELINES

Updated March 29, 2017
I. CFF/NIH-UNFUNDED GRANT AWARD OVERVIEW

The Cystic Fibrosis Foundation (CFF) has developed its research program to complement work at the National Institutes of Health (NIH). Support from CFF, through various mechanisms, is intended to provide for the development of sufficient preliminary data to make CF-related grant applications highly competitive in the NIH review process. However, as a result of funding constraints on the NIH, coupled with the growing interest in CF research, occasions arise in which highly meritorious grants are submitted to the NIH but are not funded. In an effort to assure that all meritorious CF-related research is supported, CFF has developed the CFF/NIH-unfunded Grant Award mechanism to provide funding. The objective of this grant is to support excellent CF-related research projects that have been submitted to and approved by the NIH, but cannot be supported by available NIH funds. Applications must fall within the upper 40th percentile.

CFF does not intend to assume the role of the NIH, but instead wishes to ensure that the momentum in CF research is not irreversibly slowed. The CFF/NIH-unfunded award offers a temporary mechanism for continuing highly-meritorious projects until NIH support can be obtained. The CFF will continue to vigorously encourage the NIH to assume support of meritorious CF-related projects. Please see below for applicant eligibility criteria and grant overview:

- The application must have been reviewed by an NIH study section and presented to an institute council within 12 months of applying for CFF support.
- Applications must have been submitted as an R01/R21 and fall within the upper 40th percentile.
- The application must be clearly relevant to CF.
- The investigator should not be receiving other funding for this work.
- Funding of up to US$75,000 to US$125,000 per year in Direct Costs; indirect costs are not allowed. (Note: the level of funding will be determined by CFF following review by the designated medical/scientific advisors.)
- Grants may be approved for a maximum of two (2) years. Funding for year 2 is contingent upon submission and approval of a renewal progress report and the availability of funds.
- If awarded, it is required that a resubmission to the NIH application (A0 or A1) be submitted to the NIH within one year of receipt of CFF grant. Failure to do so will result in the loss of support. A copy of the revised application must be submitted to CFF.

II. GOALS OF RESEARCH CURRENTLY OF INTEREST TO CFF

Background
The majority of morbidity and mortality associated with cystic fibrosis (CF) today is due to lung disease. In CF, innate defenses are compromised and inhaled or aspirated pathogens...
are able to establish chronic infections. CF is unique in that only a small subset of pathogens have been linked to disease progression, and the infection remains, for the most part, compartmentalized. Unfortunately, the neutrophil dominant inflammatory response causes tissue destruction and compromised organ-level function. Both the host and pathogen adapt as the initial insult evolves into an indolent, chronic infection punctuated by acute exacerbations.

Kalydeco™ (VX-770), the first drug to target the basic CFTR defect, demonstrated that CFTR modulating drugs improve clinical parameters such as sweat chloride, lung function, and body weight. CFF will continue to support efforts that improve our understanding of basic defects as well as mechanisms by which CFTR modulators improve patient outcomes. While CFTR biogenesis, trafficking, structure/function, airway defense, and microbial adaption to the CF lung remain relevant, CFF is interested in funding new areas of research that may lead to the development of new and innovative therapies. Investigators working in these areas are encouraged to submit applications for consideration.

Emerging research interests:

- Influence of CFTR modulation on the airway milieu in patients, animal models, and in vitro studies, including resident pathogens, inflammation, mucin structure (tethered and secreted), and mucociliary clearance
- Effect of CFTR activity on lung inflammation and inflammatory cell function
- Relationship between killing and clearance (mechanical and phagocytic) of inhaled bacteria and the impact upon inflammatory signaling
- Molecular characterization of CFTR mutations other than F508del
- Novel means for restoring CFTR function such as:
  - Gene editing/repair strategies
  - Delivery methods for gene, RNA, and protein to the lung and other affected tissues
  - Cellular targets for CFTR correction
    - Lung progenitor cells, airway stem cell niche
    - Induced pluripotent stem cells (iPSC)

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

III. SUBMISSION INFORMATION & GENERAL TIMELINE

Applications are accepted **January 5th through October 31st by 5:00 PM (Eastern Time).**

*If October 31st falls on the weekend, the deadline will be the following business day.*

Submit applications online through proposalCENTRAL: [https://proposalcentral.altum.com](https://proposalcentral.altum.com)

Email a PDF copy of the signed Face Page to grants@cff.org in conjunction with the online submission (only the Face Page needs to be sent by email).
Late applications will not be accepted after October 31st and the deadline will not be waived. The Foundation reviews applications electronically, and only the documents submitted online will be reviewed.

