

CF Foundation Specimen Banking			
Study Long Title	The Wisconsin Cystic Fibrosis Newborn Screening Randomized Clinical Trial (1983 to 2012)		
Short Name	Wisconsin Newborn Screening Study		
Specimens Currently Available to Other Researchers	Yes		
Current Study Status	Closed		
Study Timeline Metrics			
	Planned	Actual (Sponsor)	
Begin Enrollment		04/15/1985	
Complete Enrollment		06/30/1998	
Study Complete		06/01/2012	
Number of Patients Planned	90		
General Study Information			
Study Type	Interventional		
Intervention Type	Other		
Control Type			
Blinded	No		
Randomized	No		
Duration of Subject Participation	#Error		
Endpoints Evaluated	Spirometry, Exacerbations, LRT Microbiology, Growth		
Trial Specific Link on ClinicalTrials.gov	http://www.clinicaltrials.gov/ct2/show/NCT00014950?term=wisconsin+cystic+fibrosis+newborn+screening&rank=1		
Primary Manuscript Link	http://pediatrics.aappublications.org/content/107/1/1.long		
Primary Manuscript Citation	Pediatrics 2001;Jan(107(1)):1-13		
Eligibility Criteria			
Age	1 Years to 21 Years		
FEV1	No FEV1 requirement		
P. aeruginosa status	Not Applicable		
B. cepacia status	Not Applicable		
Other Primary Eligibility Requirements	Other key inclusion criteria include: must have been born in the State of Wisconsin, must have been born between April 15, 1985 and June 30, 1994, must have had a valid newborn screening test for cystic fibrosis in the first 28 days of life and must have a sweat chloride test greater or equal to 60 mmol/Liter		
Biorepository Specimen Information			
General Specimen Information			
Specimens were collected associated with clinical care over a longitudinal time period of at least 17 years. Left over specimen (plasma) was saved when available; thus the timeframe for specimen collection is variable. In the table below Visit 1 (baseline) represents the first sample taken and Visit 2 represents all other potential time points during this longitudinal study.			
Visit #	Time from Baseline	Specimens Collected	
1	+0 Days	EDTA plasma	
2	+17 Years	EDTA plasma	