

Parental Permission and Authorization Document

Background

Blood and urine 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 chemical substances in order to determine if a gland or organ is working properly. Your child's participation in this research study will be most helpful in providing blood samples for tests to be used to assess chemical levels. Your child will have a brief history and physical performed. This information will be used to properly establish whether or not your child has a health problem.

Study Procedures

A blood sample of 2 tablespoons will be withdrawn from your child's vein by using hollow needle designed for this purpose. This sample along with a urine sample will then be sent to the laboratory for testing for hormones and other chemicals in them. Your child's active participation will end after the blood has been withdrawn. This study is designed to collect samples that are stored for for many years to determine reference intervals for new blood and urine tests as they become available. 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.

Your child's identity will be held in confidence, but results could be made available to your physician if you make a request in writing to Dr. William Roberts.

Inclusion Criteria:

Your child will be requested to participate because he/she is a normal volunteer.

Exclusion Criteria:

Your child will not be allowed to participate if you feel he/she should not or if he/she is unwilling to allow a blood sample to be collected.

Risks

The collection of blood samples may lead to bruising, redness, soreness, or infection at the site of collection. Nausea, vomiting, and fainting may rarely occur when blood is collected.

Benefits

Your child may not benefit directly from their 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 values seen in a healthy population for a variety of clinical laboratory tests, thereby helping health care providers to identify those individuals who have abnormal clinical laboratory test results due to illness.



Alternative Procedures

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 the ARUP Laboratories. Information will be stored with strict adherence to professional standards of confidentiality. Written records will be stored in locked files and study data will be stored on password-protected computers. 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 medical information gathered from this study may be submitted to medical journals for publication. However, your name or any information that may be used to identify you will not be submitted.

Person to Contact

If you have questions, complaints or concerns about this study or think your child may have been injured from being in this study, you can contact Dr. William Roberts at (801) 583-2787 ext. 2086 or John Simmons at (801) 583-2787 ext. 2968 during regular business hours

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.

Research-Related Injury

If your child is injured from being in this study, medical care is available to him/her at the University of Utah or ARUP (Associated Regional University Pathologists) as it is to all sick or injured people. The University of Utah and ARUP does not have a program to pay you if your child is hurt or have other bad results from being in the study. The costs for any treatment or hospital care would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs.

The University of Utah is a part of the government. If your child is injured in this study, and you want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Utah Governmental Immunity Act is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See Section 63-30d-101 through 63-30d-904 of the Utah Code.



Voluntary Participation

Your child does not have to participate in this study. If he/she does elect to participate, it will not limit his/her participation in future studies. If your child does participate, he/she is free to withdraw from the study any time. You and your child are free to ask any questions before, during and after the study. If any time you desire further information regarding this study, contact Dr. William Roberts at ARUP Laboratories (801) 583-2787 ext. 2086. Dr. Roberts should be contacted if your child experiences any problems related to this study. You will receive a copy of this consent form. You also will be informed of any developments that may affect your willingness to continue participating in this study.

Unforeseeable Risks

Although the collection of blood is generally considered safe, there may be some risks that are currently not foreseeable.

Right of Investigator to Withdraw

The Investigator reserves the right to withdraw your child from participation if deemed necessary. This might occur if a medical condition is identified during the study or there are difficulties with blood collection.

Costs to Subjects and Compensation

There will be no costs to you or your child for participation in this study. If your child consents to having blood drawn after completion of the physical examination, he or she will receive a Wal-Mart gift card valued at \$30.

New Information

Your child's participation in this study may help to better distinguish between normal and abnormal values for several clinical laboratory tests. Any new information that may affect your willingness to participate in this study will be provided to you.

Number of Subjects

Approximately 2600 subjects will participate 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:

Your child's name. This will appear only on the consent form and in a number code book. The consent form and code book will be kept locked in a secured file cabinet.

Your child's birth date. This will allow us to calculate a precise age.



Your child's stage of physical development. This will allow us to record the specific stage of development necessary for analyzing the data.

Results from your child's blood and urine samples will help the researchers develop normal test ranges specific to children at various stages of development.

Others who 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 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, your child **will not be** identified by name, social security number, address, telephone number, or any other information that would directly identify him or her, unless required by law.

In records and information disclosed outside of the University of Utah Health Sciences 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 your revocation in person to the Principal Investigator or the Principal Investigator's staff, or mail it to ***William Robert, MD PhD; Department of Pathology; c/o ARUP Laboratories; 500 Chipeta Way; Salt Lake City, UT 84108.*** If you revoke this 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 does not have an expiration date. After you sign this, you will be given a copy with your signature.



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 the consent and authorization form to keep. 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

<hr/> <p>Parent or Legal Guardian's Name</p>	<hr/> <p>Parent or Legal Guardian's Signature</p>	<hr/> <p>Relationship</p>	<hr/> <p>Date</p>
<hr/> <p>Parent or Legal Guardian's Name</p>	<hr/> <p>Parent or Legal Guardian's Signature</p>	<hr/> <p>Relationship</p>	<hr/> <p>Date</p>
<hr/> <p>Name of person obtaining authorization and consent</p>	<hr/> <p>Signature of person obtaining authorization and consent</p>	<hr/> <p>Date</p>	

