

Parental Permission and Authorization Document

STUDY SUMMARY

Your child is 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 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 will allow your child to take part in this research study.

Your child's participation is voluntary, which means that you are free to decide whether to allow your child to be in this study. The purpose of the study is to evaluate the safety of the study drug being tested, <<Study Drug A>> plus <<Study Drug B>> when compared to <<Study Drug C>> in individuals with a complicated intra-abdominal infection. We are asking you to allow your child to participate in this study because s/he has a complicated intra-abdominal infection. This study is being conducted by <<Sponsor Name>>. The sponsor is paying for the University of Utah to conduct this study.

This is a Phase 2 study which means it is done on a larger number of human subjects to see if a new drug is safe. They are also done to find out if the drug works and does what it is supposed to do.

<<Study Drug A>> is an approved drug available by prescription for use in adult patients with complicated intra-abdominal infection (in combination with <<Study Drug B>>) and for complicated urinary tract infections, including kidney infections but is not approved for use in patients less than 18 years of age yet. <<Study Drug C>> is an approved drug available by prescription in children and adults for treatment of different types of infections.

About 120 patients will be in the study. Your child will be in the study about 5-7 weeks. Your child will be screened to find out if they should be in the study. There will be a review of your child's medical record and a physical exam. Blood will be drawn from your child and some blood tests will be done. Your child will be randomized to receive one of the two treatments and your child will be given the drug through an IV. The study procedures will be explained in detail later in this document.

There are known side-effects that may occur as a result of the drugs used in this study. The study team does not know all the effects that the study drug may have on your child. These effects may be mild or serious. In some cases, these effects might be long lasting, or permanent, and may even be life threatening. There is also the risk of an allergic reaction to the drugs. The risks are explained in detail later in this document.

There are no direct benefits to your child from your taking part in this study. The information we get from this study may help us treat future patients. We hope that this study will help your child, however, this cannot be guaranteed.

You may choose not to allow your child to participate in this study. If you do not want to take part in the study, there are other choices such as other approved antibiotics for intra-abdominal infections. You may discuss these options with your child's doctor.

STUDY PROCEDURES

After signing this consent document, the study will begin with a screening visit. The purpose of the screening visit is to find out if your child meets all of the requirements to take part in this research study. Below are the procedures and assessments that will be completed during the study, including screening. If your child does not meet the requirements, the study doctor will explain why and will discuss with you/your child other treatment options, if available.

The study doctor or staff may do any or all of the following to measure if the drug is working and/or to monitor your child's health during the study:

- Your child's medical history will be reviewed including a review of current and past medications
- A physical exam review of your child's surgical wound
- Body weight and height measurements, for calculation of study drug dose
- Your child's pulse, breathing rate, temperature, and blood pressure will be measured
- You/your child will be given a subject identification card. This identifies your child as a participant in a research trial. This card will contain study contact information for your child in case of emergency.
- The study drug will be administered.
- Review of any adverse events
- Collect sample from the site of the infection in your child's abdomen, if applicable.
 - This will include the collection of a small amount of fluid from the site of infection in your child's abdomen as part of the treatment that is being done for their infection. This would be done routinely, even if your child was not taking part in this study.
- **Blood draw:** A needle will be used to draw blood from a vein in your child's arm. If the blood can be drawn from the same IV line that is put in for your child's standard medical treatment, after it is put in, that would be allowed. Taking blood may cause bruising at the place where the needle goes into the skin. Fainting, and in rare cases infection, may occur.
 - A total of about up to about 9 ½ teaspoons (46.25mL) of blood will drawn during the entire study. Sometimes a blood test may need to be repeated. If this happens the total amount of blood drawn will be more than this.
- If the blood tests show that your child has liver lab results that are not normal, the study doctor or staff will ask your child to provide additional samples of blood to get more information about these results. If you do decide to allow additional samples to be collected from your child the study staff will discuss with you the amount of blood that will be taken and the tests that will be performed.

The tests that may be performed include HIV and viral hepatitis tests to find out if HIV or hepatitis is the reason your child's results are abnormal.

The results of all of your blood tests, just like all other laboratory test results, will be provided to the Sponsor. Positive HIV and Viral Hepatitis test results are required to be reported to local health authorities.

