

Subject ID: _____
Date of Visit: _____

ChiLDReNLink: PROBE

Eligibility PRO

A1 Participant Name:
First Last

A2 Patient Identifier:

A3 Visit Date

 Month Day Year

B1 Date of Birth

 Month Day Year

B2 Is the infant's age less than or equal to 180 days at initial presentation with cholestasis to the site?
 --
 No
 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?
 --
 No
 Yes

B4 Have the patient's parent(s)/guardian(s) provided informed written consent for the patient?
 --
 No
 Yes

B4a Consent Date

 Month Day Year

B5 Has a BA diagnosis been confirmed at this point?
 --
 No

Subject ID: _____
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C1 Does the patient have acute liver failure?

 -- No Yes

C2 Has the patient had previous hepatobiliary surgery with dissection or excision of biliary tissue?

 -- No Yes

C3 Has the patient been diagnosed with bacterial or fungal sepsis?

 -- No Yes

C3a If yes, does the patient have metabolic liver disease?

 -- No Yes Pending

C4 Has the patient been diagnosed with hypoxia, shock, or ischemic hepatopathy within the past two weeks?

 -- No Yes

C5 Has the patient been diagnosed with any malignancy?

 -- No Yes

C6 Has the patient been diagnosed with a hemolytic disorder?

 -- No Yes

C6a If yes, does the patient have biliary atresia or other cholestatic disease?

 -- No Yes Pending

C7 Has the patient been diagnosed with any drug or TPN-associated cholestasis?

 -- No Yes

C7a If yes, does the patient have biliary atresia or other cholestatic disease?

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-
- No
- Yes
- Pending

C8 Has the patient been diagnosed with ECMO-associated cholestasis?

-
- No
- Yes

C9 Was the patient's birth weight less than 1500 g?

-
- No
- Yes

C9a If yes, does the patient have biliary atresia?

-
- No
- Yes
- Pending

D1 Are you requesting an eligibility exemption for this subject?

-
- No
- Yes

Informed consent has been obtained for:

D2 Storing the patient's blood for cell lines:

-
- No
- Yes
- Pending

D3 Date consent obtained

Month Day Year

D4 Taking blood from the mother:

-
- No
- Yes
- Pending
- NA

D5 Date consent obtained

Month Day Year

D6 Storing the mother's blood for cell lines:

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-
- No
- Yes
- Pending
- NA

D7 Date consent obtained

Month Day Year

D8 Taking blood from the father:
 --
 No
 Yes
 Pending
 NA

D9 Date consent obtained

Month Day Year

D10 Storing the father's blood for cell lines:
 --
 No
 Yes
 Pending
 NA

D11 Date consent obtained

Month Day Year

E1 Investigator Signed?
 --
 No
 Yes

E2 Date investigator signed

Month Day Year

E3 Investigator's Comments: