

CF Foundation Specimen Banking			
<b>Study Long Title</b>	EARLY INTERVENTION IN CYSTIC FIBROSIS EXACERBATION (eICE)		
<b>Short Name</b>	eICE Home Monitoring Early Intervention (Goss/Lechtzin)		
<b>Specimens Currently Available to Other Researchers</b>	Yes		
<b>Current Study Status</b>	Closed		
Study Timeline Metrics			
	Planned	Actual (Sponsor)	
Begin Enrollment	07/01/2011	10/06/2011	
Complete Enrollment	09/21/2014	07/15/2014	
Study Complete	06/30/2015	07/07/2015	
<b>Number of Patients Planned</b>	320		
General Study Information			
<b>Study Type</b>	Interventional		
<b>Intervention Type</b>	Other		
<b>Control Type</b>	Usual Care		
<b>Blinded</b>	No		
<b>Randomized</b>	Yes		
<b>Duration of Subject Participation</b>	1 Years		
<b>Endpoints Evaluated</b>	Spirometry, Exacerbations, LRT Microbiology, CFQR, CFRSD, Other PRO		
<b>Trial Specific Link on ClinicalTrials.gov</b>	<a href="http://www.clinicaltrials.gov/ct2/show/NCT01104402?term=home+monitoring+cystic+fibrosis&amp;rank=1">http://www.clinicaltrials.gov/ct2/show/NCT01104402?term=home+monitoring+cystic+fibrosis&amp;rank=1</a>		
<b>Primary Manuscript Link</b>	<a href="https://www.ncbi.nlm.nih.gov/pubmed/28608719">https://www.ncbi.nlm.nih.gov/pubmed/28608719</a>		
<b>Primary Manuscript Citation</b>	Am J Respir Crit Care Med ;DOI 10.1164/rccm.201610-2172OC		
Eligibility Criteria			
<b>Age</b>	>= 14 Years		
<b>FEV1</b>	>= 26 Percent Predicted		
<b>P. aeruginosa status</b>	Not Applicable		
<b>B. cepacia status</b>	Negative		
<b>Other Primary Eligibility Requirements</b>			
Eligible subjects are in a clinically stable state at baseline.			
Biorepository Specimen Information			
<b>General Specimen Information</b>			
For each subject enrolled in this study a specimen for banking is collected at baseline (subject in a stable non-exacerbated state) and a second sample is collected when the subject returns to the clinic for an acute visit at the start of an exacerbation. As such the timing between samples is variable but will be reflected in the table below as 3 months.			
Visit #	Time from Baseline	Specimens Collected	
1	+0 Days	serum, EDTA plasma	
2	+3 Months	serum, EDTA plasma	