

The mission of Cystic Fibrosis Foundation (CFF) is to assure the development of the means to cure and control cystic fibrosis (CF) and to improve the quality of life for those with the disease. To meet this mission, various types of grants are offered to support meritorious research ranging from basic laboratory investigation to clinical management of CF. For all awards, proposals that involve collaboration between an approved CFF Care Center and an institution with basic and/or clinical research programs are encouraged.

FIFTH YEAR CLINICAL FELLOWSHIP AWARDS – POLICIES AND GUIDELINES

This award offers support for training related to cystic fibrosis for physicians who have completed four years of fellowship training related to CF (generally Pulmonology or Gastroenterology) and seek support for a fifth year of training. This fifth year will be devoted to clinical or basic research related to cystic fibrosis. The research potential of the applicant, the scientific merit of the fellow's proposed study, the research environment of the training program, and the fellow's commitment to continued involvement with cystic fibrosis research and/or clinical care in an academic setting will be among the major criteria considered in selection. If applicants plan to conduct clinical research during this year of fellowship training, special attention should be given to Section C (Clinical Research only) of the Research Plan guidelines and to the completion of the Data Safety Monitoring Plan.

ELIGIBILITY

The Fifth Year Fellowship award is open only to those in the fifth year of fellowship training. Thus, an applicant in his/her fourth year of training at an institution should apply for a fifth year fellowship for the following year. Adult caregivers in CF are encouraged to apply. The applicant's institution must be accredited in pulmonary or GI medicine. Budget guidelines and restrictions follow:

- Maximum level of support available under this program is \$68,250.
- The base stipend for this fellowship is \$58,250.
- Up to \$10,000 for research expenses (supplies, travel, minor equipment, etc) may be requested for applications that include a research project.
- **U.S. citizenship or permanent resident status is required.**

SUBMISSION INFORMATION

Application Deadline: First Wednesday of September at 5:00pm (Eastern Time)

Applications must be submitted at Proposal Central: <https://proposalcentral.altum.com/>. The signed, original Face Page should be returned to CFF and **postmarked** by the same date. Late applications will not be accepted and the deadline will not be waived. The Foundation reviews applications electronically; therefore **anything not submitted online will not be reviewed.**

General Timeline:

Application Deadline.....1st Wednesday of September
Review by Research and Research Training Committee.....December
Review by Medical Advisory Council.....January
Review by Board of Trustees.....February
Applicant Notified.....Early March
Earliest Start date.....July 1

REQUIREMENTS

Training must take place in one of the CF Foundation's recognized CF Care Centers or a Center-affiliated adult CF program and the applicant must describe career goals related to a long-term commitment to CF research and/or care.

Each fellow must have a Sponsor who will be responsible for the fellow's training and research activities. Due to the limited funds available to the CF Foundation, only one fellowship will be funded per subspecialty, per year, per Center.

The Foundation encourages all CFF supported Clinical Fellows in internal medicine, pulmonology, gastroenterology, family practice, and other specialties that are involved in the care of adult patients with cystic fibrosis submit a case study to be presented during the Adult Medicine Clinical Fellows session at the annual North American Cystic Fibrosis Conference (NACFC). Similarly, Pediatric Clinical Fellows are encouraged to submit a case study for presentation during the Pediatric Clinical Fellows session. This involves submitting a one-page description of the case, including clearly defined discussion points. Please check the NACFC website at www.nacfconference.org for further details and specific deadlines.

Fellowships are not transferable either with respect to the trainee or the trainer, as they are awarded on the basis of individual and institutional merit.

STIPENDS

The base stipend for fourth and fifth year fellows is \$58,250 per year. In addition, up to \$10,000 per year may be requested for minor equipment, technician's salary, supplies, travel to a national scientific meeting, or other expenses related to the research project. Thus, the maximum level of funding for each program is \$68,250 for one year. Furthermore, the CF Foundation will award funds of up to \$7,000 per year to assist in payment of interest on grantees' educational loans.

