



CHILDRENLink: PROBE

Form 35 Final Status PROBE

B: FINAL SUBJECT STATUS

B1	Please identify the reason why the subject is leaving this study:	<input type="checkbox"/> Completed study → Complete B1a, B1b, and section G <input type="checkbox"/> Liver transplant → Complete B1b and section G <input type="checkbox"/> Transferred to another CHILDREN site (Specify site and date of transfer in B-2a and B-2b) → Complete B2a, B2b, and section G <input type="checkbox"/> Ineligible prior to start of study (Was consented and then identified as ineligible) (Specify condition in B-3) → Complete B1b, B3, and section G <input type="checkbox"/> Violated eligibility condition after start of study (Specify condition in B-3) → Complete B1b, B3, and section G <input type="checkbox"/> Investigator withdrew subject from study for reason other than eligibility (Specify reason in B-4) → Complete B1b, B4, B5, B6, and section G <input type="checkbox"/> Subject voluntarily withdrew from study (Specify reason in B-4) → Complete B1b, B3, and section G <input type="checkbox"/> Lost to follow-up → Complete sections E and G <input type="checkbox"/> Death → Complete sections E and G <input type="checkbox"/> Other early termination → Complete B1b, B4, B5, B6, and section G
B1a	If the subject completed the study, please specify the endpoint:	<input type="checkbox"/> Healthy <input type="checkbox"/> Reached age 20
If you selected "Death," "Lost to Followup," or "Transferred to another site," you'll have an opportunity to enter the relevant dates later in this form. Please fill out all available fields on the entire form.		
B1b	What is the date the subject left the study?	____ / ____ / ____
B2a	Please specify the new site:	<input type="checkbox"/> Chicago <input type="checkbox"/> Cincinnati <input type="checkbox"/> Denver <input type="checkbox"/> Philadelphia <input type="checkbox"/> Pittsburgh <input type="checkbox"/> San Francisco <input type="checkbox"/> Houston <input type="checkbox"/> St. Louis University <input type="checkbox"/> Indianapolis <input type="checkbox"/> Seattle <input type="checkbox"/> Toronto <input type="checkbox"/> Salt Lake City <input type="checkbox"/> Los Angeles <input type="checkbox"/> Atlanta
B2b	Please specify the transfer date:	____ / ____ / ____
B3	Please specify the condition causing ineligibility:	_____
B4	Please specify the reason for withdrawal:	_____
B5	Subject has requested removal of his/her information from the database:	<input type="checkbox"/> No <input type="checkbox"/> Yes
B6	Subject has requested removal of his/her samples from the repository:	<input type="checkbox"/> No <input type="checkbox"/> Yes

C: LOST TO FOLLOW-UP

C1	Reason for loss to follow-up:	<input type="checkbox"/> Care transferred to a non-ChiLDReN center <input type="checkbox"/> Lost contact <input type="checkbox"/> Other (specify): _____
C2	Date of loss to follow-up:	____ / ____ / ____
<p>The date of loss to follow-up is the date used to determine visit compliance. Visits scheduled after this date will be removed (not counted against the site). If a subject is lost to follow-up on a date within a visit window, you must mark that visit "Missed." To avoid visit compliance issues, enter the end-of-study dates as soon as you know the subject has left the study.</p>		
C3	Date of last contact:	____ / ____ / ____

E: DEATH

E1	Date of death:	____ / ____ / ____
E2	Cause of death:	_____
E5	Complications present or treated at time of death (check all that apply):	<input type="checkbox"/> None <input type="checkbox"/> Failure to thrive <input type="checkbox"/> Ascites <input type="checkbox"/> Cholangitis <input type="checkbox"/> Failed hepatoportoenterostomy <input type="checkbox"/> Coagulopathy <input type="checkbox"/> Varices <input type="checkbox"/> GI Bleed <input type="checkbox"/> Encephalopathy <input type="checkbox"/> Hepatopulmonary syndrome <input type="checkbox"/> Pulmonary hypertension <input type="checkbox"/> Hepatorenal syndrome <input type="checkbox"/> Intractable pruritus <input type="checkbox"/> Sepsis <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Unknown
E11	Autopsy performed:	<input type="checkbox"/> No <input type="checkbox"/> Yes
E12	Patient's weight:	_____ <input type="checkbox"/> kgs <input type="checkbox"/> lbs <input type="checkbox"/> oz <input type="checkbox"/> Missing <input type="checkbox"/> Not Done _____ <input type="checkbox"/> oz <input type="checkbox"/> Not Done
E13	Patient's length:	_____ <input type="checkbox"/> cm <input type="checkbox"/> feet <input type="checkbox"/> inches <input type="checkbox"/> Missing <input type="checkbox"/> Not Done _____ <input type="checkbox"/> inches <input type="checkbox"/> Not Done

E: DEATH

E14	Jaundice present	<input type="radio"/> No	<input type="radio"/> Yes	<input type="radio"/> Unknown
E15	Liver findings (check all that apply):	<input type="checkbox"/> None <input type="checkbox"/> Cirrhosis <input type="checkbox"/> Necrosis <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Unknown		
E20	Autopsy report:	<input type="radio"/> Requested	<input type="radio"/> Obtained	<input type="radio"/> Not obtained

G: INVESTIGATOR SIGNATURE

G1	Investigator Signed?	<input type="radio"/> No → Done	<input type="radio"/> Yes
G2	Date investigator signed	____ / ____ / ____	