

The mission of the 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.

**THE LEROY MATTHEWS PHYSICIAN-SCIENTIST AWARD
POLICIES AND GUIDELINES**

In honor of Dr. LeRoy Matthews' dedication and commitment to cystic fibrosis (CF) research and care, the Cystic Fibrosis Foundation (CFF) announces the Physician-Scientist Award named in his memory. The award encourages outstanding newly trained pediatricians and internists to enhance clinical proficiency in CF-related sub-specialties and to develop the necessary research capabilities to become independent biomedical investigators.

Awards will provide individuals who are either enrolled in or are about to enroll in sub-specialty training with the opportunity to undertake up to six years of support for their clinical training, research training, and the initiation of their research career. The first phase of the program will consist of clinical training in a sub-specialty related to CF. The second phase will provide the individual with the opportunity to develop skills in either basic or clinical research. Phases I and II can be combined; however, the combination of Phases I and II cannot exceed four years. At the end of this period, the person should be considered board eligible for the sub-specialty for which he/she is training.

Phase III is intended to provide funds for up to two years for the support of independent research investigations of the recipient. This support will take place at the institution where the first academic position is obtained and need not occur at the institution where Phases I and II took place.

Candidates for this award can be identified as early as their second year of residency training or at any time during their sub-specialty training (Phases I and II). It is anticipated that the award will provide the opportunity for clinicians to obtain sub-specialty training, to develop into independent investigators, and to initiate a research program. Individuals with **M.D.** and **M.D./Ph.D.** degrees are encouraged to apply.

Individuals may enter the program at any time during the Phase I or Phase II training. The duration of the award can be up to six years for Phases I, II and III combined. However, for those individuals entering during later parts of I and II, the duration of the award will be adjusted accordingly. **The award will not be given for Phase III alone.** Other programs of CFF will be available for this support.

The candidate's progress and career goals will be subject to a periodic evaluation by CFF. The evaluation will occur midway through Phases I and II. The award of Phase III will be subject to an additional review by CFF, with the scientific merit of the proposed research project being evaluated, as well as the institutional commitment to the career development of the candidate.

Candidates should demonstrate competence in clinical activities and should show outstanding research potential. Candidates must provide evidence of serious intent for an academic research career (basic or clinical) related to CF. Please note that the review process for this award is quite competitive and highly selective.

Candidates must be citizens of the United States or have obtained permanent residence in the United States prior to the time of application.

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.....	1 st 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.....	April 1

- 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 in the correct order.
- The Research Plan section of the application, **including the Literature Cited**, is limited to fifteen (15) 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 12 for a full list of Submission Guidelines.

REVIEW AND AWARD

INDIVIDUAL AWARD

Environment: Applications will be accepted, on behalf of individuals, from domestic medical schools with:

- 1) A strong, well-established CF-related research and clinical training program;
- 2) An adequate number of highly trained faculty in clinical and basic science related to CF; and
- 3) A commitment and capability to provide guidance to clinically trained individuals in the development of independent careers as cystic fibrosis researchers and clinicians.

The environment must be one which stimulates and increases interaction between basic scientists and clinical investigators and which indicates a strong commitment to CF research and care.

Candidates must be nominated by an institution on the basis of qualifications, interests, accomplishments, motivation, and potential for a research career related to CF. **Evidence of the commitment of the institution to the candidate's research and development must be provided.**

Phases: The individual award application should be designed in three phases as follows:

- Outline for clinical sub-specialty training experience (Phase I*)
- Outline for research training to occur during sub-specialty training (Phase II*)
- Independent Research Investigation (Phase III) - First Independent Application. The outline for this work can be submitted for consideration by CFF near the end of Phases I and II and at the time of the first academic

appointment. In addition to the scientific merit of the proposal, CFF will assess the institution's commitment to assuring 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 III.** The applicant institute must comply with the grant administration policies of CFF.

Only a general research plan for Phase II is required at the time of submission. Awardees and their Sponsors will be required to submit a special, detailed progress report midway through Phases I and II and prior to the initiation of Phase III.

*Phases I and II can be continued during a four year span of time. After the end of the training experience, the individual should be considered board eligible.

Sponsor: Each candidate must identify a primary Sponsor who is recognized as a physician-scientist with experience in training independent investigators, and who will provide guidance for the awardee's clinical and research development. The primary Sponsor must be committed to continue this involvement through the individual's total period of training (Phases I and II) under the award. The Sponsor may form an advisory committee, similar to a graduate student training committee, to develop a Phase I and II program for the candidate that should include course work, seminars, initial research experience, and other educational experience necessary for intensive research in Phase II.