Applicants will be notified as to the suitability of the application within 12 to 16 weeks of submission.

IV. REVIEW AND AWARD
Since applications to this program have already been reviewed and scored by an NIH study section, CFF medical/scientific advisors will focus on the following points:

- Relevance of the proposed study to issues in CF;
- Adequacy of the budget; and
- Potential for future support by the NIH.

All grants are subject to observance of CFF policies and Terms and Conditions in addition to applicable Federal regulations, based on the type of research involved. All grants and ongoing support are also contingent upon the availability of CFF funds.

V. INSTRUCTIONS FOR COMPLETING SPECIFIC APPLICATION COMPONENTS

- Font: Times New Roman 12 or Arial 11 font.
- Margins: Standard ½”.

Note: When all the documents have been uploaded to proposalCENTRAL, the system will compile them into a single PDF file in the correct sequence.

1. FACE PAGE (system generated)
The Face Page is populated automatically with data entered in the online application (applicant’s name, institution, title of application, etc.). The Face Page can be downloaded after completing the application and clicking on the “Validate” button (Proposal Section 12). The Face Page must be signed by the Principal Investigator and Authorized Institutional Official. Co-Principal Investigators, if any, are not expected to sign the Face Page. However, signed letters of collaboration from Co-Principal Investigators should be provided in the Appendix. Scan and email the signed Face Page to grants@cff.org in conjunction with the online submission. No hardcopy is required.

2. ABSTRACTS - SUMMARY OF RELEVANCE - KEYWORDS
Enter the abstracts and relevance information online (Proposal Section 7). A system-generated page will get attached to the application. There is no need to upload the same information on a separate document.
Lay Abstract
In the space provided online, provide a statement of no more than 250 words (up to 2,000 characters max, including spaces) explaining the subject of the research proposal and its relationship to CF. This statement will be used to inform the non-scientific departments of CFF and the general public of the nature of this work. Therefore, the Lay Abstract should not include proprietary or confidential information.

Scientific Abstract
In the space provided online, provide a statement of no more than 250 words (up to 2,000 characters max, including spaces) explaining the subject of the research proposal and its relationship to CF. 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 the disease the opportunity to lead full, productive lives by funding research and drug development, promoting individualized treatment, and ensuring access to high-quality, specialized care.

Provide a statement of no more than 250 words (up to 2,000 characters max, 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.

Keywords
From the lists of options provided, select all applicable research topics, keywords, and relevant areas of CF research for the proposed project. A minimum of one option per category must be selected.

3. LETTER(S) OF SUPPORT FOR INVESTIGATORS NEW TO CF RESEARCH (upload documents)
(Not required for experienced CF investigators, e.g. recipients of CFF/CFFT funding, investigators with recent publications in the field.)

Investigators new to CF research are strongly encouraged to consult or collaborate with an established CF investigator/clinician either at their own institution or another. A letter of support from the collaborator/consultant should be included with the application, explicitly describing how the proposed work is relevant to CF and how the collaborator/consultant will assist the investigator. Upload a PDF of the signed, Letter(s) of Support as appendices (in Proposal Section 10).
4. RESULTS OF PAST AND CURRENT CFF/CFFT SUPPORT (template available online)
Use the form provided for download on proposalCENTRAL. 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 Account #
- Principal Investigator (PI)
- CFF/CFFT Project Title
- Applicant’s Title on Project
- Project Start/End Dates
- Total CFF/CFFT Award Amount
- Results of Support

Save the completed form as a PDF and upload it to proposalCENTRAL (Proposal Section 10).

5. COPY OF NIH-UNFUNDED APPLICATION (upload document)
A PDF copy of the entire NIH-unfunded grant application should be uploaded to proposalCENTRAL (in Section 10) of the online application.

- Describe attachments as “NIH-unfunded Application”.
- Select “Copy of NIH-unfunded Application” attachment type from drop-down menu.

6. COPY OF NIH SUMMARY STATEMENT (upload document)
A PDF copy of the entire NIH Summary Statement associated with the NIH-unfunded grant application must be uploaded to Proposal Section 10 of the online application:

- Describe attachment as “NIH Summary Statement”.
- Select “Copy of NIH Summary Statement” attachment type from drop-down menu.