You do not have to allow additional blood samples to be collected from your child. However, if you decide not to allow the collection of additional samples, your child may need to leave the study for his/her own safety (as the cause of the abnormal liver lab results may not be able to be determined without them).

A research trial usually involves comparing different treatments. In a trial, one group will get one treatment and another group will get a different treatment. In a “randomized trial” people are put in one group or the other by random chance (like a flip of the coin). This means that a computer will decide by chance which group a person is in, not the doctors running the trial.

- Your child will be assigned by chance to get either:
 - <<Study Drug A>> + <<Study Drug B>>
 - <<Study Drug C>> + placebo (look-alike with no active ingredients)

In this trial, neither you nor your doctor will know which treatment group your child is in (although, if your doctor needs to find out for important medical reasons, he can do so).

Placebo: A placebo is a dummy treatment such as a pill which looks the same as the pill that contains the study drug but does not contain any medicine. Placebos contain no drugs or active ingredients. Study participants are given placebos so that the effects of a drug can be compared against no drug. Use of placebos also prevents the participant and the doctor from knowing whether or not the subject is getting the drug.

The amount of study drug your child receives will be based on his/her age and weight and will be given as 60 minute infusions (into a vein) approximately every 8 hours (3 times a day).

After receiving at least 9 doses of study drug, the study doctor may switch your child to an antibiotic that is available by prescription and can be taken orally. The study doctor will discuss this with you if it applies to your child. Total time that your child will be on study treatment (IV study drug only or IV study drug + prescription oral drug) is a minimum of 5 days to a maximum of 14 days. Your child will be asked to stay in the hospital during IV study treatment. This hospital stay is part of your child’s normal standard of care and you/your insurance will be billed.

What will my child be asked to do?

If your child takes part in the study, you will need to ensure your child does the following:

- Meets with the study doctor and staff as instructed.
- Tells the study doctor about any illnesses or other problems s/he has during the time your child is part of the study.
- Tell the study doctor about any medicines your child has taken or take during the study.
- Be available for phone calls from the study staff for follow-up, as applicable. The study doctor and staff will discuss this with you.
- You and your child may be asked to return to the hospital after discharge for additional testing.
- Take study drug(s) at the hospital by intravenous (IV) infusion.

RISKS

Any research has some risks, which may include things that could make your child feel unwell, uncomfortable, or harm your child. Your child might experience negative effects related to the study drug while taking part in the study. All research participants taking part in the study will be watched carefully for any negative effects; however, the study team does not know all the effects that the study drug may have on your child. The research study team may give your child medicines to help reduce negative effects. These effects may be mild or serious. In some cases, these effects might be long lasting, or permanent, and may even be life threatening.

- **Blood samples:** drawing blood from your child's arm may cause pain, bruising, lightheadedness, and rarely, infection.
- **IV Infusion:** The insertion of IV lines may cause faintness, swelling of the vein, pain, bruising, or bleeding at the site of the puncture. There is also a slight chance of infection.

About The Study Drug(s)

For <<Study Drug A>>:

<<Study Drug A>>, is a combination product, and is available by prescription for use in adults for the treatment of complicated urinary tract infections, including pyelonephritis (serious infection of the kidney) and complicated intra-abdominal (stomach or other organs in the abdomen) infections. <<Study Drug A>> has been approved in several countries, including the US and EU.

<<Study Drug A>> is being studied by the Sponsor to see if it has any effect in treating infections of the lungs and to see what side effects are caused by <<Study Drug A>>. The Sponsor is also studying <<Study Drug A>> in children with complicated urinary tract infections and complicated intra-abdominal infections.

As of 30 June 2018, <<Study Drug A>> has been given to about 1630 subjects in completed clinical trials, of which 1229 were enrolled in Phase 3 comparator-controlled clinical trials of complicated intra-abdominal infections and complicated urinary tract infections.

What side effects could the study drug(s) cause?

The side effects seen with <<Study Drug A>> were generally mild or moderate in severity. <<Study Drug A>> is in the family of beta-lactam antibacterial medications called cephalosporins. Hypersensitivity reactions (allergic reactions that can be from mild to severe) have been reported with cephalosporins or beta-lactams. Diarrhea is a common problem caused by antibacterial drugs. Sometimes, frequent watery or bloody diarrhea may occur and may be a sign of a more serious intestinal infection.

