Consent and Authorization Document

**Note to the Investigator:** Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research participant. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the participant population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study’s purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in “lay language”, (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the participants’ future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.

**DIRECTIONS FOR USE OF THIS TEMPLATE:**
- Do not adjust the bottom margin or use the footer. Do not delete the watermark fields in the footer.
- Replace bracketed items in the header, such as “[Title of Study]” with the requested information.
- Read guidelines for each section, complete as applicable for your project and then delete the template guidelines.
- Example text may be used if needed but should not be italicized. Instructions in red font should be replaced or deleted.
- Phrases such as “I understand...” or “You understand...” are not appropriate and should not be included in the document.
- The document should be written at an appropriate grade level for the group of participants. Most word processors include the ability to assess the reading level.

**BACKGROUND**

Explain that the study involves research and explain the purpose of the research. Briefly tell the participant why this research is being done, why the individual is being invited to participate and how this study will address the problem. Briefly explain who is conducting the study and who is sponsoring the study. If applicable, describe why current therapies are not satisfactory and why an alternative treatment or approach will be used. If applicable, state that the drug or device used in the study is or is not investigational and whether or not it has been approved by the FDA. Other suggested elements appear in the first example.

Example: 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 and discuss it with friends and relatives if you wish. Ask the research doctor or staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study. Example: The purpose of the study is <<explain purpose of the research using simple, accurate language>>. This study is being conducted by <<insert sponsor, granting agency, investigator, etc.>>.
For studies involving **Phase I, II, or III** the following sample explanations may be included.  
*Example: Phase 1 studies are early human studies done after the animal models have given basic data. They are done on a small number of people to find out about safe dose ranges.*  
*Example: Phase 2 studies are 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.*  
*Example: Phase 3 studies test a new drug longer and on more people. They are done to learn details about the use of the new drug in many people during their usual activities of daily living.*

**STUDY PROCEDURES**  
This section should tell the participant about what they will have to do, undergo or experience in the study. Describe all procedures in lay language using simple terms and short sentences. Include a description of the study procedures involved and identify which treatments or procedures that are experimental. (Standard therapy should be included if it is part of the study protocol.) Provide a timeline description (e.g. week 1, week 2, 4 weeks later, etc.) of the procedures that will be performed, the drugs that will be administered, all hospitalizations, and all outpatient visits, etc. Include the total length of time that the participants will be involved both in the active study and for follow-up.

If applicable, include information regarding pregnancy testing for women of childbearing potential and indicate the frequency of pregnancy testing.

The following are suggested lay definitions which may be included if applicable:  
**Randomized Trial:** 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. This means that a computer will decide by chance which group a person is in, not the doctors running the trial.

Patients should be told what chance they have of getting the study drug/treatment e.g. a one in four chance, a 50:50 chance, etc.

**Single Blind Trial:** In a blind trial you will not know which treatment group you are in.

**Double Blind Trial:** In this trial, neither you nor your doctor will know which treatment group you are in (although, if your doctor needs to find out for important medical reasons, he/she can do so).

For studies involving **placebo or withheld treatment**, the following must be addressed:  
- The reason for the placebo or withheld treatment must be explained.  
- "Placebo" should be defined in lay terms.  
- Any withheld treatment must be detailed.  
- Any related procedures should be detailed in this section. If applicable, include any plan for rescue therapy, special monitoring, or crossover to placebo.
Example definition of placebo: A placebo is a dummy treatment such as a pill which looks like the pill that contains the study drug but is not. 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.

RISKS
Include a description of any reasonably foreseeable risks, discomforts or side-effects the participant may experience for each procedure and drug (including the possibility that an experimental treatment may be ineffective). List all side effects which are life-altering or potentially life-altering, no matter how rare. Minor risks such as the possible breach of confidentiality should be listed.

For studies involving placebo or withheld treatment, potential risks must be adequately explained, including any risks of non-treatment.