7. RESPONSES TO NIH SUMMARY STATEMENT (template available online)
A “Responses to NIH Summary Statement Template” is available for download on proposalCENTRAL. Please provide a point-by-point response to the critiques noted in the NIH Summary Statement and specific plans to address identified weaknesses. There is no page limit to the responses; however, be as concise and succinct as possible.

8. REVISED BUDGET AND JUSTIFICATION (separate templates available online)
Complete the online budget summary in addition to a budget detail and budget justification (templates provided in Proposal Section 10) for all years of support requested. Be sure the budget detail matches the online budget summary.

CFF does not allow indirect costs on CFF/NIH-unfunded Grant Awards.
- **Budget Detail – Direct Costs**

**Personnel** - List the names and positions of all professional and non-professional personnel involved in the project, whether or not salaries are requested. Indicate the percent effort on the project for professional personnel. For each individual, list dollar amounts separately for institutional base salary and fringe benefits. 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 US$187,000; when calculating salary requests, the NIH cap must be adhered to. 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 of any consultant who has agreed to serve in this capacity, including statisticians and physicians in connection with patient care 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.

**Equipment** - List all items of equipment requested and the cost of each item. If funds are requested to purchase equipment that is equivalent to items listed under Facilities Available, justify the duplication. Justify any item of equipment for which the need may not be obvious.

**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.

**Travel** - Describe the purpose of any travel. Expenses for travel outside the North American continent, including travel to Hawaii, Puerto Rico, and other U.S. territories, are not allowable expenses. Travel expenses are limited to US$1,250 per person. Registration fees associated with conferences should be listed under “Other Expenses.”

**Other Expenses** - Itemize other expenses by major categories, such as duplication costs, publication costs, computer charges, equipment maintenance, etc. Justify all items.

**Subcontracts** – The total cost of each subcontract (direct costs only) should be listed under “Other Expenses” and included in the applicant’s direct costs. Detailed budgets for each subcontract must be provided for each year of support. Negotiations of subcontracts are between the applicant institution and the subcontractor.

- **Budget Justification**

Describe costs listed in the Budget Detail. Use major categories, such as Personnel, Consultant Costs, Equipment, etc. **CFF does not allow indirect costs on CFF/NIH-unfunded Grant Awards.**
9. REVISED RESEARCH PLAN (template available online)

**Page limit:** Ten (10) single-sided pages, plus Literature Cited. Applications exceeding this page limit will not be reviewed. Key figures and legends must be included in the Research Plan. If uploaded as Appendices, they will NOT be reviewed.

The Revised Research plan should not be a copy of the submitted NIH-unfunded application. Instead, this section should highlight the scope of work and experiments that will be completed using the funds from CFF if the grant is funded. This section should specifically address weaknesses noted in the NIH Summary Statement as well as the reduced CFF budget. The Revised Research Plan must also include a clear strategy for resubmission of the original (A0/A1) application to the NIH. Information should be presented in a clear, concise manner, while being specific and informative.

At the top of each page, type the PI's name. Each page must be sequentially numbered at the bottom.

a. **Hypothesis and Specific Aims (one page).** 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.

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 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.** Discuss 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 studies are involved, provide details of the methods for patient selection and care. Discuss potential difficulties and/or limitations of the proposed procedures and alternative approaches to achieve aims. Point out any procedures, situations or materials that may be hazardous to personnel or patients and the precautions to be exercised. 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).
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.

e. **Consultant Arrangements.** If the proposed project includes consultant arrangements and/or collaboration with other individuals outside the applicant’s group, describe the working relationships and support this description by letter(s) of intent signed by collaborating individual(s). If clinical material required by this grant is to be furnished by other individuals, include a statement from these individuals agreeing to their participation and precautions taken to ensure anonymity of patients.

f. **Literature Cited.** References should be numbered in the sequence that they appear in the text and listed at the end of the Research Plan. Each citation must include the names of authors, the name of the journal or book, volume number, page number and year of publication (titles are optional).

10. **INTERNATIONAL INSTITUTION FORM (template available for download, if applicable)**

Applicants whose awardee institution is not based in the United States 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 Exemption Letter, if institution is nonprofit.
- A description of other sources of support, such as official grants, 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 must provide English translations for all non-English documents, including material provided in support of the Research Plan.