The following **common** side effects were seen in 1 to 10% of people who were given <<Study Drug A>>:

- Rash
- Trouble falling and/or staying asleep
- Headache
- Fever
- Anxiety

- Dizziness
- Low blood pressure
- Nausea
- Diarrhea
- Constipation
- Vomiting
- Stomach ache
- Increase in the number of cells in the body that help blood to clot
- Changes in blood test results including those that may show liver damage or low potassium
- Discomfort or irritation at the intravenous insertion site when the drug is given

The following **uncommon** side effects were seen in less than 1% of people who were given <<Study Drug A>>:

- Vaginal or mouth yeast infections
- Decrease in the number of cells in the blood that carry oxygen (anemia)
- Inflammation at the intravenous insertion site when the drug is given
- Rapid heartbeat
- Chest pain
- Inflammation of the stomach lining
- Stomach bloating
- Upset stomach
- Increased gas
- Blockage of the intestine
- Hives
- Urinary tract infections
- Stroke
- Kidney damage
- Blood clot
- Shortness of breath
- A type of abnormal heart rhythm
- A positive blood test (Coombs test) that may indicate a special type of anemia that causes breakage of red blood cells
- Changes in blood test results including those that may show high sugar, low magnesium and low phosphorous
- A severe intestinal condition (Clostridium difficile-associated diarrhea) due to a type of bacteria. This condition may occur during treatment or a week to months after treatment has stopped. Tell your child's doctor right away if your child develops persistent diarrhea, abdominal or stomach pain/cramping, or blood/mucus in their stool.

With any drug, there is the potential for an allergic reaction. The most commonly reported symptoms associated with allergic reactions are:

- Rash
- Nausea
- Cough
- Dizziness
- Fainting
- Hives
- Itching
- Facial flushing
- Fever
- Muscle aches
- Chest tightness
- Shortness of breath/difficulty breathing

Rarely, a more severe allergic reaction may occur and may result in death. Additional symptoms may include:

- Swelling of the face, lips, throat and tongue
- Painful rash with blisters in the body
- Low blood pressure
- Loss of consciousness

<<Study Drug A>> does not work as well in some patients who have kidney damage. If a patient has changing kidney function, it should be measured each day and the dose of <<Study Drug A>> may need to be discontinued.

For <<Study Drug B>>:

What is known about this study drug?

<<Study Drug B>> is an approved drug available by prescription in children and adults. It is used to treat serious infections caused by susceptible anaerobic bacteria. In a mixed aerobic and anaerobic infection, antibiotics appropriate for the treatment of the aerobic infection should be used in addition to <<Study Drug B>>.

What side effects could the study drug(s) cause?

Undesirable effects are mainly associated with prolonged use or high doses. The most commonly observed effects include nausea, abnormal taste sensations and the risk of numbness, weakness or pain, usually in the hands and feet, in case of long term treatment.

The following **common** side effects were seen in 1% (1 in 100) to 10% (1 in 10) of people who were given <<Study Drug B>>:

- Decreased appetite
- Dry mouth
- Mouth pain and swelling
- Nausea
- Stomach pain
- Strange taste
- Vaginal yeast infection
- Vomiting

The following **uncommon** side effects were seen in 0.1% (1 in 1000) to 1% (1 in 100) of people given <<Study Drug B>>:

- Darkening of the urine

The following **rare** side effects were seen 0.01% (1 in 10,000) to 0.1% (1 in 1000) of people who were given <<Study Drug B>>:

- Changes in EKG (a test of heart function)
- Pseudomembranous colitis: inflammation of the large bowel causing diarrhea
- Severe allergic reactions

The following **very rare** side effects were seen in less than 0.01% (1 in 10,000) people given <<Study Drug B>>:

- A decrease in the numbers of some types of blood cells that help blood to clot, fight infection and carry oxygen
- Blisters
- Confusion or seeing/hearing things that are not there
- Convulsions (seizures)
- Damage to the liver, in some cases requiring liver transplant
- Dizziness
- Drowsiness
- Headache
- Pancreatitis
- Problems with coordination and balance
- Rash, itching, flushing, hives
- Severe skin reactions
- Slurred speech
- Temporary double vision, near-sightedness, blurred vision, worsening of vision, and changes in ability to see colors
- Vertigo (feeling of spinning)
- Yellowing of the skin (jaundice)