PAYBACK AGREEMENT

After completion of CF Foundation-supported training, it is expected that the recipient of CF Foundation support will engage in biomedical research, teaching, and patient care, or a combination of these activities, in an academic environment. Failure to commence in such activities, and failure to sustain such activities for a period equal to the support of CF Foundation (12 months – 2nd year; 12 months – 3rd year; 12 months – 4th year; 12 months – 5th year) will subject the trainee to payback provisions as follows:

1 st year	\$ -0-
2 nd year	\$23,500.00
3 rd year	\$33,000.00
4 th year	\$33,000.00
5 th year	\$33,000.00

Further details of these payback provisions are outlined in the attached Letter of Agreement. **This agreement must be signed and uploaded as a PDF to Proposal Central. The original agreement should be included with the application Face Page at the time of submission.**

FISCAL MANAGEMENT

Payments are made to the sponsoring institution on a quarterly basis in arrears, with the first payment of the project period being made after the close of the first quarter, the second payment after the close of the second quarter, and so forth. The final payment is made only after the final progress report is received from the fellow and the sponsor(s) and the final expense report is received from the sponsoring institution. **No indirect costs are paid to the institution.**

REVIEW AND AWARD

Applications are reviewed either by the Research and Research Training (RRT), for basic science projects, or by the Clinical Research Committee (CRC), for clinically based projects. The recommendations are reviewed by the Medical Advisory Council (MAC) and 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 RRT or CRC and the MAC. Relevance of the proposed study to issues in CF is also considered in determining awards as necessary. All fellowships awarded are subject to the observance of the regulations, policies and objectives of the CF Foundation related to that category of research support and are contingent upon the availability of funds.

The chief causes for assigning low priority scores to applications during review include:

1. Insufficient information or documentation.
2. Inadequate statement of hypothesis, experimental design or methods.
3. Failure of the applicant to demonstrate awareness of and plans for coping with key problems and pitfalls associated with the proposed research. Such pitfalls may include insufficient numbers of potential study subjects, insufficient project duration to accomplish aims, or lack of documentation of access to necessary databases.
4. Insufficient or improper controls, especially in human clinical studies.
5. Failure of the applicant to describe potential relevance of the proposed study to issues in CF.
6. Failure of the applicant to document the necessary skills/training to accomplish the proposal's goals.
7. Failure of the applicant to meet all of the criteria described in the policy statement for a given award.
8. Failure of the applicant to describe career development goals as they may be related to a long-term commitment to CF research.
9. Insufficient evidence of Sponsor's involvement in the development of the research plan.

INSTRUCTIONS FOR COMPLETING SPECIFIC APPLICATION COMPONENTS

- Application must be typed in Times New Roman 12 or Arial 11 font.
- Margins should be no less than a half inch on each side.
- Each section may be numbered individually. Once all documents are uploaded to Proposal Central, the system will compile them into one PDF file.
- The Research Plan section of the application, **including the Literature Cited**, is limited to ten (10) pages. Applications that exceed this page limit will not be reviewed.
- All signatures, on all parts of the application, must be in **BLUE INK ONLY**.
- See page 11 for a full list of Submission Guidelines.

FACE PAGES

The Face Page will be populated automatically with the application information (applicant's name, institution, title of application, etc.) entered into the Proposal Central website. Print the Face Page from the website for the hardcopy. It will include a second page with institution and contact information. **Sign the Face Page in BLUE INK ONLY**. Photocopied, stamped, or scanned signatures will not be accepted.

ABSTRACTS

Lay Abstract

Please provide a statement of no more than 250 words 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. Please write in terms applicable to an informed lay readership.

Scientific Abstract

Please provide a statement of no more than 250 words explaining the subject of your research proposal and its relationship to CF. This statement will be used to inform the scientific community of the nature of this work.

Please note that the abstracts should be completed online. An Abstracts page will be generated from the information entered in Proposal Central and a PDF will be created as part of the application. To avoid confusion, do not upload a separate abstracts document to Proposal Central.

BUDGET AND BUDGET JUSTIFICATION

Please complete the online budget summary in addition to a detailed budget and budget justification for support requested. Be sure that the detailed budget matches the online budget summary. Only one year of support should be requested.

Detailed Budget – Direct Costs Only

Personnel - List the name and title of the applicant. Indicate dollar amounts separately for salary and fringe benefits. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all sponsors. The total salary and benefits cannot exceed \$58,250.

Equipment - List all items of minor equipment requested, their cost and a brief justification. If funds are requested to purchase equipment that is equivalent to items listed under Facilities Available, justify the duplication. Computers, laptops, and/or other computer equipment are not allowable expenses on fellowship grants.

Supplies - Itemize supplies, such as glassware, chemicals, animals, etc., 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. Funds for travel outside the North American continent are not permitted. Also note that requests for travel funds should be limited to \$750.

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

The maximum level of support available under this fellowship program is \$68,250. CFF does not provide indirect costs on fellowship grants.

FACILITIES AVAILABLE

Describe the facilities and equipment available at the applicant organization that will be used for this study. Describe their pertinent capabilities, proximity and anticipated extent of use. If facilities or equipment at a consultant or collaborative site will be used, they should be identified and clearly described. Use continuation pages, if necessary.