11. **ORGANIZATION ASSURANCES & CERTIFICATIONS**

**Research Involving Human Subjects:** The IRB application must be submitted to your institution before the CFF application deadline. CFF policy pertaining to the protection of individuals as research subjects requires that for each proposal submitted, the applicant 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 Department of Health and
Human Services policies. This certification should accompany the application and must be received prior to activation of any grant. If the IRB approval is pending, give the date when it is expected. The approved certification should be submitted as soon as it is available.

**Research Involving Recombinant DNA:** All research involving recombinant deoxyribonucleic acid (DNA) techniques and human gene transfer supported by CFF must meet the requirements contained in the document *NIH Guidelines for Research Involving Recombinant DNA Molecules (updated April 2016).* This publication and announcements of modifications and changes to the NIH Guidelines may be accessed at [http://osp.od.nih.gov/office-biotechnology-activities/biosafety/NIH-guidelines](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/NIH-guidelines).

The purpose of the *NIH Guidelines* is to specify practices for the construction and handling of: (i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids; (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or (iii) molecules that result from the replication of those described in (i) or (ii) above.

Many types of studies involving recombinant DNA are exempt from the NIH Guidelines while others are prohibited. The applicant organization is required to establish and implement policies that provide for the safe conduct of the research in full conformity with the NIH Guidelines. This responsibility includes establishing an Institutional Biosafety Committee to review all recombinant DNA research to be conducted at or sponsored by the applicant organization, and to approve those projects it finds are in conformity with the Guidelines.

CFF policy pertaining to recombinant DNA research requires that the applicant institution certify in writing that an institutional committee has reviewed and approved the procedures involving recombinant DNA in accordance with the NIH Guidelines. **Applicants that do not have institutional committee approval must submit a recombinant DNA application to the applicant institution before the CFF application deadline.**

Certifications need not accompany the application, but all required certifications should be available upon request by CFF.

**Research Involving Animals:** Grant applications submitted to CFF involving the use of animals must meet the guidelines of the National Institutes of Health, U.S. Public Health Service, which require that all proposed studies be reviewed and approved by an Institutional Animal Care and Use Committee (IACUC). In addition, CFF grantee 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. **Applicants that do not have institutional committee approval must submit an IACUC application to the applicant institution before the CFF application deadline.** Certifications need not accompany the application. Applicants must be able to provide copies of all required certifications upon request by CFF.

12. VERIFICATION OF APPLICANT INSTITUTION’S TAX STATUS (upload documents)
CFF’s 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, on file. CFF’s Grants and Contracts Office will not issue Award Letters to Grantees 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 Form 147C, or other documentation verifying the organization’s Federal tax status. Grants 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.

13. APPENDICES
Appendices are restricted to the following four (4) categories:

- Certification of IRB approval, or statement indicating that such approval is pending and the date when such approval is expected. Other applicable organization assurances documents such as IACUC and IBC Approval Letters.
- Up to three (3) reprints of the applicant’s work relating to the general area of research in the grant proposal may be uploaded in PDF format.
- Signed Letters of Support and/or Collaboration: A Letter of Collaboration from Co-PIs, if any, should be uploaded and included in the application. Investigators new to CF research are strongly encouraged to consult/collaborate with an established CF investigator/clinician either at their own institution or another. The letter from the collaborator/consultant should be explicit as to how the proposed work is relevant to CF and how he/she will assist the investigator new to CF research.
- Additional NIH Biographical Sketches, that are not already included in the original NIH application, should be completed/uploaded for any new key project personnel named in the CFF application. (CFF defines “key project personnel” as any individual with an advanced degree that will plan an instrumental role in the accomplishment of the research project).

No other types of Appendices will be reviewed.
VI. ELECTRONIC SUBMISSION GUIDELINES

Applications are accepted between January 5th and October 31st, 2017 by 5:00 PM (ET).

The annual CFF/NIH-unfunded grant application cycle closes at 5:00 pm (Eastern Time) on October 31st. If the application deadline falls on a weekend, the deadline will be moved to the following business day.

Applications must be submitted online at proposalCENTRAL: https://proposalcentral.altum.com.

Late applications will not be accepted and the deadline will not be waived. A PDF copy of the signed Face Page should be emailed to grants@cff.org by the same date. Please do not mail any hardcopy to CFF.

Register at proposalCENTRAL if you have not already done so. If you have registered already, and cannot remember the password, click on the “Forgot Your Username/Password?” link located below the “Application Login” fields.