The following side effects were seen with **unknown frequency** in people given <<Study Drug B>>:

- Aseptic meningitis: non-infectious irritation of the lining of the brain
- Cerebellar Syndrome: Irritation of a part of the brain that may cause difficulty with balance, coordination and walking, difficulty speaking/slurred speech, involuntary eye movement and shakiness which may resolve with discontinuation of the drug
- Constipation
- Decreased hearing
- Diarrhea
- Inflammation of the inner eye and nerves of the eye that may affect vision
- Insomnia (Difficulty falling and/or staying asleep)

- Intense feeling of sadness (depression)
- Loss of bladder control
- Numbness, tingling or pain in the hands and feet due to irritation of the nerves
- Pain and inflammation of the rectum
- Pain with urination
- Ringing in the ears
- Tongue discoloration/furry tongue

For <<Study Drug C>>:

What is known about this study drug?

<<Study Drug C>> is an approved drug available by prescription in children and adults. It is used to treat infection affecting the lungs (pneumonia), lung infections in patients suffering from cystic fibrosis, complicated urinary tract infections, complicated infections in the abdomen, infections that you can catch during or after the delivery of a baby, complicated skin and soft tissues infections, and acute bacterial infection of the brain (meningitis).

What side effects could the study drug(s) cause?

The following **common** side effects were seen in 1 to 10% people who were given <<Study Drug C>>:

- Stomach pain
- Nausea
- Vomiting
- Diarrhea
- Headache
- Rash
- Pain and inflammation
- Constipation
- Itching
- Irritation or inflammation of the veins where the medicine is given
- Difficulty breathing
- Bleeding events
- Increase in the number of cells in the body that help blood to clot
- Changes in blood test results including those that show how well your liver is working
- Changes in blood pressure that affect blood flow
- Whole-body inflammatory response to an infection (sepsis). Common symptoms include fever, increased heart rate, and increased breathing rate.

The following **uncommon** side effects were seen in 0.1 to 1% people who were given <<Study Drug C>>:

- Sore veins where the medicine is injected
- Changes in blood tests, including tests that show how well your kidneys are working
- Trouble falling and/or staying asleep
- Confusion or seeing/hearing things that are not there

- Sudden onset of severe rash or blistering or peeling skin
- Infections of the mouth or the vagina that are caused by a fungus or yeast
- Swelling
- Drowsiness
- Changes in heart rate
- Severe allergic reaction
- Hives
- Fever and chills
- Pain
- Abdominal enlargement
- Fainting
- Inflammation of the bowel with diarrhea
- Damage to the heart, liver, or kidneys
- Decrease in the amount of oxygen in the body
- Intense feeling of sadness
- Difficult or painful urination
- Increased fluid in the blood
- Blockage of the intestine
- Decrease in body weight
- Upset stomach
- Coughing
- Increased gas
- Sweating
- Tingling
- Anxiety or nervousness
- Dizziness
- Weakness
- Lung damage, including fluid build-up or a blood clot
- Heart attack
- Changes in blood test results such as decreased numbers of cells in the body that help blood to clot, increased numbers of some white blood cells, decreased numbers of other white cells, decreased in the number of cells in the blood that carry oxygen (anemia), low potassium, and increased amounts of a substance called 'bilirubin'

The following **rare** side effects were seen in less than 0.1% of people who were given <<Study Drug C>>:

- Fits (seizures/convulsions).

People taking <<Study Drug C>> have developed a positive test (Coombs test) which indicates the presence of antibodies that may destroy red blood cells. Contact your doctor if your child has signs of:

- unexpected breathlessness
- red or brown urine

<<Study Drug C>> should not be used in patients with a history of allergic reactions to <<Study Drug C>> or any of the ingredients in this medicine. <<Study Drug C>> can cause a decrease in the level of valproic acid or divalproex sodium in patients taking these medications together. The use of <<Study Drug C>> and valproic acid or divalproex sodium together is generally not recommended as there is an increased chance of breakthrough seizures.

