GUIDELINES FOR CLINICAL SPECIMEN ACCESS
LETTER OF INTENT

The Cystic Fibrosis Foundation has collected and stored biospecimens from clinical trials to be used by future investigators to support CF scientific investigation. The CF Foundation also developed a clinical trial database that links the biospecimens to the actual research data.

The CF Foundation requires that investigators who seek access to the Clinical Specimen Biorepository submit in advance a Letter of Intent (LOI). The deadlines for submitting letters of intent are April 1st and October 1st.

Letters of Intent must be submitted via email to Ldo@cff.org by 5:00pm (EDT) on April 1st and October 1st.

If April 1st or October 1st falls on the weekend, the deadline will be the following business day.

The Foundation reviews all LOIs electronically; therefore, anything not submitted electronically will not be reviewed.

We have initiated this early review to assess feasibility of the samples being requested using our Clinical Sample Database (CSDB). All LOIs must contain a completed Clinical Specimen Inquiry Form which is used by the CF Foundation in evaluating the availability of samples and the impact the request will have on the repository.

All feasible requests will receive a biorepository score and will then be forwarded for committee review to examine the scope and goals of the research project and to assess the scientific validity and merit. In general, the CF Foundation requires that requests which yield a high biorepository score (i.e., high sample depletion request) have a higher scientific impact.

Please complete the Clinical Specimen Access paperwork and email them to the address noted above. All applications should include:

- **Abstract**: Provide a general audience summary and a technical audience summary – 250 words up to 2,000 characters max, including spaces.
• **Budget Summary:** Provide a brief description of where funding will come from for this project. If applying for CFF funding, budget estimate not to exceed $200,000/yr (direct costs only).

• **Cover Letter:** The signed, original cover sheet should be returned to the CF Foundation

• **Project Description:** The brief description of the research project (maximum of 3 pages) should include:
  
  o Statement of hypothesis
  o Goals of the research
  o Brief study design

• **Complete Clinical Specimen Inquiry Form**

The CF Foundation will review letters of intent and notify applicants as to the suitability of the study. Please contact **Linh Do** at (301) 841-2648 or [Ldo@cff.org](mailto:Ldo@cff.org) if you have any questions regarding the program.