

## Parental Permission and Authorization Document

### PEDIATRIC REFERENCE INTERVAL DETERMINATIONS FOR CLINICAL COAGULATION LABS PARENTAL PERMISSION and AUTHORIZATION DOCUMENT

**BACKGROUND:** Your child is being invited 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.

This study is being done to collect blood samples from healthy children to determine normal values for a number of clotting proteins that are present in the blood. Blood tests are commonly used to assess how well the body is functioning. A physician will use this information to decide if someone should be treated for a particular problem. It is important to have normal reference ranges for various substances in the blood (such as blood clotting proteins) to determine if a certain organ is working properly. In order to determine the normal reference ranges for these substances, normal children must be tested.

Your child is being asked to participate in this study because he/she is having elective surgery or having blood drawn for some other reason as determined by your treating physician (before surgery or as part of well child care). If your child participates in the study, we ask that a sample of blood be taken for the purposes of testing various blood clotting proteins.

**STUDY PROCEDURES:** If you agree to allow your child to participate in this study, an extra amount of blood (9 mL, about two teaspoons) will be drawn. If your child is scheduled for an elective surgical procedure, this extra blood draw will be drawn in the operating room after your child has been anesthetized (given medicines to help them sleep) so that he/she will not experience any discomfort from the blood draw. If your child is having blood drawn in the laboratory for clinical reasons, we would ask that an additional blood sample be collected for this study at the time of the blood draw. This study is designed to collect samples that are stored for blood clotting research. 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:** The collection of blood may lead to bruising, redness, soreness, or infection at the site of collection. Nausea and vomiting may rarely occur when blood is collected.

**BENEFITS:** Your child may not benefit directly from his/her participation in this study. However, if an unexpected abnormal result that might affect your child's health is found, this information will be made known to you and your physician, if you desire. By participating in this study, your child will help define the normal range of blood clotting values seen in a healthy population, thereby helping health care providers to identify those individuals who have abnormal clinical laboratory test results due to illness.



**ALTERNATIVE PROCEDURES:** Participating in this study is completely voluntary. You may choose NOT to have your child participate in the study, and there will be no impact on your child's clinical care because of non-participation.

**CONFIDENTIALITY:** All information collected during the study will be confidential and retained by ARUP laboratories. Information will be accomplished with strict adherence to professional standards of confidentiality. For purposes of study reporting, your child will be identified by a code only. However, your child's name and address will be kept on record in case you need to be contacted in the future about this study. The code key and patient data will be kept in a locked file cabinet in the Pediatric Hematology-Oncology division.

The medical information gathered from this study may be submitted to medical journals for publication. However, your child's name or any information that may be used to identify him/her will not be submitted.

**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 your child will take part. If you do decide that your child will take part you will be asked to sign this consent form. If you decide your child will take part you are still free to withdraw your child and permission to use his/her sample at any time and without giving a reason. This will not affect the relationship you have with the investigator or staff nor standard of care your child receives.

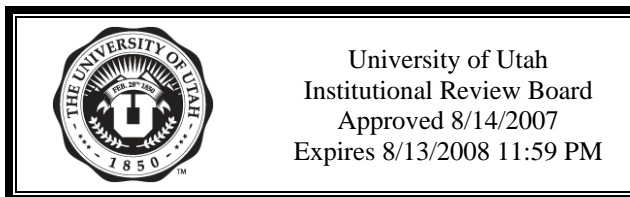
**COSTS TO SUBJECTS AND COMPENSATION:** There will be no costs to you/your child for participation in this study. There will be no compensation for participation in this study.

**APPROVAL TO USE YOUR CHILD'S 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 your child will participate in this research study. However, in order for your child to participate you have to sign this consent and authorization form.

This is the information we will use:

- Name
- Date of birth
- Gender
- Race/Ethnicity
- Past Medical History
- Current medications



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 the University's and Primary Children's Medical Center 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 the University of Utah Health Sciences Center and/or 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 University of Utah Health Sciences Center and/or 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 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 revocation in person to the Principal Investigator or the Principal Investigator's staff, or mail it to William Roberts, MD, c/o ARUP Laboratories, 500 Chipeta Way, Salt Lake City, UT 84108. If you revoke authorization, we will not be able to collect new information about you, and you 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 and all follow up is finished.

**CONSENT:** I confirm that I have read and understand this consent 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 my child at any time, without giving any reason, without my medical care or legal rights being affected. I will be given a signed copy of this document. **I agree to allow my child to participate in this research study and permit you to use and disclose health information about my child for this study, as you have explained in this document.**

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

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

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

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

\_\_\_\_\_  
Date

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

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

\_\_\_\_\_  
Date