Placebo Risk:

Certain research participants in this study will receive a placebo along with the <<Study Drug C>>. Taking a placebo may be similar to not taking any medication. If your child is one of the research participants who receives placebo, your child's disease may stay the same or get worse, or your child's condition may suddenly get better just as it may have done without additional treatment.

REPRODUCTIVE RISKS

It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not take part in this study, nor should women who plan to become pregnant during the study. Women who are at risk of pregnancy will be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. If your child could become pregnant, your child must use an effective contraceptive during the course of this study.

Acceptable methods of birth control include abstinence (no sexual intercourse) or by using (or having partner use) reliable birth control from study start (Visit 1, Screening) through at least 30 days after the last dose of study drug. The following birth control methods are allowed during the study:

Single method (one of the following is acceptable):

- Intrauterine device (IUD)
- Vasectomy of a female subject's male partner
- Contraceptive rod implanted under the skin

Combination method (requires use of **two** of the following):

- Diaphragm with spermicide (cannot be used in conjunction with cervical cap/spermicide)
- Cervical cap with spermicide (only for women who have never given birth)
- Contraceptive sponge (only for women who have never given birth)
- Male condom or female condom (cannot be used together)
- Hormonal contraceptive: oral contraceptive pill (estrogen/progestin pill or progestin-only pill), contraceptive skin patch, vaginal contraceptive ring, or subcutaneous contraceptive injection
- Periodic abstinence and withdrawal are not acceptable methods of contraception

There may be risks if you are male and your partner is pregnant or trying to become pregnant. If you are male and your partner is able to have a baby, you and your partner must use a reliable birth control method from study start (Visit 1, Screening) through at least 30 days after your last dose of study drug. The birth control methods are the same as those listed above.

If your child becomes pregnant while taking part in the study, you or your child must immediately tell your research doctor. Options will be discussed with you and your child at that time. Whether or not your child remains on study treatment, we will follow the outcome of your child's pregnancy and we will continue to follow your child according to the study plan.

UNFORESEEABLE RISKS

In addition to the risks listed above, your child may experience a previously unknown risk or side effect.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, you can contact <<PI Name>> at <<phone number>>. If you think your child may have been injured from being in this study, please call <<contact information>>.

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 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.

RESEARCH-RELATED INJURY

If your child is injured from being in this study, medical care is available at Primary Children's Hospital, as it is to all sick or injured people. The University of Utah Primary Children's Hospital has not set aside any money to pay the costs for such care. Primary Children's Hospital will work with you to address costs from injuries. Costs 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 your child receives. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

If you are injured as a direct result of the study drug or a properly performed procedure required by the study plan, the study sponsor will pay the reasonable costs of medical treatment. The study sponsor will not provide any other form of compensation. You are not being asked to release or waive any of your legal rights against the institution, the investigator or the sponsor for liability for negligence.

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 Governmental Immunity Act of Utah 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 sections 63G -7-101 to -904 of the Utah Code.

VOLUNTARY PARTICIPATION

If you decide to allow your child to take part, you are still free to withdraw your child at any time and without giving a reason. Refusal to allow your child to participate or the decision to withdraw your child from this study will involve no penalty or loss of benefits to which your child is otherwise entitled. If your child doesn't take part, your child can still receive all standard care that is available to your child. This will not affect the relationship you or your child has with your child's doctor or other staff, nor decrease the standard of care that your child receives as a patient.

If you decide to stop your child from being in this study, please let the research doctor know. That way you can find out what should be done about your child's routine care outside of the study.

RIGHT OF INVESTIGATOR TO WITHDRAW PARTICIPANTS

Your child's study doctor or the sponsor can stop your child from taking part in this study at any time if he or she believes it is in your child's best interest to stop or if the study is stopped early. Some other reasons this could happen include:

- Your child needs treatment not allowed in this study
- Your child does not follow instructions given by the study team

The study doctor will tell you and your child if this happens, and will help your child leave the study safely.

COSTS

You will not be charged, nor will your insurance company be charged, for any test or visit that is completed solely for the purpose of this study. All trial medication and trial-related tests will be provided at no cost to you.

The part of your child's care that would normally be done as standard treatment (done whether your child is in the study or not) will be billed to you or your insurance company.