Describe facilities in terms of relevant areas, such as laboratory, clinical, animal, computer, office, etc. Provide any additional information about the environment, including any support services available that will be utilized for this project.

BIOGRAPHICAL SKETCH

A biographical sketch in CFF format should be completed for all key project personnel, beginning with the **applicant (fellow), the Sponsor(s), and other key personnel**. CFF defines “key project personnel” as anyone with an advanced degree who will play an instrumental role in the accomplishment of the training or project. The complete Biographical Sketch should not exceed three (3) pages. Clearly identify the results of any previous CFF support (i.e., funding from other sources, journal articles, invited presentations, etc.). Prior publications relevant to the present application should be clearly identified. **NIH Biosketches are NOT accepted as CFF requires additional information.**

OTHER SUPPORT

Other Support pages should be completed for all key project personnel. List only current funding. There is no page limitation for other support.

PROOF OF CITIZENSHIP

CFF fellowships are restricted to individuals who are United States citizens or Permanent Residents. Proof of Citizenship or Permanent Residency must be provided (e.g., copy of passport, birth certificate, or Permanent Resident Visa).

NAMES AND ADDRESSES OF REFERENCES

Letters of recommendation and/or support **must** be submitted by the following:

- The Sponsor of the first two years of the clinical fellowship training.
- The Sponsor(s) for this award.
- The CF Center Director(s) at the sponsoring (or nearby) institution, if s/he is not a Sponsor.
- The Applicant’s Division or Section Chief, if s/he is not the Center Director.
- At least one other individual familiar with the applicant’s scientific interests and abilities.

The letter of support from the current Sponsor(s) should describe the types of CF learning experiences to which the applicant will be exposed. In addition, the letter should detail how the Sponsor(s) will work to provide the applicant with the tools and resources necessary to enable the applicant to develop into a CF-focused independent investigator capable of critical thinking.

The support letter from the Division/Section Chief should detail career and faculty development plans and opportunities, as well as institutional resources available and relevant to the applicant.

In the applicable section on Proposal Central, list the names and addresses, including e-mail addresses, of the individuals who have been asked to submit letters of recommendation. **The applicant should inform those individuals 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 must be submitted. Once the applicant has submitted his/her application, no further documents can be added on-line. Therefore, if the application is submitted prior to the Sponsor(s) or other Referee(s) uploading their letters, the Sponsor(s)/Referee(s) will be unable to do so.

Letters uploaded to Proposal Central 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 the documents.

Letters of recommendation and support are weighted heavily during the review. These letters must be submitted electronically through the Proposal Central website BEFORE the application deadline and the original letters must be sent directly to the Foundation from the referee.

PREVIOUS FELLOWS

The Sponsor(s) must provide a list of all previous fellows under his/her supervision over the past 10 years, including the fellows' source(s) of support.

DESCRIPTION OF PREVIOUS TRAINING AND FUTURE PLANS

The applicant should prepare a brief description of the first four years of his/her clinical fellowship and a summary of future plans. This section should note previous and anticipated future involvement with and career development focused on CF-related research and/or clinical care.

PROPOSED TRAINING PLAN

This section should be completed in conjunction with the Sponsor(s) and should outline the plan for training the applicant for a career in CF-related clinical care and/or research. The anticipated clinic and rounds schedule should be included, as well as information on participation in supplemental course work and special seminars. Estimates of time dedicated to research/scholarly pursuits and clinical care should be delineated.

CRITIQUE RESPONSE

If the application is a resubmission or a competitive renewal of a previously awarded Clinical Fellowship, please provide a point-by-point response to the prior reviews. Make certain to address the reviewers' concerns, as well as highlight how the research plan has been modified to incorporate their feedback. Be concise and succinct.

RESEARCH PLAN

The Research Plan is limited in length to ten (10) single-sided pages, **including the Literature Cited. Applications exceeding this page limit will not be reviewed.** Information should be presented in a clear, concise manner, while being specific and informative. Please include sufficient information to permit effective review without reference to previous applications.

- A. Hypothesis and Specific Aims.** State concisely and realistically the intent of the proposed research and the hypothesis to be tested. Do not exceed one page.
- B. Significance.** Briefly describe the background of the present proposal. 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 addition, the applicant should describe the relationship of the proposed work to his/her long-term career goals. Preference will be given to those applicants who have expressed an interest in a long-term career in CF-related research.
- C. Preliminary Results.** If applicable, provide a detailed discussion of any preliminary results. If the application is a competitive renewal of a previously funded CFF Clinical Fellowship, a specific discussion of progress made during the previous funding period should be included.
- 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 design; 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 time-line; drugs and dosage; measures of compliance; follow-up schedule including a time-line for full project up to three years; ascertainment of response variables: efficacy and safety, training, data collection, 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. The number of CF patients in the participating CF Center(s), as well as the number in relevant control groups, must be specified. 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. Please provide a copy of your institution's IRB approval and/or protocol with proposed patient consent forms.