REPRODUCTIVE RISKS
For studies involving possible reproductive risks, please include a section that includes the following:
1. State any known risks in pregnancy, either to mother or child.
2. State that there may be unforeseeable risks to the participant (or to the embryo or fetus) if the participant is pregnant or becomes pregnant during the study.
3. List the acceptable methods of birth control for this research project.
4. Describe what action will occur in the event of pregnancy (i.e. follow-up of pregnancy outcome, immediate withdrawal from the study, etc.)

Example: 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 you could become pregnant must use an effective contraceptive during the course of this study. Acceptable methods of birth control include <<list acceptable methods>>. If you become pregnant while taking part in the study, you must immediately tell your research doctor. Options will be discussed with you at that time. Whether or not you remain on study treatment, we will follow the outcome of your pregnancy and we will continue to follow you according to the study plan.

BENEFITS
This section should describe any potential benefits to the participant or to others which may reasonably be expected from the research. DO NOT include any compensation to be offered to participants. The description of benefits to the participant should be clear and not overstated to avoid coercion. If no direct benefit is anticipated, it should be stated. If research results will be given to the participant, it should be stated.

Example: We cannot promise any benefits to you from your being in the study. However, possible benefits may include <<list benefits>>.
Example: There are no direct benefits to you from your taking part in this study. The information we get from this study may help us treat future patients.
Example: We hope that this study will help you, however, this cannot be guaranteed.

ALTERNATIVE PROCEDURES
Describe any alternative procedures or courses of treatment that might be advantageous to the participant. To enable a rational choice about participating in the research study, individuals should be aware of the full range of options available to them including palliative or comfort care (if applicable). If standard therapy is part of the study protocol, the participant must be told he/she can receive it outside of the study.

Example: You may choose not to participate in this study. If you do not want to take part in the study, there are other choices such as <<list alternatives>>. You may discuss these options with your doctor.

CONFIDENTIALITY
Describe the procedures used to maintain the confidentiality of the records and data pertaining to the participant, how the participant’s privacy will be protected and who may inspect the records. If you are collecting social security numbers, inform participants of this fact. Tell participants whether they can withhold their social security number and still participate. If the research is subject to FDA regulation, a statement must be included that notes the possibility that the FDA may inspect the records.

Example: Results of this study may be published, but your identity will not appear in any such publication.
Example: We will keep all research records that identify you private to the extent allowed by law. Records about you will be kept <<indicate how records are kept, e.g. locked in filing cabinets, on computers protected with passwords or encryption, etc.>>. Only those who work with this study or are performing their job duties for <<the University, the VA, Primary Children’s Medical Center, etc.>> will be allowed access to your information.
Example: Representatives from <<insert name of group(s) e.g. FDA, NIH, DHHS, sponsor, etc.>> may inspect and/or copy the records that identify you. Results of the study may be published; however, your name and other identifying information will be kept private. We will do everything we can to keep your records private, but cannot guarantee this.

If this research represents a clinical trial that must be registered on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), you must include the following statement verbatim:
A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If applicable, please provide a description of the Certificate of Confidentiality and any voluntary disclosure plans by the investigator(s). For more information regarding Certificates of Confidentiality, please refer to the IRB website.
If HIV testing is performed as a result of study participation, state that additional consent will be required for the University of Utah Hospitals and Clinics or PCMC (as applicable) which describes how results will be given to the participant and the methods or opportunities participants will be given for appropriate counseling and medical care.

If testing is performed as a result of study participation for any communicable or infectious diseases reportable by Utah State law, the following must be addressed in this section (refer to [http://health.utah.gov/epi/report.html](http://health.utah.gov/epi/report.html) for a current list of Utah’s reportable diseases):

- Tell the participant about the state reporting.
- Describe how results will be given to the participant to comply with state reporting requirements.
- Describe the methods or opportunities participants will be given for appropriate counseling and medical care.

**PERSON TO CONTACT**

Explain whom participants should contact with any questions, complaints, and concerns about the research or related matters. If the study involves serious risks, a number with 24-hour availability must be provided. If the number is a pager or the hospital operator include further instructions for contacting the appropriate individual.

