**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**

<table>
<thead>
<tr>
<th></th>
<th>Planned</th>
<th>Actual (Sponsor)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Begin Enrollment</td>
<td></td>
<td>04/15/1985</td>
</tr>
<tr>
<td>Complete Enrollment</td>
<td></td>
<td>06/30/1998</td>
</tr>
<tr>
<td>Study Complete</td>
<td></td>
<td>06/01/2012</td>
</tr>
</tbody>
</table>

**Number of Patients Planned**
90

**General Study Information**

**Study Type**
Interventional

**Intervention Type**
Other

**Control Type**
No

**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.

<table>
<thead>
<tr>
<th>Visit #</th>
<th>Time from Baseline</th>
<th>Specimens Collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>+0 Days</td>
<td>EDTA plasma</td>
</tr>
<tr>
<td>2</td>
<td>+17 Years</td>
<td>EDTA plasma</td>
</tr>
</tbody>
</table>