Postdoc-to-Faculty Transition Award

POLICIES AND GUIDELINES

Published: October 1, 2018
Application Deadline: December 3, 2018
I. ABOUT THE CYSTIC FIBROSIS FOUNDATION
The mission of the Cystic Fibrosis Foundation (CFF) is to cure cystic fibrosis (CF) 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 treatment.

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

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

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

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

• **Phase I: Research training to occur during the fellowship:** This phase of the award is intended to provide support for up to three (3) years to develop research and professional development skills and undertake research training in an area of priority to CFF. As part of this application, applicants are only required to submit a Research Plan for Phase I. Grantees and their mentors will be required to submit additional materials prior to the initiation of Phase II.

• **Phase II: Independent Research Investigation (first independent application):** This phase is intended to provide support for up to two (2) years for independent research studies. This support need not occur at the institution where Phase I took place. The outline for this work should be submitted for consideration by CFF near the end of Phase I, coinciding with the first academic appointment. In addition to scientific merit, CFF will assess the institution’s commitment to the research career development of the recipient in his/her first academic appointment. **At least 75% of the candidate’s time must be devoted to CF-related research during Phase II.**

The award will not be made for Phase II independently. Grantees who transition to an independent faculty position before the start of their third year of training support (at an institution other than where they received their Phase I training) may add a maximum of one (1) additional year onto Phase II of the award. Transition early into Phase II of the award must be approved by the CFF Program Director.
The candidate’s progress and career goals will be subject to annual evaluation by CFF throughout Phase I. Transition to Phase II will be subject to an additional review by CFF, with the scientific merit of the proposed research project evaluated, as well as the institutional commitment to the career development of the candidate.

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

**General Guidelines and Eligibility:**
- Candidates must be U.S. citizens or U.S. permanent residents.
- Postdoctoral applicants (Ph.D., M.D., D.V.M. or equivalent) engaged in or planning CF-related basic science research projects are eligible. Candidates who are clinical fellows should apply to the CFF Clinical Fellowship Program for the appropriate year, or for the LeRoy Matthews Physician-Scientist Award Program.
- Successful candidates for this award will demonstrate outstanding research potential and provide evidence of serious intent for an academic research career related to CF. Please note that the review process for this award is highly selective.
- Postdoc-to-Faculty Transition Awards are awarded based on individual merit, program relevance, and institutional environment. Therefore, **Phase I awards are not transferable** to other individuals or institutions, unless previously approved by the CFF Program Director.
- Each candidate must identify a primary Mentor with substantial experience in training, and who will provide primary guidance for the grantee's research and professional career development. The Mentor is encouraged to form an advisory committee to develop and monitor the Phase I program and should include course work, seminars, research experience, and other educational experience deemed necessary for the development of an independent research career in Phase II.
- Individuals entering Phase II are encouraged to apply for additional external research support to fund their program. Program overlap of external funds is allowed.
- Awardees are required to inform CFF annually for a period of five years subsequent to completion of the award about academic status, publications, and research grants or contracts received. In addition, all grantees and institutions must comply with CFF grant policies.

**Funding levels:**
The first year of funding requested should coincide with the year of postdoctoral experience as outlined in the following table:
### Phase I: Postdoctoral Year

| Phase I: Postdoctoral Year | Stipend  
<table>
<thead>
<tr>
<th>(salary + fringe)</th>
<th>Research*</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>First-year Postdoc</td>
<td>$58,850</td>
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<td>Sixth-year Postdoc</td>
<td>$70,500</td>
<td>$10,000</td>
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Phase I stipends may only be used to support the postdoctoral fellow. During Phase II, salary support may be used to support the PI or research staff.

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

The maximum level of support available under this program during Phase I is $80,500.