Include specific information about who the participant should contact in case of a research-related injury. This should include name(s), telephone number(s), and when the person(s) listed may be contacted. If applicable, provide information about who to contact if the participant has questions about the billing of costs in the study.

*Example: If you have questions, complaints or concerns about this study, you can contact <<insert name>> at <<insert phone number>>. If you think you may have been injured from being in this study, please call <<insert name>> at <<insert phone number>>. <<Insert name>> can be reached at this number during <<specify hours or state it is a number available 24-hours a day>>.*

Include the following statement verbatim: **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.

Include the following statement verbatim: **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**
Include the Research-Related Injury section as outlined:

If you are injured from being in this study, medical care is available to you at the University of Utah and Primary Children's Medical Center, as it is to all sick or injured people. The University of Utah and Primary Children's Medical Center has not set aside any money to pay the costs for such care. The University and Primary Children’s Medical Center 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 you receive. 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 have a sponsor or other party who is assuming responsibility for research-related injury, please include the language here. If you have questions, please contact the IRB office for guidance.

Insert the following language verbatim: The University of Utah is a part of the government. If you are injured in this study, and 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.

If your study takes place at Shriners, please add the following additional language: Also, in the event of injury or undesirable reaction from participation in research-related activities, Shriners Hospitals for Children can only provide those medical services available at the Shriners Salt Lake City Hospital. Shriners Hospitals for Children has no program to provide any financial compensation for a research-related injury or an undesirable reaction. If you believe that you have sustained an injury as a result of participating in this research program, please also contact the investigators and/or Chief of Staff, Shriners Hospitals for Children, Salt Lake City Hospital, at (801) 536-3600. By signing this document you are not giving up your right to pursue legal action against any and all parties involved with this research.

VOLUNTARY PARTICIPATION
State that participation is voluntary. Indicate that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. Also indicate that the participant may discontinue participation at any time without any penalty or loss to benefits. If applicable, state that the participant may withdraw and still receive the same standard of care that he or she would otherwise have received.

Example: It is up to you to decide whether or not to take part in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. Refusal to participate or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled. If you don’t take part, you can still receive all standard care that is available to you. This will not affect the relationship you have with your doctor or other staff, nor decrease the standard of care that you receive as a patient.
Explain any possible consequences of a participant’s decision to withdraw from the research. Describe any adverse effects on the participant’s health or welfare, or any extra follow-up that may be requested, if the participant decides to withdraw from the study. Explain the procedures for an orderly termination of participation. Such an explanation may be omitted if there are no adverse consequences to withdrawal.

Example: If you want to stop being in this study, please let the research doctor know. That way you can find out what should be done about your routine care outside of the study.

UNFORESEEABLE RISKS
State that participation in the study may involve risks that are currently unforeseeable.

Example: In addition to the risks listed above, you may experience a previously unknown risk or side effect.

RIGHT OF INVESTIGATOR TO WITHDRAW
Describe foreseeable circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent. This section may be omitted if there are no anticipated circumstances under which the subject’s participation may be terminated. If withdrawal of a participant by the investigator can occur, possible reasons should be listed. Describe any procedures required for an orderly termination of participation.

Example: The investigator can withdraw you without your approval. Possible reasons for withdrawal include <<list reason(s) why the participant may be withdrawn>>.

Include a description of any adverse effects on the participant’s health or welfare, or follow-up that may be requested if the participant is withdrawn from the study.

COSTS AND COMPENSATION TO PARTICIPANTS
Costs related to standard of care and costs related to research procedures should be separated and explained. Any additional costs to the participant that may result from the research should also be clearly indicated. If applicable, state that the participant may want to check whether their health insurance will cover research-related costs. When costs may be billed to the participant, the insurance company, or both, statements such as “will be billed to you or your insurer in the ordinary manner” are preferred.

