



ChiLDReNLink: PROBE

Eligibility PROBE

A: VISIT DATE

A1	Participant Name	_____
A2	Patient Identifier	_____
A3	Visit Date	____ / ____ / _____

B: INCLUSION CRITERIA

B1	Date of Birth	____ / ____ / _____
B2	Is the infant's age less than or equal to 180 days at initial presentation with cholestasis to the site?	<input type="radio"/> No <input type="radio"/> Yes
B3	Has the infant been diagnosed with cholestasis where cholestasis is defined by serum direct or conjugated bilirubin ≥ 2 mg/dl and > 20 % of total bilirubin?	<input type="radio"/> No <input type="radio"/> Yes
B4	Have the patient's parent(s)/guardian(s) provided informed written consent for the patient?	<input type="radio"/> No → go to B5 <input type="radio"/> Yes
B4a	Date approached for consent:	____ / ____ / _____
B5	Has a BA diagnosis been confirmed at this point?	<input type="radio"/> No <input type="radio"/> Yes

C: EXCLUSION CRITERIA

C1	Does the patient have acute liver failure?	<input type="radio"/> No <input type="radio"/> Yes
C2	Has the patient had previous hepatobiliary surgery with dissection or excision of biliary tissue?	<input type="radio"/> No <input type="radio"/> Yes
C3	Has the patient been diagnosed with bacterial or fungal sepsis?	<input type="radio"/> No → go to C4 <input type="radio"/> Yes
C3a	If yes, does the patient have metabolic liver disease?	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Pending
C4	Has the patient been diagnosed with hypoxia, shock, or ischemic hepatopathy within the past two weeks?	<input type="radio"/> No <input type="radio"/> Yes
C5	Has the patient been diagnosed with any malignancy?	<input type="radio"/> No <input type="radio"/> Yes
C6	Has the patient been diagnosed with a hemolytic disorder?	<input type="radio"/> No → go to C7 <input type="radio"/> Yes
C6a	If yes, does the patient have biliary atresia or other cholestatic disease?	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Pending

C: EXCLUSION CRITERIA

C7	Has the patient been diagnosed with any drug or TPN-associated cholestasis?	<input type="radio"/> No → go to C8	<input type="radio"/> Yes
C7a	If yes, does the patient have biliary atresia or other cholestatic disease?	<input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> Pending
C8	Has the patient been diagnosed with ECMO-associated cholestasis?	<input type="radio"/> No	<input type="radio"/> Yes
C9	Was the patient's birth weight less than 1500 g?	<input type="radio"/> No → go to D1	<input type="radio"/> Yes
C9a	If yes, does the patient have biliary atresia?	<input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> Pending

D: SUMMARY

D1	Are you requesting an eligibility exemption for this subject?	<input type="radio"/> No	<input type="radio"/> Yes
Informed consent has been obtained for:			
D2	Blood draws for DNA from the participant:	<input type="radio"/> No → go to D4 <input type="radio"/> Pending → go to D4	<input type="radio"/> Yes <input type="radio"/> NA → go to D4
D3	Date consent obtained	____ / ____ / ____	
D4	Consent to research blood draws from the mother:	<input type="radio"/> No → go to D6 <input type="radio"/> Pending → go to D6	<input type="radio"/> Yes <input type="radio"/> NA → go to D6
D5	Date consent obtained	____ / ____ / ____	
D6	Consent to blood draws for DNA from the mother:	<input type="radio"/> No → go to D8 <input type="radio"/> Pending → go to D8	<input type="radio"/> Yes <input type="radio"/> NA → go to D8
D7	Date consent obtained	____ / ____ / ____	
D8	Consent to research blood draws from the father:	<input type="radio"/> No → go to D10 <input type="radio"/> Pending → go to D10	<input type="radio"/> Yes <input type="radio"/> NA → go to D10
D9	Date consent obtained	____ / ____ / ____	
D10	Consent to blood draws for DNA from the father:	<input type="radio"/> No → go to E1 <input type="radio"/> Pending → go to E1	<input type="radio"/> Yes <input type="radio"/> NA → go to E1
D11	Date consent obtained	____ / ____ / ____	

E: INVESTIGATOR SIGNATURE

E1	Investigator Signed?	<input type="radio"/> No → Done	<input type="radio"/> Yes
E2	Date investigator signed	____ / ____ / ____	
E3	Investigator's Comments:		