Harry Shwachman Cystic Fibrosis Clinical Investigator Award

POLICIES AND GUIDELINES

June 9, 2017
I. MISSION
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.

Established in 2000, Cystic Fibrosis Foundation Therapeutics, Inc. (CFFT) is the non-profit drug discovery and development affiliate of the Cystic Fibrosis Foundation. CFFT supports and governs activities related to cystic fibrosis drug discovery through the many stages of drug development and clinical evaluation.

II. HARRY SHWACHMAN CYSTIC FIBROSIS CLINICAL INVESTIGATOR AWARD OVERVIEW
The Harry Shwachman CF Clinical Investigator Award provides the opportunity for promising, clinically-trained physicians with a commitment to research to develop into independent biomedical researchers who have active involvement in CF-related areas. The award helps facilitate the transition from postdoctoral training to an academic career as an independent investigator.

The award enables candidates to undertake three years of research, tailored to the individual’s interests and needs, with a sponsor(s) who is/are competent to provide appropriate research guidance and supervision. This award provides support for three years at a level of up to $130,000 in direct costs annually (indirect costs are not allowable). Funds may be used to support up to $100,000 in personnel costs, including awardee or other research staff working on the proposed project. Support is based on a full-time, 12-month appointment.

General Guidelines and Eligibility:
- Candidates must be U.S. citizens or U.S. permanent residents (must have obtained permanent residency prior to the time of application)
- Junior faculty and senior fellows are eligible to apply
- In general, a successful candidate has: (i) previous relevant research training; (ii) expertise in a related research technique; and (iii) a minimum of one (1) manuscript or abstract accepted for publication
- Supplementation of salary from other sources is allowable
- A minimum of 70% of the applicant’s time must be devoted to research
- Up to $30,000 per year may be requested for supplies, travel, minor equipment, etc.

III. GOALS OF RESEARCH CURRENTLY OF INTEREST TO CFF
Proposed research must be relevant to the CFF’s mission and to the health and well-being of CF patients. Applicants are encouraged, but not required, to address an emerging area of potential interest stated below. All applications are reviewed and scored not only on scientific merit but also on relevance to the CFF’s mission.
Emerging areas of interest to the CF Foundation:

- Development and characterization of model systems, including patient derived samples (such as nasal and intestinal cells) and induced pluripotent stem cells (iPSC) for the study 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
    - Lung progenitor cells, airway stem cell niche
- Understand defects associated with nonsense mutations and approaches for overcoming these effects
- 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)
- Approaches to understand and treat CF related GI issues and the impact of nutritional deficiencies
- Effects of endocrine system dysfunction in CF, including Cystic Fibrosis Related Diabetes (CFRD)

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

CFF’s Research and Research Training (RRT) Committee or the Clinical Research Committee (CRC) will evaluate all applications. The RRT Committee recommendations are reviewed by the Medical Advisory Council (MAC) and/or the Board of Trustees for final approval and funding. Funding of awards is based on the priority score awarded each application and the recommendations of the CRC or RRT and MAC. Relevance of the proposed study to issues in CF is also considered in determining awards. All research awards are subject to observance of the regulations and policies of CFF related to that category of research support and are contingent upon the availability of CFF funds.
Applications will be evaluated in the following areas:

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

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, if applicable.
- 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 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: Wednesday, September 13, 2017 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: September 13, 2017
- Review by Research and Research Training Committee: December 2017
- Notification to Applicants: March 2018
- Earliest Start Date for Awarded Projects: April 1, 2018

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/. If you have registered and cannot remember your password, click on the “Forgot Your Username/Password?” link below the “Application Login” fields. Note: Use the Customer Service link on the top right of each screen as needed.

Grant and award opportunities, including this, 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 “Harry Shwachman CF Clinical Investigator 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, “Manage Proposals”, and then the “Edit” button.

The following sections are listed in the gray navigation box 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 previously reviewed (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 Sketches for Key Personnel, Sponsor’s Results of Past and Current CFF/CFFT Support, Other Support, Facilities Available, Budget Detail, Budget Justification, Critique Response (if resubmission), Research Plan, Data Safety Monitoring 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. 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 Reference are weighted heavily in the review. At least four (4) Letters of Support/Reference are required as follows:
   - **The Sponsor(s) of the clinical fellowship training** – A Letter of Support from the fellowship Sponsor(s) should clearly identify the merits of the applicant and must include a description of CF-specific and other training the applicant received while working under the Sponsor’s direction.
   - **The Research Sponsor(s) for this award** – The letter should clearly describe the institution’s commitment to the professional growth of the applicant.
• **The CF Center Director(s) (at least one) at the sponsoring (or nearby) institution** – (if s/he is not the sponsor).

