

CF Foundation Specimen Banking			
Study Long Title	Baby Observational and Nutritional Study (BONUS)		
Short Name	BONUS - Baby Observational and Nutrition Study		
Specimens Currently Available to Other Researchers	Yes		
Current Study Status	Closed		
Study Timeline Metrics			
	Planned	Actual (Sponsor)	
Begin Enrollment	12/01/2011	01/17/2012	
Complete Enrollment	05/31/2014	05/31/2014	
Study Complete	05/31/2015	04/28/2015	
Number of Patients Planned	225		
General Study Information			
Study Type	Observational		
Intervention Type			
Control Type			
Blinded	No		
Randomized	No		
Duration of Subject Participation	12 Months		
Endpoints Evaluated	Sweat Chloride, LRT Microbiology, Growth		
Trial Specific Link on ClinicalTrials.gov	http://clinicaltrials.gov/ct2/show/NCT01424696?term=bonus+and+cystic+fibrosis&rank=1		
Primary Manuscript Link	https://www.ncbi.nlm.nih.gov/pubmed/28437538		
Primary Manuscript Citation	JAMA ;DOI 10.1001/jamapediatrics.2017.02		
Eligibility Criteria			
Age	1 Days to 15 Weeks		
FEV1	No FEV1 requirement		
P. aeruginosa status	Not Applicable		
B. cepacia status	Not Applicable		
Other Primary Eligibility Requirements	Babies with CF will be identified via newborn screening and enrolled by 3.5 months of age.		
Biorepository Specimen Information			
General Specimen Information			
Babies are enrolled within 3.5 months of birth. Blood samples will be collected at enrollment (between 1 to 3.5 months of age), and then at 6 months and 12 months of age. Urine and stool will be collected 1 month after enrollment (unless the baby is already 3 months old at enrollment). A buccal swab for DNA will be collected at enrollment. Throughout the study, any "extra" OP swabs will also be saved and banked at Colorado Children's Hospital.			
Visit #	Time from Baseline	Specimens Collected	
1	+1 Months	Lith-Hep Plasma, buccal DNA	
2	+2 Months	Lith-Hep Plasma, stool, urine	
3	+3 Months	Lith-Hep Plasma, stool, urine	
4	+4 Months	stool, urine	
5	+5 Months	stool, urine	
6	+6 Months	Lith-Hep Plasma, stool, urine	
8	+8 Months	stool, urine	
9	+10 Months	stool, urine	
10	+12 Months	Lith-Hep Plasma, stool, urine	