Duration and effort: This is a non-renewable award based on up to six, full-time, 12-month appointments. All funds must be used on behalf of the original candidate. Support is divided into three distinct phases that relate to the individual's progress in becoming an independent investigator. The level of effort requested for Phases I and II is commensurate with acquiring board eligibility in the sub-specialty and developing proficient skills in the area of CF-related research. It is required that a minimum of 75 % effort during Phase III be devoted to the research and research training program. The balance of effort can be devoted to other clinical and teaching pursuits only if they are consonant with the program goals.

It is desirable for individuals to complete all three phases without interruption. It may be permissible, however, to interrupt the award and delay the start of Phase III in order to engage in further clinical or research training. In the event such a contingency arises, the awardee and the Sponsor must justify the interruption to CFF to assure that funds will be available to resume the award so that the candidate may complete the program.

ALLOWABLE COSTS

Salary: Individual compensation based on the institution's salary scale for fellows or junior faculty at an equivalent experience level should not exceed the following:

Yr. 1 - up to \$48,000	Phase I and II
Yr. 2 - up to \$49,750	
Yr. 3 - up to \$58,500	
Yr. 4 - up to \$58,500	
Yr. 5 - up to \$76,000	Phase III - Junior Faculty Award (75% research effort)
Yr. 6 - up to \$76,000	

The salaries will be in compliance with institutional guidelines and can be supplemented by the institution. No Sponsor support will be provided by CFF.

Research and development support: May include funds for technical costs, i.e. supplies, minor equipment, candidate travel to a national scientific meeting.

Year 1 and 2 - \$10,000
Year 3 and 4 - \$15,000
Year 5 and 6 - \$15,000

The maximum level of support available under this program is \$91,000 per year. CFF does not provide indirect costs on physician-scientist training awards.

Concurrent awards: Individuals entering Phase III are encouraged to apply for additional research support from CFF or other funding agencies.

EVALUATION

Awardees must agree to inform the 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 awardees and institutions must comply with CFF grant policies.

METHODS AND CRITERIA FOR REVIEW

All applications are evaluated by CFF's Research and Research Training (RRT) Committee, whose recommendations are reviewed by the Medical Advisory Council (MAC) and the Board of Trustees for final approval and funding. Applicants will be assessed on potential for career development and on scientific and technical merit of the research proposal.

Funding of awards is based on the priority score awarded each application and the recommendations of the 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.

REVIEW CRITERIA FOR THE PHYSICIAN-SCIENTIST AWARD:

Individual Award

The Candidate

- Competence in clinical activities and potential for a career in independent research related to CF
- Commitment to, or intent to pursue, a research career related to CF

The Sponsors

- Accomplishments in the clinical and basic science research area(s) related to CF
- Commitment of the primary Sponsor for the duration of the candidate's development and research plan
- Experience of the Sponsor in training individuals for basic biomedical research

The Environment

- Presence in the institution of highly trained faculty in clinical and basic sciences related to CF
- Institution's CF research and research training programs
- Interaction between basic and clinical investigators
- Institution's commitment and ability to provide the opportunities and facilities necessary for the clinical and research career development related to CF

The Training and Research Development Plan

- Feasibility and value of the proposed plan
- Specific didactic work to be required of the candidate
- Scientific and technical merit of the proposed research
- Ability of the proposed plan to develop research skill of the candidate
- Difference between Phase I and Phase II
- Relationship to candidate's career development

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 in the correct order.
- The Research Plan section of the application, **including the Literature Cited**, is limited to fifteen (15) 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 12 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.

Abstract of Training/Research Plan

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 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.

CRITIQUE RESPONSE

If the application is a resubmission, please provide a **one page** point-by-point response to the prior reviews.

BUDGET AND BUDGET JUSTIFICATION

Please complete the online budget summary in addition to a detailed budget and budget justification for all years of support requested. Be sure that the detailed budget matches the online budget summary.

Detailed Budget

Salary level and research related expenses should not exceed levels indicated in program guidelines. Do not include budget for Phase III of this award. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all sponsors. Funds for travel outside the North American continent are not permitted. Also note that requests for travel funds should be limited to \$750.

The maximum level of support available under this program is \$91,000 per year. CFF does not provide indirect costs on physician-scientist training awards.

Budget Justification

For each year of the grant, please explain the basis for the budget categories requested following the instructions for the First Budget Period, including anticipated postdoctoral levels.

FACILITIES AVAILABLE

Describe the facilities and equipment available at the applicant's organization that will be used for this project. 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. 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, 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

LeRoy Matthews Physician-Scientist Training Awards 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).

