CF Foundation Specimen Banking	
Study Long Title	A Multicenter Longitudinal Study of CFTR-dependent Disease Profiling in Cystic Fibrosis
Short Name	PROSPECT Prospective Biomarkers Study
Specimens Currently Available to Other Researchers	Not Yet
Current Study Status	Completed

Study Timeline Metrics

	Planned	Actual (Sponsor)
Begin Enrollment	03/15/2015	03/25/2015
Complete Enrollment	03/31/2017	
Study Complete	03/31/2018	

Number of Patients Planned	260

General Study Information

Study Type	Observational
Intervention Type	
Control Type	
Blinded	No
Randomized	No
Duration of Subject Participation	15 Months
Endpoints Evaluated	Sweat Chloride, Sputum Inflammatory Mediators, LRT Microbiology, MCC, LCI, Other PRO
Trial Specific Link on ClinicalTrials.gov	https://clinicaltrials.gov/ct2/show/NCT02477319
Primary Manuscript Link	
Primary Manuscript Citation	

Eligibility Criteria

Age	>= 6 Years
FEV1	No FEV1 requirement
P. aeruginosa status	Not Applicable
B. cepacia status	Not Applicable

Other Primary Eligibility Requirements

Participants in Part B are required to have two copies of the F508del CFTR Mutation and to be prescribed Orkambi. The initial study visit must occur before the participant begins taking Orkambi.

Biorepository Specimen Information

General Specimen Information

Part A and B:

Human Nasal Epithelial (HNE) Cells will be collected from subjects who signed the informed consent indicating willingness to participate in the OPTIONAL genomic component of the study. Nasal cells are only to be collected one time and the timing of collection is not visit specific. Buffy Coat (WBC) samples will be obtained only from subjects who signed the informed consent indicating willingness to participate in the OPTIONAL genomic component of the study.

Part B :

Visit 4 is the baseline for Part B of the study (only F508Del subjects are eligible for Part B). Day 1 is designated as the start of treatment with lumacaftor/ivacaftor. Visit 5 should occur 30 days after first dose of lumacaftor/ivacaftor (Day 1).

Visit #	Time from Baseline	Specimens Collected
1	+0 Days	serum, EDTA plasma, buffy coat, sputum, urine
2	+14 Days	serum, EDTA plasma, buffy coat, sputum, stool, urine
3	+90 Days	serum, EDTA plasma, buffy coat, stool, urine
4	+0 Days	serum, EDTA plasma, buffy coat, sputum, urine

5	+60	serum, EDTA plasma, buffy coat, sputum, urine
6	+90	serum, EDTA plasma, buffy coat, urine
7	+180 Days	serum, EDTA plasma, buffy coat, sputum, urine
8	+360 Days	serum, EDTA plasma, buffy coat, sputum, urine