

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.

**PILOT AND FEASIBILITY AWARDS
POLICIES AND GUIDELINES**

Pilot and Feasibility awards are offered to support projects that will develop and test new hypotheses and/or new methods (or those being applied to the problems of CF for the first time), and to support promising new investigators as they establish themselves in research areas relevant to CF. The intent of these awards is to enable investigators to collect sufficient data to compete successfully for support from the NIH or other funding agencies. Special consideration will be given to those projects that propose innovative and creative approaches to the problems of cystic fibrosis. Applications for continued funding of the same project, or for long-term support of an investigator, will not be considered.

Applications for Pilot and Feasibility awards will be accepted only after submission of a letter of intent (LOI) due May 1. CFF strictly adheres to the LOI and award application deadlines. Applications received without an approved LOI on file will not be reviewed.

- Funding of up to **\$40,000 per year**, plus eight percent (8%) indirect costs may be requested.
- Grants may be approved for up to a 2-year period. Funding for year 2 is contingent upon submission and approval of a renewal progress report and the availability of funds.
- Multiple CFF Pilot and Feasibility Grants held by a single investigator will not be permitted when the total combined funding exceeds \$40,000 per year. In such cases, the most recent application submitted will be considered administratively ineligible.
- Applicants must be independent investigators. Fellows will be considered if they will hold a faculty appointment at the time of the award.
- Applicants need not be U.S. citizens or hold a U.S. permanent visa to apply for this award.
- International applicants and institutions are required to submit additional information in accordance with U.S. anti-terrorist restrictions.

Pilot and Feasibility award applications should focus on basic science research. Those proposals that include methodologies requiring sampling of materials from human subjects will be considered under this mechanism only if the sampling method constitutes minimal patient risk (e.g., venipuncture) and the sample will be utilized in bench research. All other projects utilizing human subjects must submit a Clinical Research Letter of Intent.

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:

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|---|--|
| 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 |

REVIEW AND AWARD

All applications are evaluated by CFF's Research and Research Training (RRT) Committee, whose recommendations are reviewed by the Medical Advisory Council (MAC) and 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 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.

Chief causes for assigning low priority scores to applications during review include the following:

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;
4. Insufficient or improper controls;
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 or training to accomplish the goals of the proposal;
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 goals as they may be related to a long-term commitment to CF research.

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 8 for a full list of Submission Guidelines.

FACE PAGE

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 the research proposal and its relationship to CF. This statement will be used to inform the scientific community of the nature of this work.

CRITIQUE RESPONSE

Please provide a point-by-point response to the limitations noted in the CFF Letter of Intent critique. If the application is a resubmission, please provide a point-by-point response to the prior reviews. Be concise and succinct.

BUDGET AND 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 – Direct Costs

Personnel - List the names and positions of all professional and non-professional personnel involved in the project, whether or not salaries are requested. Indicate the percent of time or effort per week on the project for professional personnel; indicate the hours per week for each non-professional. For each individual, list 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 percentage of salary requested cannot exceed the percent effort for each professional and non-professional personnel.

Consultant Costs - Give the name and institutional affiliation of any consultant who has agreed to serve in this capacity, including statisticians and physicians in connection with patient care if they are not listed under personnel. Under budget justification, briefly describe services to be performed, the number of days, rate of compensation, per diem and any other associated costs.

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

Supplies - Itemize supplies, 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 \$750.00.

Patient Care Costs - Funds may be requested for patient care costs specifically related to the proposed research. The basis for estimating funds requested in this category should be justified. The scientific need for patient care costs will be considered in the review of the application. Please note that patient travel, lodging, and sustenance should be listed in "Other Expenses;" consulting physician charges should be listed under "Consultant Costs."

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

Subcontracts – The total cost of each subcontract (directs plus indirects) should be listed under “Other Expenses” and included in the applicant’s direct costs. The applicant institution may request indirects only on the first \$25,000 of each subcontract. Detailed budgets for each subcontract must be provided for each year of support. Negotiations of subcontracts are between the applicant institution and the subcontractor.

Budget Justification

Use this page to describe the nature of costs listed in the “Detailed Budget.” Costs should be described in terms of major categories, such as Personnel, Consultant Costs, Equipment, etc. Include the institutional indirect cost rate (up to eight percent).

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 should be completed for all key project personnel, beginning with the Principal Investigator. 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. Each individual's complete Biographical Sketch should not exceed three (3) pages. Clearly identify the results of past CFF support (i.e., subsequent funding from other sources, journal articles, and invited presentations.) Prior publications relevant to the present application also should be clearly identified. **NIH Biosketches are NOT accepted as CFF requires additional information.**

OTHER SUPPORT

List all other support that all key project personnel are currently receiving. There is no page limitation for Other Support. **NIH Other Support pages are NOT accepted as CFF requires additional information.**

NAMES AND ADDRESSES OF REFERENCES

For **junior investigators**, letters of support or reference must be submitted by the following:

- The Chair of the applicant's department at the sponsoring institution.
- At least two other individuals familiar with the applicant's scientific interests and abilities

The letter of support from the Department Chair should indicate the release of sufficient space and facilities for the work described, as well as guarantee the time commitment of the investigator to the project. If the applicant is a fellow currently, the letter of support should include confirmation of the pending faculty appointment.