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

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

### III. GOALS OF RESEARCH CURRENTLY OF INTEREST TO CFF

The majority of morbidity and mortality associated with 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 will prioritize funding of projects that are focused in areas of research that may lead to the development of new and innovative therapies. Investigators working in these areas are encouraged to submit an application for consideration.
Emerging areas of potential interest to the CF Foundation:

- Molecular characterization of CFTR mutations other than F508del
- Direct and indirect influences of CFTR modulation on the airway milieu in patients, animal models, and in vitro studies, including resident pathogens, inflammation, mucin structure (tethered and secreted), airway surface liquid (ASL), and mucociliary clearance
- Novel means for restoring CFTR function
  - Gene editing/repair strategies
  - Delivery methods for gene, RNA, and protein to the lung and other affected tissues
  - Cellular targets for CFTR correction
    - Airway progenitor cells, airway stem cell niche
- Mechanisms associated with mRNA stability and translational regulation, specifically related to nonsense mutations and means to overcome them
- Development and characterization of model systems, including patient derived samples (such as nasal and intestinal cells) and induced pluripotent stem cells (iPSC)
- Biological mechanisms involved in lung allograft dysfunction/rejection and transplant immunology
- Effect of CFTR activity on lung inflammation, inflammatory cell function, and bacterial killing and clearance
- Difficult to treat CF infections (i.e. NTM, MRSA, Aspergillus)

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

IV. REVIEW AND AWARD

All applications are evaluated by CFF’s Research and Research Training (RRT) 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 RRT. Relevance of the proposed study to issues in CF is also considered in determining awards. All awards are subject to compliance with applicable regulations and CFF policies and are contingent upon the availability of CFF funds.

Applications will be reviewed and scored by the RRT 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. Applicants must address reviewer critiques in order to resubmit their applications during future application cycles.
Applications will be evaluated in the following areas:

<table>
<thead>
<tr>
<th>Candidate</th>
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<tr>
<td>• Commitment to, or intent to pursue, a research career related to CF</td>
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<tr>
<td>• Potential to develop an independent research career related to CF</td>
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<td>• Research accomplishments</td>
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<tr>
<th>Mentor(s)</th>
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<tr>
<td>• Established expertise in CF-related basic research or related research areas of high priority to CFF</td>
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<tr>
<td>• Commitment of the primary Mentor for the duration of the candidate’s development and research plan</td>
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<td>• Track record of the Mentor in training individuals for basic biomedical research</td>
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<tr>
<th>Environment</th>
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<tr>
<td>• Quality (breadth and depth) of faculty in basic and/or clinical sciences related to CF at applicant institution</td>
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<tr>
<td>• Quality of institution’s CF research and training programs</td>
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<tr>
<td>• Demonstrated interaction between basic and clinical investigators</td>
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<tr>
<td>• Institution’s commitment and ability to provide opportunities and facilities necessary for research career development related to CF</td>
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<tr>
<th>Training and Research Development Plan</th>
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<tr>
<td>• Feasibility and impact of the proposed plan</td>
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<tr>
<td>• Didactic course work required by the candidate (if indicated)</td>
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<tr>
<td>• Scientific and technical merit of the proposed research</td>
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<tr>
<td>• Ability of the proposed plan to develop research skills of the candidate needed for independence</td>
</tr>
<tr>
<td>• Relationship to candidate’s career development</td>
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Chief causes for assigning low priority scores to applications during review include the following:

• Inadequate environment for training
• Inadequate mentor’s statement of support and training plan
• 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
• Failure of the applicant to describe career goals as they may be related to a long-term commitment to CF research.
V. SUBMISSION INFORMATION & GENERAL TIMELINE

Application Deadline: Monday, December 3, 2018 at 5:00 PM (ET)

Submit online through proposalCENTRAL: https://proposalcentral.altum.com/
(Refer to Section VI 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. Late applications will not be accepted, and the deadline will not be waived.

General Timeline:

- Application Deadline: December 3, 2018
- Review by Research and Research Training Committee: March 2019
- Notification to Applicants: April 2019
- Earliest Start Date for Awarded Projects: May 1, 2019

VI. FULL APPLICATION GUIDELINES

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

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

First-time applicants must register to create a user name 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.

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 the listing for the “Postdoc-to-Faculty Transition Award” 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 next to the in-progress application.

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 and indicate whether this is a resubmission of an application that was reviewed earlier (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 only), Biographical Sketch, 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, and Appendices.

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. Check the “Auto Notify” box and then “Save”.

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 Reference are weighted heavily in the review. At least four (4) Letters of Support/Reference 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 Reference through proposalCENTRAL**

Letters of 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 for Junior Investigators” template and upload it in Section #10.

