



## GUIDELINES FOR CLINICAL RESEARCH LETTER OF INTENT

Cystic Fibrosis Foundation Therapeutics, Inc. (CFFT) requires that investigators who seek support from the Foundation for small or pilot/feasibility clinical research grant applications submit, in advance, a **BRIEF DESCRIPTION** of the research topic. The deadlines for submitting letters of intent (LOI) are June 1<sup>st</sup> and December 1<sup>st</sup>.

**E-mail the entire LOI as ONE FILE to [CFFTAwards@CFFTherapeutics.org](mailto:CFFTAwards@CFFTherapeutics.org)  
Mail a hard copy of ONLY the FACE PAGE with original signatures to CFFT. An LOI  
will NOT be accepted if these requirements are not fulfilled.**

The coversheet *must be postmarked NO* later than June 1<sup>st</sup> or December 1<sup>st</sup>. If June 1<sup>st</sup> or December 1<sup>st</sup> does NOT fall on a business day, then the cover sheet should be postmarked no later than the next business day. Also, the cover sheet should be included as the first page of the electronic LOI submission; however, it is NOT necessary to include the signatures on the electronic submission.

We have initiated this early review because of the high number of clinical research applications that duplicate or overlap previously funded topics, are unrealistic in scope, or are inappropriate for the goals of clinical research currently supported by CFFT. We hope to avoid unnecessary time spent by both investigators preparing grants and CFFT staff and consultants reviewing these applications. Funding priority is placed on those projects developing and/or testing therapeutic interventions to interrupt the abnormal pathophysiology associated with CF. Limited descriptive projects that would permit the formulation of an interventional hypothesis would be considered.

Our definition of clinical research: serial observations and measures of cystic fibrosis patients over time with and without intervention. Any clinical trial applications must originate from an accredited CF Care Center in the US or the equivalent of an accredited care center outside the US.

Please submit a description in (Arial 11 for PC or Helvetica 11 for MAC, 1-3 pages maximum). The submission should be submitted as **ONE ELECTRONIC FILE** and include:

1. Completed face page
2. Project title (not to exceed 53 characters, including spaces)
3. Statement of hypothesis
4. Goals of the research
5. Brief study design—must include a detailed power or sample size analysis on the primary and major secondary analyses. These analyses should include formulas and estimates used to arrive at the sample. One exception to this approach would be a feasibility study where the statistical section should focus on the precision of estimates that will be used to design future studies.
6. Specific statistical analysis section for the primary and secondary end points.
7. Budget estimate not to exceed \$100,000 yr. (plus 8% indirect costs) for a single center clinical research award or \$225,000/yr. (plus 8% indirect costs) for a multi-center clinical research award. All clinical research grants are awarded for a maximum of three years.
8. Attach curricula vitae listing only the last five years (no longer than 2-3 pages). Or last ten publications for the two professional personnel most involved in the project.
9. Please note that a biostatistician is required for all projects, a minimum of 5% time, including consultation for the letter of intent.

CFFT's Clinical Research Committee will review letters of intent and notify applicants as to the suitability of the study. Please contact the Office of Grants and Contracts Management at [CFFTAwards@cffttherapeutics.org](mailto:CFFTAwards@cffttherapeutics.org) or (301) 951-4422 if you have any questions regarding the program.

**Cystic Fibrosis Foundation Therapeutics, Inc.**  
**Cover Sheet for Clinical Research Letter of Intent**  
*Submit Electronically and As Hard-Copy*

**PRINCIPAL INVESTIGATOR:** \_\_\_\_\_

**CO-PRINCIPAL INVESTIGATORS (if applicable):** \_\_\_\_\_

**PROJECT TITLE:** \_\_\_\_\_

**PROPOSED PROJECT PERIOD:** \_\_\_\_\_

**PI's MAILING ADDRESS:** \_\_\_\_\_

**PHONE NUMBER:** \_\_\_\_\_

**FAX NUMBER:** \_\_\_\_\_

**E-MAIL ADDRESS:** \_\_\_\_\_

**SPONSORING INSTITUTION:** \_\_\_\_\_

We, the undersigned, certify that the statements herein are true and complete to the best of our knowledge and agree to conform to the regulations, policies and objectives of the Cystic Fibrosis Foundation Therapeutics, Inc. concerning this type of research project.

**Signature of PI:** \_\_\_\_\_

**Signature of Co-PI (if applicable):** \_\_\_\_\_

**Signature of 2<sup>nd</sup> Co-PI (if applicable):** \_\_\_\_\_