- 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.
- 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).

DATA SAFETY MONITORING PLAN (Required for Clinical Research projects)

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. CFFT-funded Phase III clinical trials must utilize a Data Safety and Monitoring Board (DSMB). In addition, CFFT recommends that investigators utilize a DSMB for any Phase I or II clinical trials that are:

- Multi-center;
- Blinded to the investigator;
- 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.

Address the following areas in the DSMP:

Assessment of Risk (see table on following page) – 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.

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 a DSMB, provide a composition of the board, the functions of the board, the frequency of meetings, the reporting requirements, including AEs, and the procedure for interim reporting as necessary.

Minimal Risk	Low Risk	Moderate Risk	High Risk
<ul style="list-style-type: none"> • Study poses no more risk than expected in daily life (blood draw, physical exam, etc.); • Behavioral studies; • Nutritional studies; • Observational studies; • MRI studies; • Survey or questionnaire studies 	<ul style="list-style-type: none"> • Studies of normal volunteers using well-described research procedures (IV infusion, euglycemic clamp, etc.) • Studies which might meet requirements for minimal review but include special populations or invasive procedures; • Post-marketing study Phase IV drug or device, as defined by FDA 	<ul style="list-style-type: none"> • Subjects treated with placebo for a recognized disease; • Involves subjects with HIV/AIDS, hepatitis, or cancer on a treatment study; • Substantial risk (>5%) of a Serious Adverse Event originating from the underlying condition of the enrolled subject; • Phase I or II study with available safety data in humans; • Industry sponsored Phase III clinical trial 	<ul style="list-style-type: none"> • Involves an intervention or invasive procedure with substantial risk; • An investigator-initiated IND trial; • Implantation of device with an IDE; • 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); • Investigator-initiated multi-center trial • Investigator-initiated Phase III clinical trial; • Involves the manufacturing of agents on campus; • Study has provisions to waive consent in emergency circumstances; • Involves vulnerable populations (e.g. pediatric, pregnant, etc.); • Blinded Phase I and II trials

APPENDIX

Research Involving Human Subjects

CF Foundation 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 before activation of any grant. If approval does not accompany the application, there should be a statement in the application indicating that such approval is pending and the date when such approval is expected. **The IRB application must be submitted to the applicant institution BEFORE the CFF application deadline.** 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* (revised September 2009). This publication and announcements of modifications and changes to the *NIH Guidelines* are available from the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD, 20892-7985 or accessed on-line at http://oba.od.nih.gov/rdna/nih_guidelines_oba.html. The purpose of the *NIH Guidelines* is to specify practices for the construction and handling of: (i) recombinant deoxyribonucleic acid (DNA) molecules, and (ii) organisms and viruses containing recombinant DNA molecules. As defined by the *NIH Guidelines*, recombinant DNA molecules are either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or (ii) molecules that result from the replication of those described in (i) 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 *NIH Guidelines*.

CF Foundation policy pertaining to recombinant DNA research requires that the grantee institution certify in writing that an institutional committee has reviewed and approved the procedures involving recombinant DNA in accordance with the *NIH Guidelines*. This certification should accompany the application and **must** be received before activation of any grant. If approval does not accompany the application, there should be a statement in the application indicating that such approval is pending and the date when such approval is expected. **The recombinant DNA application must be submitted to the grantee institution BEFORE the CFF application deadline.** The approved certification should be submitted as soon as it is available.

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). Written documentation of approval should accompany the application and **must** be received before activation of any award. If approval does not accompany the application, there should be a statement in the application indicating that such approval is pending and the date when such approval is expected. **The IACUC application must be submitted to the applicant institution BEFORE the CFF application deadline.** A copy of the IACUC approval should be submitted as soon as approval is received. 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.

Additional Material

- CFF Payback Agreement with signature
- For clinical research, a copy of the IRB application and patient consent forms
- Other written confirmation of organizational assurances (if applicable)
- Up to four reprints of the applicant's or Sponsor(s)'s work relating to the general area of research in the grant proposal may be uploaded in PDF format.
- Other materials pertinent to the grant proposal, not already described.

Keep in mind that extensive appendix material may not be reviewed. Please upload only the most relevant documents.