The opening screen, after logging in to proposalCENTRAL, includes multiple grant opportunities organized by Grant Maker and Program. If this screen does not appear, click on the gray tab labeled “Grant Opportunities” found on the upper right hand side of the page. Click on the light blue “Filter by Grant Maker” button to the left and scroll down to locate Cystic Fibrosis Foundation in the list.

Locate “CFF/NIH-unfunded Grant Award” in the list of CFF opportunities and click on the “Apply Now” button that appears on the far right in the “Apply” column to begin the application.

Instructions and templates are provided for review/download in related sections of the application. If you need tech support, please use the contact information that is provided on each screen.

Applicants may stop at any point, each time remembering to click the SAVE button before exiting, and continue/revise until clicking on the SUBMIT button. When logging in to continue, click on the blue tab, “Manage Proposals,” and then the “Edit” button.

Access may be designated to another registered individual, such as an assistant, in Section #3: “Enable Other Users to Access This Proposal.” Enter the designated individual’s full name and email address and then, in the “Permissions” column, use the drop-down menu to select the type of access you wish to give.

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. Late applications will not be accepted, and the deadline will not be waived.
Upon validating the application, follow the prompts to print the system-generated face page. Please hit the SUBMIT button to complete the application process. Sign, scan and email the Face Page to grants@cff.org in conjunction with the online submission (only the Face Page needs to be scanned and sent by email, but it needs to be sent at the time you submit the application on proposalCENTRAL).

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.

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. (ET)

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

Applications are accepted January 5th through October 31st at 5:00 PM (ET) via https://proposalcentral.altum.com/. If the application deadline falls on a weekend, the deadline will be moved to the following business day. A PDF copy of the signed Face Page should be emailed to CFF (grants@cff.org) in conjunction with the online submission.

☐ Face Page, which includes:
  ☐ Signatures
  ☐ Principal Investigator (Co-PI’s are not required to sign)
  ☐ The Official authorized to sign on behalf of the Grantee Institution
  ☐ Applicant/PI information (online)
  ☐ Complete Institution and PI Contact information, including correct mailing address (online)
  ☐ Organization Assurances (check those that apply online)
    ☐ Human Subjects Certification
    ☐ Recombinant DNA Biosafety information
    ☐ Institutional Animal Care and Use Committee information

☐ Research Plan, Supporting Documents and Appendix:
  ☐ Abstracts - Summary of Relevance - Keywords (online)
  ☐ Letter(s) of Support for Investigators New to CF Research (Upload as Appendices)
  ☐ Results of Past and Current CFF/CFFT Support
    ☐ Copy of NIH-unfunded Application (upload online)
    ☐ Copy of NIH Summary Statement (upload online)
    ☐ Responses to NIH Summary Statement
    ☐ Revised Budget and Budget Justification for each year
    ☐ Revised Research Plan
      ☐ Hypothesis and Specific Aims
      ☐ Background and Significance
      ☐ Preliminary Results
      ☐ Experimental Design and Methods
      ☐ Consultants/Collaborative Arrangements
      ☐ Literature Cited (not included in Research Plan page limitation)

☐ Organization Assurances & Certifications (uploaded as appendices)
  CFF policy requires applicant institutions to certify in writing that an IRB has reviewed and approved procedures for the use of human subjects, that an institutional committee has reviewed and approved procedures involving r-DNA, and that an institutional Animal Care and Use Committee (IACUC) has reviewed and approved studies involving the use of animals.

☐ International Institution Form (upload, if applicable)
  ☐ Institution’s most recent Mission Statement
  ☐ Institution’s Tax Exemption Letter, if institution is nonprofit
  ☐ Description of other sources of support, such as official grants, private endowments, and commercial activities, received by the 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

☐ Verification of Applicant Institution’s Tax Status (upload as PDF documents)
  ☐ W-9
☐ 501(c)3, IRS Form 147C or equivalent tax status letter
☐ W-8BEN-E form and tax equivalency letter (if non-US applicant)
☐ **Appendices (upload as PDF documents)**
   ☐ Certification of IRB approval, or statement indicating a pending approval and anticipated date.
   Other applicable organization assurances documents such as IACUC and IBC Approval Letters
☐ Up to (3) copies of the applicant’s work relating to the general area of research in the proposal
☐ Letters of Support and/or Collaboration
☐ Any additional NIH Biographical Sketches that are not already included in the original NIH application