AFTER OBTAINING PARENT SIGNATURE, FAX TO 801-585-7395
Participant ID number assigned within REDCap (online) Data Entry _____
(This will allow study investigators to ensure the deidentified information is for a consented patient)

Parental Permission Document

BACKGROUND
You are being asked to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study.

The purpose of the study is to determine the cause of acute bilirubin encephalopathy (ABE). The information collected about your baby, along with the blood test will help us to understand what are the causes of ABE and how often these causes occur across the united states. In the past, we did not know what caused most cases of ABE.

Many babies with ABE will be enrolled in our study throughout the United States. We now have technology that may help us identify the cause in each case. If we can understand the different causes of the disease, we may be able to prevent them in the future.

STUDY PROCEDURE
We are asking your permission to enter your baby's medical information into a secure database. We will not enter any identifying information (name, birthdate, place of birth more specific than state, contact information, photographs, or insurance information). We are also asking to obtain a one-time blood sampled of 1 mL (one-fifth of a teaspoon). We will then look for genetic markers that tell us the cause of your baby's case of ABE. The staff at your hospital will draw your baby's blood, using sterile and routine techniques, and will place a bandage on the site and place pressure on it for a few minutes to reduce the chance of bleeding.

In this research, we are only looking for changes in your baby's genes that are related to ABE. But it is possible, though very unlikely, that we may come across changes that are related to other health conditions. These other findings may be important to your baby's health care or the health care of your family members. It is the responsibility of the ordering physician to notify you of all findings from this genetic test. In this study about ABE, we are not looking for results related to other conditions. This means that you might have changes in your genes related to other health conditions that we will not identify in this study.

In most cases we may need to retest your original blood sample or obtain a new sample for clinical testing. We may refer you to clinical specialists where retesting could be done to verify results. If you choose to receive results, the cost of clinical retesting may be billed to your insurance or you.

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RISKS
The risks of this study are minimal. Blood drawing can be uncomfortable. There is also risk of infection and blood loss associated with blood draw, but these risks are minimal.

BENEFITS
There are no direct benefits for taking part in this study. However, we hope the information we get from this study may help develop a greater understanding of Acute Bilirubin Encephalopathy in the future.

CONFIDENTIALITY
Procedures are in place to make sure all information collected about your child is kept secure. Research information will be stored on password protected computers. As stated before, no information that can identify your child (name, date of birth, place of birth, etc.) will be collected in our registry. No information will be transferred or transported outside of our institution.

PERSON TO CONTACT
If you have any questions, complaints or if you feel you have been harmed by this research please contact Timothy Bahr, Department of Pediatrics, University of Utah at (801) 581-4178.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION
Research studies include only people who choose to take part. You can tell us that you don't want your baby to be in this study. If you choose to have your baby's blood drawn then choose to stop the study later, the genetic study will not be run. At anytime during the study you may choose to have your baby withdrawn, and all information about your baby will be deleted from our registry and database. This will not affect your relationship with your doctor or the investigator.

COSTS AND COMPENSATION TO PARTICIPANTS
There are no costs or compensation for study participation.

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«Institution»
«IRB»
«Approved» «ApprovedDate»
«Expiration» «ExpirationDate»
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CONSENT:

By signing this consent form, I confirm I have read the information in this parental permission form and have had the opportunity to ask questions. I will be given a signed copy of this parental permission form. I voluntarily agree to allow my child to take part in this study.

_____
Child's Name

_____
Parent/Guardian's Name

_____ _____
Parent/Guardian's Signature Date

_____
Relationship to Child

_____
Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

I confirm that I was present as a witness for the consent process for this study. I confirm that the participant named above was read the information in the consent document and that the participant has agreed to take part in the research study.

_____
Name of Witness

_____ _____
Signature of Witness Date

«Image:Stamp»
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