SUBMISSION GUIDELINES

Application Deadline: First Wednesday of September at 5:00pm (Eastern Time)

Applications must be submitted at Proposal Central: <https://proposalcentral.altum.com/>. The signed, original Face Page should be returned to CFF and **postmarked** by the same date. Late applications will not be accepted and the deadline will not be waived. The Foundation reviews applications electronically; therefore **anything not submitted online will not be reviewed.**

- Application must be typed in Times New Roman 12 or Arial 11 font.
- Margins should be no less than a half inch on each side.
- Each section may be numbered individually. Once all documents are uploaded to Proposal Central, the system will compile them into one PDF file.
- The Research Plan section of the application, **including the Literature Cited**, is limited to ten (10) pages. Applications that exceed this page limit will not be reviewed.
- Original letters of recommendation and support should be submitted directly to the CFF and uploaded to the Proposal Central website **by the referee 1 week before** the application deadline.
- All additional material (Use of Animals Certification, publications, etc.) should be scanned and uploaded as PDF appendix material online.
- The Face Page and Payback Agreement must be signed in **BLUE INK ONLY** and returned to CFF:
Cystic Fibrosis Foundation
Grants and Contracts Office
6931 Arlington Road
Bethesda, MD 20814

To submit the electronic application, please visit: <https://proposalcentral.altum.com/>. **REMEMBER TO CLICK “SUBMIT” WHEN THE APPLICATION IS FINISHED.** An e-mail will be generated automatically from Proposal Central confirming that the application has been successfully uploaded. **If you DO NOT receive a confirmation e-mail, please contact Proposal Central (see e-mail address and telephone number below).**

Do not submit an incomplete application. An application will be considered incomplete if it fails to comply with instructions or if the material is insufficient to permit adequate review.

Revisions, insertions or appendices to applications will not be accepted after the receipt date unless agreed to by CFF’s Grants and Contracts Office. Even if a part of an application is approved for late submission, there is no guarantee that the application will be reviewed. Only Human Subjects Certification, Use of Animals Certification, and Recombinant DNA Approval will be accepted apart from the body of the grant application if they are not available at time of submission.

Requests to submit supplemental data must be received before November 1st, and even if accepted, review of these items is not guaranteed.

For questions regarding application contents:

E-mail CFF’s Grants and Contracts Office at grants@cff.org or call (301) 951-4422.

For questions regarding the application website:

E-mail Proposal Central at pcsupport@altum.com or call (800) 875-2562 during business hours (Monday – Friday, 8:30am – 5:00pm Eastern).

ELECTRONIC APPLICATION CHECKLIST

- ❑ **Face pages which include:**
 - ❑ **Signatures***
 - Principal Investigator
 - Sponsor(s)
 - The Official authorized to sign on behalf of the Sponsoring Institution
 - ❑ Applicant/PI Information
 - ❑ Organizational Assurances
 - Human Subjects Certification
 - Recombinant DNA Biosafety Certification
 - Research Involving Animals Certification
 - ❑ Complete Institution and PI Contact information, including correct mailing address

- ❑ **Training Plan, Supporting Documents, and Appendix**
 - ❑ Abstracts
 - ❑ Budget and Budget Justification
 - ❑ Facilities Available
 - ❑ Biosketches for all key personnel (*use CFF format*)
 - ❑ Other Support for all key personnel (*use CFF format*)
 - ❑ Proof of Citizenship or Permanent Residency
 - ❑ Names and Addresses of References
 - ❑ Letters of Support and Recommendation
 - Electronically submitted **by the referee** through the Proposal Central website
 - Original sent **by the referee** directly to the Foundation
 - ❑ List of Previous Fellows of Sponsor(s)
 - ❑ Description of Previous Training/Future Plans
 - ❑ Training Plan
 - ❑ Critique Response (if applicable)
 - ❑ Research Plan
 - ❑ Specific Aims
 - ❑ Significance
 - ❑ Experimental Design and Methods
 - ❑ Consultants/Collaborative Arrangements
 - ❑ Literature Cited
 - ❑ Data Safety Monitoring Plan (for Clinical Research projects)
 - ❑ CFF Payback Agreement with **Signature***
 - ❑ Appendix
 - ❑ For clinical research, a copy of the IRB approval, protocol, and patient consent forms
 - ❑ Written confirmation of organizational assurances (if applicable)
 - ❑ Reprints
 - ❑ Other supporting documents

* CFF does not expect signatures to be included in the electronic copy, but the submitted hardcopy must include **original** signatures on the Face Page **in blue ink**. Photocopied, stamped, or scanned signatures will not be accepted