  **Note:** If a letter from any one referee listed above fulfills two of the required roles, additional letters from references who can speak to the applicant’s scientific and clinical abilities, interests, and potential to become an independent investigator must be provided to meet the minimum requirement of four (4) letters.

• **The Chair of the applicant’s Department at the sponsoring institution** – The letter should clearly describe the institution's commitment to the professional growth of the applicant.

Enter the email addresses of the individuals who will be asked to submit Letters of Support/Reference for the applicant. Automated emails (with instructions) will be sent to each Referee through the proposalCENTRAL website. The letters must be uploaded by the referees prior to submitting the application, **at least one (1) week prior to the application deadline**, so make sure to start the process early. Additionally, applicants must complete the “Names and Addresses of References” template and upload it in Section #10.

**Note:** Detailed Instructions on how to invite referees to submit the Letters of Support/Reference are also available in a downloadable document found in Section #2. 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.

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:** 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. 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.
**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 and applicable amounts for each year of support requested by completing the online fields (Period 1, 2, 3). The total requested salary and benefits must not exceed $100,000 per year. The total budget requested cannot exceed $130,000 per year. **Note:** The Budget Detail and Budget Justification templates downloaded in Section #2 must also be completed for each year of support requested and uploaded in Section #10.

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 L. 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, choose the file to be uploaded, and click the “Upload Attachment” button to upload the file. Do this for each attachment.

   Below are instructions specific to each template as well as additional information regarding other application components.

   **A. BIOGRAPHICAL SKETCHES FOR KEY PERSONNEL (template available online)**
   Complete and upload an NIH Biographical Sketch for all key project personnel, beginning with the Applicant/Principal Investigator (fellow) and the Sponsor(s). (CFF defines “key project 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. SPONSOR’S RESULTS OF PAST AND CURRENT CFF/CFFT SUPPORT (template available online)**
   Sponsors 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 an “Other Support” form for all key project personnel, beginning with the Applicant/Principal Investigator (fellow) and the Sponsor(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. 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 Detail(s) match the amounts in the online budget summary in Section #8).

- **Budget Detail – Direct Costs Only**
  - 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. At least 70% of the applicant’s time must be devoted to research. Total personnel costs (salary and benefits) requested through this program cannot exceed **$100,000 per year**. 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. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all funding agencies and foundations.
  - 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 US$1,250 per person per year. 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, minor equipment items under $5,000, conference registration fees, etc.

*Note: The maximum level of support that can be requested is $130,000 per year for up to three (3) years (direct costs only).*

- **Budget Detail – Indirect Costs**
  Indirect costs are not allowable on Harry Shwachman CF Clinical Investigator 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 Principal Investigator's name. Each page must be sequentially numbered at the bottom.
- **Page limit:** Ten (10) 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.

*Note: If applicants plan to conduct clinical research during their fellowship training, special attention should be given to Section d of the Research Plan (Experimental Design and Methods for Clinical Research only) and, for studies that place human subjects at more than minimal risk, to the completion of the Data Safety Monitoring Plan (DSMP).*

**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 in 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 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.

**Experimental Design and Methods (for applicants proposing to carry out Clinical Research through this support mechanism):** Provide a detailed discussion of the experimental design and procedures to be used to accomplish specific aims. Please discuss: study hypothesis; primary and secondary outcome measures; study sample-inclusion and exclusion criteria; sample size estimates*; subject enrollment including age range; puberty status; gender distribution; randomization scheme if applicable; description of experimental procedures and schedule including a study time-line; drugs and dosage; measures of compliance; follow-up schedule including a study time-line for full project up to three years; efficacy and safety evaluation, data monitoring and quality control; and a description of your proposed data analysis and statistical procedures for your hypothesis testing. Although no page limit is specified for this section, make every attempt to be concise and succinct.

*For sample size estimates, please* provide all estimates of means, standard deviations, rates or proportions used to calculate each of your sample size or power estimates. Please include in the statistical section whether you will use a one or two-tailed test, the power selected for such a test (if making a sample size calculation), and the reference for your sample size or power calculation. In instances of pilot studies where some of these parameters are unknown, we will accept your best estimates of the unknown parameters if preliminary data are not available, and if your calculation is a preliminary estimate before formal sample size can be calculated for a larger study. Please identify if you are making estimates from data or from personal estimates. This section must document access to adequate numbers of subjects.
Discuss the potential difficulties and limitations of the proposed procedures and alternative strategies for achieving the aims. If the Sponsor(s) is not a CF Center Director or Co-Director, a letter of support from the Center Director is required.

e. **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).