7. **Abstracts/Relevance/Keywords:** In the space provided online for abstracts, 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. 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 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 in this section, select all applicable research type, research topics, and keywords for the proposed project. A minimum of one (1) option must be selected per category. Click each keyword you want to select, then the arrow tab, until you have all applicable keywords selected on the list to the right.

8. Budget Summary: Fill in the start and end date, as well as the amounts, for each year of Phase I of support requested by completing the applicable online fields (Period 1, 2, 3, 4 & 5). Note: The Budget Detail and Budget Justification templates downloaded in Section #2 need to be completed for each year of Phase I and uploaded in Section #10. Budget Detail and Justification templates are not required for Phase II until that portion of the award is activated.

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.

   **Budget Detail & Budget Justification**
   Complete the online budget summary in addition to a budget detail and budget justification for each year requested (templates provided online in Proposal Section #2). Be sure the detailed budget matches the online budget summary.

   A. BIOGRAPHICAL SKETCHES (template available online)
   Complete and upload an NIH Biographical Sketch for the Applicant/Principal Investigator (PI) (fellow) and the Mentor(s). Do not exceed five (5) pages per person.

   B. MENTOR’S RESULTS OF PAST AND CURRENT CFF/CFFT SUPPORT (template available online)
   Mentors 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 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

C. OTHER SUPPORT (template available online)
Complete and upload the “Other Support” form for the Applicant/Principal Investigator (PI) (fellow) and the Mentor(s). There is no page limitation.

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 all years of support requested for Phase I. In the space provided on the templates, indicate the year as well as start and end dates for the proposed budget period. (Be sure the amounts entered in the Budget Details match the amounts in the online budget summary in Section #8).

• Budget Detail – Direct Costs Only
Personnel - List the name and title of the applicant. Indicate the percent effort on the project. 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 $189,600. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all funding agencies and foundations. Salary levels should not exceed levels indicated below.

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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. 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 consent from the CFF Grants & Contracts Office. **Travel expenses may not exceed $1,250 per person per year.** Registration fees associated with conferences should be listed under “Other Expenses.” Applicants are encouraged to attend the North American Cystic Fibrosis Conference (NACFC) and submit an abstract on their work each year of the award.

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

- **Budget Detail – Indirect Costs**
  Indirect costs are not allowable on Postdoc-to-Faculty Transition Awards.

- **Budget Justification**
  Describe costs listed in the Budget Detail. Use major categories, such as Personnel, Supplies, etc. Justify all items.

F. **CRITIQUE RESPONSE (template available online, if applicable)**
If the application is a resubmission, 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)**
- Key figures and legends must be included in the Research Plan. If uploaded as Appendices, they will NOT be reviewed.
- At the top of each page, type the applicant’s name. Each page must be sequentially numbered at the bottom.
- **Page limit:** Seven (7) single-sided pages, not including the Literature Cited. Applications exceeding this page limit will not be reviewed. A template is available for download on proposalCENTRAL. 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.
- If the application is a resubmission of an earlier one, revisions should 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:** 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 potential 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 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. Since Postdoc-to-Faculty Transition Awards are reviewed by CFF’s Research and Research Training Committee, applications that include methodologies requiring sampling of materials from human subjects will only be considered under this mechanism if the sampling method constitutes minimal patient risk (e.g., venipuncture, nasal cell brushing) and patient samples or data are anonymous. Describe the level of risk and measures taken to assure patient anonymity to the PI and other professional personnel, unless the PI or other professional personnel are care providers.

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 (template available online)
List the names, titles, and contact information of the individuals who have been asked to submit Letters of Support/Reference on the applicant’s behalf. A PDF copy of the completed form should be uploaded.

J. VERIFICATION OF APPLICANT INSTITUTION’S TAX STATUS (upload as PDF documents)
CFF’s Grants & 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 & 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. Awards are not issued prior to having these documents on file with the CFF Grants & Contracts Office.

K. ORGANIZATION ASSURANCES & CERTIFICATIONS
Research Involving Human Subjects: CFF policy pertaining to the protection of individuals as research subjects requires that for each proposal awarded, 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 found at https://www.hhs.gov/ohrp/regulations-and-policy/index.html. IRB status must be indicated on the “Organization Assurances” section of the application in proposalCENTRAL. CFF will not release awarded funds until this certification of IRB approval is received and on file with the CFF Grants & Contracts Office. This certification of IRB approval, if available at the time of application, should be included as an appendix to the application. The IRB submission date (indicated in proposalCENTRAL in the “Organization Assurances” section “Approved or Pending Date” field) must precede the date of application for CFF funding.