MEDICAL SCHOOL TRANSCRIPTS

Candidate must supply a copy of his/her medical school transcripts.

NAMES AND ADDRESSES OF REFERENCES

Letters of reference/support must be submitted by the following:

- The Sponsor for this award.
- The Chair of the applicant's department at the sponsoring institution.
- At least four (4) other individuals familiar with the candidate's scientific interests and abilities, especially with respect to CF related research and care, including previous preceptors and mentors. The letters of recommendation should attest to the candidate's academic qualifications, motivation, research potential, and commitment to CF related research and care.

Letters from the Sponsor and the Department Chair should clearly describe the institution's commitment to the professional growth of the applicant. It is recommended that one of the letters of reference/support be from the CF Center Director(s) at the sponsoring (or nearby) institution.

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 reference/support. **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 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.

CF RELATED ACTIVITIES OF THE SPONSOR AND APPLICANT INSTITUTION

This section should include a complete description of the CF related clinical and research activities of the applicant institution. The Sponsor and the applicant institution should include a list of their previous trainees (past 10 years) and the current affiliations of these trainees.

PREVIOUS TRAINING AND FUTURE PLANS

The applicant must prepare a brief summary of his/her previous research and/or clinical fellowship training, including the reasons for entering fields related to CF research and care. In conjunction with the Sponsor, a future training plan should be completed in and should outline the general plan for training the applicant in CF-related research. Participation in supplemental course work and special seminars should be included. Further, this section should clearly indicate plans for introducing the applicant to research study planning and design, statistical methods, data management, etc. **This section must not exceed 5 pages.**

RESEARCH PLAN

The research plan for Phase II of this award is limited in length to 15 single-sided pages, **including the literature cited. Applications exceeding this page limit will not be reviewed.**

In the research plan, 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.

- Note - For individuals entering the program early in their fellowship experience, the CFF reviewers will not expect a fully developed research plan, but will analyze the training component in its review.
- A. **Hypothesis and Specific Aims.** State concisely and realistically what the research described in the application is intended to accomplish during the period of the grant and/or the hypothesis to be tested. *Do not exceed one page. When preparing the specific aims, keep in mind the mission of the Cystic Fibrosis Foundation.*
- B. **Background and 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.
- 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 and precautions taken to ensure anonymity of patients.
- F. **Literature Cited.** References should be numbered in the sequence that they appear in the text and listed at the end of the Research Plan. Each citation must include the names of authors, the name of the journal or book, volume number, page number and year of publication (titles are optional).

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

- ❑ Up to four reprints of the applicant's work relating to the general area of research in the grant proposal may be uploaded in PDF format.
- ❑ Letters of Collaboration (if applicable).
- ❑ For clinical research, a copy of the IRB application and patient consent forms.
- ❑ 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 in the correct order.
- The Research Plan section of the application, **including the Literature Cited**, is limited to fifteen (15) pages. Applications that exceed this page limit will not be reviewed.
- Original letters of support and recommendation 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 (IACUC/IRB/IBC approvals, publications, etc.) should be scanned and uploaded as PDF appendix material online.
- The Face Page 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:**
 - Original Signatures****
 - Principal Investigator
 - Sponsor(s)
 - The Official authorized to sign on behalf of the Sponsoring Institution
 - Applicant/PI information
 - Organization Assurances
 - Human Subjects Certification
 - Recombinant DNA Biosafety Certification
 - Research Involving Animals Certification
 - Complete Institution and PI Contact information, including correct mailing address

- Research Plan, Supporting Documents and Appendix**
 - Abstracts
 - Critique Response (when applicable)
 - Budget and Budget Justification
 - Facilities Available
 - Biosketches (use CFF format)
 - Other Support (use CFF format)
 - Proof of Citizenship (copy of passport, birth certificate, or Permanent Resident Visa)
 - Applicant's Medical School Transcripts
 - 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 CFF.
 - CF-Related Activities of the Sponsor and Applicant Institution
 - Previous Training and Future Plans
 - Research Plan
 - Hypothesis and Specific Aims
 - Background and Significance
 - Preliminary Results (when applicable)
 - Experimental Design and Methods
 - Consultants/Collaborative Arrangements
 - Literature Cited
 - Data Safety Monitoring Plan (required for Clinical Research projects)
 - Appendix
 - Letters of collaboration (when applicable)
 - Written confirmation of organizational assurances (when applicable)
 - For clinical research, a copy of the IRB application and patient consent forms
 - 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