H. **TRAINING PLAN (template available online)**
The applicant, in conjunction with the Sponsor(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, including plans for introducing the applicant to research study planning and design, statistical methods, data management, etc. Do not exceed five (5) pages.

I. **DATA SAFETY MONITORING PLAN (for clinical research projects only; template available online)**
In compliance with Federal regulations, all applicants must submit a general description of the Data Safety Monitoring Plan (DSMP) for any proposed study that places human subjects at more than minimal risk. A DSMP helps to ensure subject safety, as well the validity and integrity of the data. Furthermore, a DSMP allows for the monitoring of study data to assess whether or not an early termination is necessary for safety or efficacy reasons.

The extent of monitoring required for a study is dependent on the level of risk involved for the subjects, as well as the size and complexity of the study. Large, multi-center CFFT-funded interventional clinical trials must utilize the CFFT Data Safety and Monitoring Board (DSMB). In addition, CFFT may require that investigators utilize the CFFT DSMB for any other interventional CF clinical trial that meets one or more of the following criteria:

- Multi-center;
- Randomized;
- Conducted in an emergency setting;
- Use high-risk interventions, such as gene therapy or gene transfer; or
- Include particularly vulnerable study populations, such as pediatric patients.

**Note:** On the available template, please check whether a DSMP is required and upload the template regardless of the response.
Address the following areas in the DSMP:

**Assessment of Risk** – Describe the level of risk the proposed research presents to subject participants and provide a detailed justification for the level of risk. Discuss who will monitor the study.

**Level of Risk**
- **Minimal Risk**
  - Study poses no more risk than expected in daily life (blood draw, physical exam, etc.)
  - Observational studies
  - Survey or questionnaire studies
- **Low Risk**
  - Post-marketing study Phase IV drug or device, as defined by FDA
- **Moderate Risk**
  - Substantial risk (>5%) of a Serious Adverse Event (SAE) originating from the underlying condition of the enrolled subject
  - Phase I or II study with available safety data in humans
- **High Risk**
  - Involves an intervention or invasive procedure with substantial risk
  - Involves the use of a new chemical or drug for which there is little or no toxicology data in humans
  - A gene therapy study or research involving recombinant DNA molecules (gene transfer)
  - Involves vulnerable populations (pediatric, pregnant, etc.)

**Anticipated Adverse Events and Grading Scale** – Describe anticipated adverse events (AEs), including expected frequency and the grading scale to be used. Discuss plans for addressing AEs.

**Reporting of AEs** – Detail the plan for reporting AEs, including who shall be notified in the event an AE should occur.

**Safety Monitoring Plan** – Describe all tests, evaluations, and exclusion criteria that will be implemented to ensure and monitor the safety of human subjects. Discuss plans for stopping the study if necessary.

**Safety Reviews** – Describe the process for monitoring and reviewing subject safety data, including the frequency of such reviews. Include details as to who will perform the monitoring and plans for reporting. If utilizing the CFFT DSMB, provide the frequency of meetings, the reporting requirements, including AEs, and the procedure for interim reporting as necessary. If this information is not available at the time of submission of the application, note that CFFT will not release awarded payments until it is provided.
Registrations for Investigator-Initiated Clinical Trials:

- **Clinicaltrials.gov (United States):** Applicants are required to register all non-exempt human subject studies in the ClinicalTrials.gov database to ensure information is freely available on CFFT-funded trials within the community. The registration should be no later than twenty-one (21) days after the first subject is enrolled. CFFT requires copies of documentation confirming this registration, when applicable.

J. **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 via Section #6 in proposalCENTRAL. A PDF copy of the completed form should be uploaded.

K. **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.

L. **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. For interventional and observational studies involving human subjects, the IRB submission date must occur within 30 days following award notification. For all other studies involving human subjects, 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
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](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.
M. 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 grant proposal may be uploaded in PDF format.

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. 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.

13. 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. Scan and email the signed Face Page to grants@cff.org in conjunction with the application submission on proposalCENTRAL. No hardcopy is required.

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
VII. ELECTRONIC APPLICATION CHECKLIST

Application Deadline: Wednesday, September 13, 2017 at 5:00 PM (ET)

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

A PDF copy of the signed Face Page should be emailed to CFF (grants@cff.org) by the application deadline. The complete application must be submitted online, and no other documents will be reviewed.

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/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 DNA/Biosafety Information
  - Research Involving Animals Information

Research Plan, Supporting Documents and Appendices:
- Abstracts ~ Summary of Relevance ~ Keywords - (complete online)
- Biographical Sketches for Key Personnel - (upload)
- Sponsor’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)
- Data Safety Monitoring Plan (for clinical research projects only – upload)
- Training Plan
- 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