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 Referee(s) uploading their letters, the Referee(s) will be unable to do so.

Senior investigators are not required to submit letters of reference; however, letters of collaboration or support should be provided as needed.

RESEARCH PLAN

The Research Plan for Pilot & Feasibility Award applications is limited in length to fifteen (15) single-sided pages, **including the Literature Cited.** Applications exceeding this page limit will not be reviewed.

In the Research Plan, include sufficient information to permit effective review without reference to previous applications. Information should be presented in a clear, concise manner, while being specific and informative. **If this application is a resubmission of an earlier proposal, the changes should be clearly indicated by a change in the typeface, underlining, or marks in the margins. Proposals that have not been revised should not be resubmitted and will not be reviewed.**

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

- 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. **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. Since Research Grants are reviewed by CFF's Research and Research Training Committee those applications that include methodologies requiring sampling of materials from human subjects will only be considered under this mechanism if the sampling method constitutes minimal patient risk (e.g., venipuncture) and patient samples or data are anonymous. The level of risk and measures taken to assure patient anonymity to the PI and other professional personnel, unless the PI or other professional personnel are care providers, should be described.
- 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).

INTERNATIONAL APPLICANTS

International Institution Form

Those applicants whose sponsoring institution is not a United States based entity must complete the International Institution Form. **The completed and signed form should be uploaded with the following documents:**

1. A copy of your organization's most recent Mission Statement;
2. A copy of your organization's Tax Exemption Letter, if organization is not-for-profit;

3. A description of other sources of support, such as official grants, private endowments, and commercial activities, received by your organization;
4. A copy of your organization's Standard Operating Procedure(s) or relevant policy to ensure that funds provided are neither distributed to terrorists or their support networks nor used for activities that support terrorism or terrorist organizations; and
5. For-profit organizations must submit a complete list of key employees, members of the governing board, and/or other senior management.

Any documents that cannot be uploaded to Proposal Central must be submitted to CFF's Grants and Contracts Office.

English translations must be provided for any documents that are written in the applicant's or sponsoring institution's native language, including material provided in support of the Research Plan.

APPENDIX

Research Involving Human Subjects

CF Foundation policy pertaining to the protection of individuals as research subjects requires that for each proposal submitted, the grantee 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 grantee 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 April 2002). This publication and announcements of modifications and changes to the 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 this document is to specify practices for the construction and handling of recombinant DNA molecules and organisms or viruses containing recombinant DNA. As defined by the Guidelines, recombinant DNA molecules are either: (1) 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 (2) DNA molecules that result from the replication of those described in (1) above.

Many types of studies involving recombinant DNA are exempt from the 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 Guidelines. This responsibility includes establishing an Institutional Biosafety Committee to review all recombinant DNA research to be conducted at or sponsored by the applicant organization, and to approve those projects it finds are in conformity with the Guidelines.

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 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 grantee 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 Support and Collaboration.
- 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.
- 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.
- Letters of collaboration and support should be scanned and uploaded as PDF appendix material online.
- Those applicants whose sponsoring institution is not a United States based entity must complete the International Institution Form. Any documents that cannot be uploaded with the application should be submitted to CFF's Grants and Contracts Office.
- 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

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**.

Face page which includes:

Original Signatures*

- Principal Investigator
- The Official authorized to sign on behalf of the Sponsoring Institution
- Applicant/PI information
- Organization Assurances
 - Human Subjects Certification - Minimal patient risk only
 - 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 for each year
- Facilities Available
- Biosketches for all key personnel
- Other Support for all key personnel
- 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
- Research Plan
 - Specific Aims
 - Background and Significance
 - Preliminary Results
 - Experimental Design and Methods
 - Consultants/Collaborative Arrangements
 - Literature Cited
- International Institution Form (if applicable)
 - Organization's most recent Mission Statement
 - Organization's Tax Exemption Letter, if organization is not-for-profit
 - Description of other sources of support, such as official grants, private endowments, and commercial activities, received by organization
 - Organization's Standard Operating Procedure(s) or relevant policy to ensure that funds provided are neither distributed to terrorists or their support networks nor used for activities that support terrorism or terrorist organizations
 - For-profit organizations must submit a complete list of key employees, members of the governing board, and/or other senior management
- Appendix
 - Letters of collaboration (when applicable)
 - Written confirmation of organizational assurances (when applicable)
 - Reprints
 - Other supporting documents

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