

## Parental Permission and Authorization Document

### Background

You are being asked to give your child permission 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 and discuss it with friends and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you want to allow your child to take part in this research study.

Laboratory testing is needed to diagnose diseases and review the effects of treatment. This is done by looking at the amount of different substances in blood. To be able to measure a person's test result correctly, that result is compared to what we know to be normal in adults. We need to do more testing to be sure that we have the correct measurements for children.

### Study Procedure

Since your child is already having surgery, an IV (plastic tube inserted in your child's blood vein, usually in the arm or hand) will already be placed. We would like to take a sample of blood (1½ to 2 teaspoons) using that tube and measure certain levels of different substances. No additional time in surgery is expected. Since we do not know the normal levels for the substances we are testing in children, you will not receive the test results for anything done in this study. This study is designed to collect samples that are stored for this research study. These samples will be used for as long as possible to complete this study, but will not be saved for other research in the future. If there are any samples remaining when we decide to stop this study, they will be destroyed.

### Risks

Since your child is already getting the IV placed for surgery, we do not expect that there will be any more risk to him/her while being in this study. However, there is a slight risk that the information we collect about your child could be seen by someone not involved in this study. We will make all efforts possible to protect this information. This is described in more detail below.

### Benefits

Your child will not receive any direct benefit from being in this study. What we learn about measurements of the different substances in blood will help us to know how to correctly read results from children in the future.

### Alternative Procedures

Since this study is voluntary, you can choose not to allow your child to participate.

### Confidentiality

We will keep all research records that identify your child private to the extent allowed by law. Records about him/her will be kept locked in filing cabinets or on computers protected with passwords. Only those who work with this study will be allowed access to your child's



information. Results of the study may be published; however, you and your child's names and other identifying information will be kept private.

### Person to Contact

If you have any questions, complaints, or concerns regarding this study or if you believe that our child has been hurt because of the study, you can contact William Roberts, MD, PhD at (801) 583-2787 ext. 2086 from 8:00 a.m. - 5:00 p.m.

### Institutional Review Board

Contact the Institutional Review Board (IRB) if you have questions regarding your child's 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](mailto:irb@hsc.utah.edu).

### Voluntary Participation

It is up to you to decide whether or not to allow your child to take part. If you do decide to do so you will be asked to sign this permission form. If you decide to allow your child to take part you are still free to withdraw him/her at any time and without giving a reason. This will not affect the relationship you and your child have with the investigator or staff nor standard of care he/she will receive.

### Costs to Participants and Compensation

There are no additional costs to you for your child's participation in this study. You or your child will not be paid for being in this study.

### Authorization for Use of Your Protected Health Information

Signing this document means you allow us, the researchers in this study, and others working with us to use information about your child's health for this research study. You can choose whether or not he/she will participate in this research study. However, in order to participate you have to sign this consent and authorization form.

This is the information we will use:

- Name
- Medical Record Number
- Date of Birth
- Address
- Height
- Weight
- Ethnicity
- When your child last ate.
- Any medications taken prior to surgery.
- Type of surgery performed.

Others who will have access to your child's information for this research project are the University's Institutional Review Board (the committee that oversees research studying people) and authorized members of Primary Children's Medical Center's workforce who need the



information to perform their duties (for example: to provide treatment, to ensure integrity of the research, and for accounting or billing matters).

If we share your child's information with anyone outside Primary Children's Medical Center he/she will not be identified by name, social security number, address, telephone number, or any other information that would directly identify him/her, unless required by law.

In records and information disclosed outside of the Primary Children's Medical Center your child's information will be assigned a unique code number. We will keep the key to the code in a locked file and/or in a password protected computer. We will destroy the key to the code at the end of the research study.

You may revoke this authorization. This must be done in writing. You must either give your revocation in person to the Principal Investigator or the Principal Investigator's staff, or mail it to William Roberts, M.D., Ph.D., ARUP Laboratories, 500 Chipeta Way, Salt Lake City, Utah 84108. If you revoke this authorization, we will not be able to collect new information about your child, and he/she will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization lasts until this study is finished.

**Permission**

I confirm that I have read and understand this parental permission and authorization document and have had the opportunity to ask questions. I understand that my child's participation is voluntary and that I am free to withdraw him/her at any time, without giving any reason, without his/her medical care or legal rights being affected. I will be given a signed copy of the consent and authorization form to keep.

**I agree to allow my child to participate in this research study and authorize you to use and disclose health information about him/her for this study, as you have explained in this document.**

\_\_\_\_\_  
Child's Name

\_\_\_\_\_  
Parent's/Guardian's Name

\_\_\_\_\_  
Relationship to Child

\_\_\_\_\_  
Parent's/Guardian's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Person Obtaining Authorization and Consent

\_\_\_\_\_  
Signature of Person Obtaining Authorization and Consent

\_\_\_\_\_  
Date