COMPENSATION

You will receive \$50 for each completed visit (Screening through TOC visit). In addition, you will receive \$25 for completing the Long Term Follow Up visit when performed in-clinic.

Taxation: Payment received as compensation for participation in research is considered taxable income to the research subject. If payment exceeds \$600 in any one calendar year, the University of Utah will file a 1099 (Miscellaneous Income) form with the Internal Revenue Service (IRS). The University of Utah will need your name, address, and social security number.

NEW INFORMATION

Sometimes during the course of a research project, new information becomes available about the study drug that is being studied. If this happens, your child's research doctor will tell you about it and discuss with you whether you want your child to continue in the study. If you decide to withdraw your child at that time, the research doctor will make arrangements for your child's medical care to continue. If you decide to allow your child to continue in the study, you will be asked to sign an updated consent form. Also, on receiving new information the research doctor might consider it to be in your child's best interests to withdraw your child from the study. He/she will explain the reasons and arrange for your child's medical care to continue.

During the study, we may learn something about your health that could help you and your doctors make decisions about your healthcare. If this happens, we will tell you about these results. We will contact you and make arrangements to discuss this with you.

NUMBER OF PARTICIPANTS

We expect to enroll about 120 patients will be in the entire study. We also expect to enroll about 3 participants at University of Utah/Primary Children's Hospital.

AUTHORIZATION FOR USE OF 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 some information about your child's health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like: name, address, date of birth and telephone number
- Social Security Number: You can choose not to provide your or your child's Social Security Number but we may not be able to reimburse you or your child as described above
- Related medical information about your child like family medical history, allergies, current and past medications or therapies, and information from physical examinations, such as blood pressure reading, heart rate, temperature, and lab results
- All tests and procedures that will be done in the study

How we will protect and share your child's information:

- We will do everything we can to keep your child's information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.
- The information collected about your child for this study will not be used for future research studies.
- A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify your child. At most, the website will include a summary of the results. You can search this website at any time.
- <<Data collection center>> has administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of your personal information. Your personal information will be used and disclosed only to support the described activities, including to service providers who assist us in managing, administering or delivering the Services. Your or your child's personal information will not be shared, sold, used or distributed for any other purpose. Your or your child's information will be retained for as long as necessary to provide the described activities and for compliance with applicable laws.
 - You or your child can exercise the right to access, correct, modify, or delete your or your child's information at any time by contacting the study staff. If consent is withdrawn, the study staff will not further transfer your or your child's personal information to <<data collection center>>, however, this may not effect processing that occurred

before consent was withdrawn.

- **In** order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
 - Members of the research team and University of Utah Health, Primary Children's Hospital;
 - The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your child's rights;
 - The study sponsor <<sponsor name>> and its representatives
 - Contractors or consultants working for the sponsor
- **If** we share your child's identifying information with groups outside of Primary Children's Hospital, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.
- **Your** child may be tested for HIV or Hepatitis if lab test results that check the liver come back abnormal. You/your child will have appropriate counseling regarding this testing if the results are positive for either HIV or hepatitis. The results of your child's HIV and hepatitis test and other tests will be confidential, but will appear in your child's University of Utah and Primary Children's Hospitals medical records.

Utah State law requires it reportable to the Utah Department of Health (UDOH). In this instance the Study Doctor will offer you and your child the information relevant to your child's health and advise you and your child on the next steps regarding your child's medical care and appropriate counseling. Confidentiality of your child's data will be respected at all times.

- **If** you do not want us to use information about your child's health, you should not agree to allow your child to be part of this research. If you choose not to allow your child to participate, your child can still receive health care services at Primary Children's Hospital.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want your child to be in this study and do not want us to use your child's health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about your child, and your child 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. You have a right to information used to make decisions about your child's health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

CONSENT:

I confirm that I have read this parental permission document and have had the opportunity to ask questions. I understand that taking part in this study is voluntary. I will be given a signed copy of the parental permission 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 my child for this study, as you have explained in this document.**

Child's Name



Parent/Guardian's Name

Parent/Guardian's Signature

Date

Relationship to Child for Parent/Guardian

Name of Person Obtaining Authorization and Consent

Signature of Person Obtaining Authorization and Consent

Date