Research Involving Recombinant DNA: 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 2016). 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 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) recombinant nucleic acid molecules; (ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, or (iii) cells, organisms, and viruses containing such molecules.
Many types of studies involving recombinant and synthetic nucleic acids are exempt from the NIH Guidelines while others are prohibited. The applicant institution is required to establish and implement policies that provide for the safe conduct of the research described in the application in full conformity with the NIH Guidelines. This responsibility includes establishing an Institutional Biosafety Committee (IBC) to review all recombinant and synthetic nucleic acid research to be conducted at or sponsored by the applicant institution, and to approve those projects it finds are in conformity with the Guidelines.

CFF policy pertaining to recombinant and synthetic nucleic acid research requires that the applicant institution certify in writing that an IBC has reviewed and approved the procedures involving recombinant and synthetic nucleic acids in accordance with the NIH Guidelines. IBC status must be indicated on the “Organization Assurances” section of the application in proposalCENTRAL. CFF will not release awarded funds until this certification of IBC approval is received and on file with the CFF Grants & Contracts Office. This certification of IBC approval, if available at the time of application, should be included as an appendix to the application. The IBC submission date (indicated in proposalCENTRAL in the “Organization Assurances” section “Approved or Pending Date” field) must precede the date of application for CFF funding.

Research Involving Animals: Award 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 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. IACUC status must be indicated on the “Organization Assurances” section of the application in proposalCENTRAL. CFF will not release awarded funds until this certification of IACUC approval is received and on file with the CFF Grants & Contracts Office. This certification of IACUC approval, if available at the time of application, should be included as an appendix to the application. The IACUC submission date (indicated in proposalCENTRAL in the “Organization Assurances” section “Approved or Pending Date” field) must precede the date of application for CFF funding.

L. APPENDICES (template available online, upload materials as PDF documents)
Appendices are restricted to the following two (2) categories:
• Certification of organization assurances (i.e. IRB, IACUC and IBC approvals), if applicable.
• Up to three (3) reprints of the applicant’s work relating to the general area of research in the proposal.
11. **PI Data Sheet:** Fill in the required fields, save and exit.  
   *Note:* when completing the Professional Profile in proposalCENTRAL, applicants must indicate whether they are U.S. citizens or U.S. permanent residents to fulfill the eligibility criteria for this award.

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. 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.

   **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 & Contracts at grants@cff.org or 301-841-2614

**Instructions to complete and submit application for Phase II (to be completed at the end of the Fellowship period only)**

Below is a list of the application materials that will need to be submitted to CFF for review and approval before Phase II of the award can be initiated. Before this transition, you should contact the CFF Grants & Contracts Office to get a detailed description of the materials needed for submission.

- Face Page (signed and reflective of Phase II requested budget and project period)
- Letter from Department/Division Chair (indicating institutional support)
- Letters of Support/Collaboration (2 individuals)
• Other Support (NIH Format)
• Facilities Available
• Budget Detail for each year
• Budget Justification for each year
• Faculty Development Plan
• Research Plan
• Copies of applicable Organization Assurances and Certifications (IRB, IACUC, IBC, etc.)
• Verification of Applicant Institution’s Tax Status (W-9 and 501(c)3 letter)
VII. ELECTRONIC APPLICATION CHECKLIST

Application Deadline: Monday, December 3, 2018 at 5:00 PM (ET)

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

Phase I:

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/complete the required information)
  - Human Subjects Certification
  - Recombinant DNA/Biosafety Information
  - Research Involving Animals information
- Applicant/PI information (online)

Research Plan, Supporting Documents and Appendices:
- Abstracts ~ Summary of Relevance ~ Keywords - (complete online)
- Biographical Sketches - (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 of Phase I - (upload)
- Budget Justification for each year of Phase I - (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 (upload)
- Verification of Applicant Institution’s Tax Status - (upload)
  - W-9
  - 501(c)3, IRS Form 147C or equivalent tax status letter
- Appendices (upload, 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