Example: All costs associated with this study will be billed to you or your insurance company in the ordinary manner. Your insurance company may not pay for the costs associated with research. Therefore, these costs <<state who will be responsible e.g. “will be your responsibility” or “will be paid by the sponsor” or “the sponsor has agreed to pay $XX”, etc.>>. Example: 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.
Example: The parts of your care that would normally be done as standard treatment such as
<<list procedures or refer to the procedures identified as standard of care in the “Procedures”
section>> will be billed to you or your insurance company.

Explain whether participants will be compensated. If not, please state. Specify the overall amount,
schedule of payment(s) and any plan for prorating payments if a participant does not complete the
study.

NEW INFORMATION
State that new findings developed during the course of the research that may affect the participant’s
willingness to continue participation will be provided to the subject. This section may be omitted if new
information could not reasonably used to alter participation (e.g. one-time interventions).

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

NUMBER OF PARTICIPANTS
State the approximate number of participants to be enrolled. Indicate whether this study is part of a
national study.

Example: We expect to enroll <<enter number>> participants at the <<University of Utah, PCMC
or Shriner’s Hospital>>.
Example: We also expect to enroll <<enter number>> participants at <<enter number>> other
medical centers.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION
Include the Authorization section as outlined:

Signing this document means you allow us, the researchers in this study, and others working with us to
use information about your health for this research study. You can choose whether or not you 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: Modify the following list as appropriate – delete or add items as
necessary.
- <<Name>>
- <<Address>>
- <<Telephone number>>
- <<Family medical history>>
- <<Allergies>>
- <<Current and past medications or therapies>>
- <<Information from a physical examination, such as blood pressure reading, heart rate, breathing rate, and temperature>>
- <<All other tests and procedures that will be performed in the study>>
- <<Any other personal health information that will be obtained from other sources to be used in the research record, including prior medical history, tests or records from other sites>>

Others who will have access to your information for this research project are the University’s Institutional Review Board (the committee that oversees research studying people) and authorized members of the <<insert appropriate institution(s) e.g. University of Utah Health Sciences Center, Primary Children’s Medical Center, Shriners Hospital>> 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).

Use one of the following 2 disclosure options, as applicable:

Disclosure Option 1: If you might disclose PHI to anyone outside the University, Primary Children’s Medical Center and/or Shriners use the following language:

In conducting this study, we may share your information with groups outside the <<insert appropriate institution(s) e.g. University of Utah Health Sciences Center, Primary Children’s Medical Center, Shriners Hospital>>. The information we share may include information that directly identifies you. These are the groups:

Modify this list as appropriate - delete or add items as necessary. For EACH LISTING, include a brief description of WHY they will receive the information. The examples below are suggestions and may be used as applicable.

- Other local hospital(s) that we are working with: <<list VA Salt Lake City Health Care System or any other local hospitals where information could be shared>> who are working with the investigators in studying the impact of this treatment;
- Other academic research centers we are working with: <<list all other academic centers including those at the University that may not be within UUHSC, and explain their roles in project>> who are working with the investigators in studying the economic impact of this treatment;
- <<Name of group or company>>, a research data coordinating office that is responsible for collecting results and findings from all the researchers;
- <<Name of group or company>>, a pharmaceutical company that will use the results for submissions to the Food and Drug Administration;
- <<Name of agency>>, a federal agency that needs to confirm the accuracy of the results submitted to the government;
- <<Name of group or company>>, a contract research organization, whose job is to review and correct any mistakes before the results are given to the sponsor or government;
- <<name any other groups and why they will receive the results>>

Information disclosed to groups outside the << insert appropriate institution(s) e.g. University of Utah Health Sciences Center, Primary Children’s Medical Center, Shriners Hospital >> may no longer be covered by the federal privacy protections.

**Disclosure Option 2:** If you not going to disclose PHI to anyone outside the University of Utah Health Sciences Center, Primary Children’s Medical Center and/or Shriners Hospital, describe how you will protect and share de-identified information. The next 2 paragraphs are sample statements. Include one of the following or a similar statement, as applicable.

*Example: If we share your information with anyone outside the << insert appropriate institution(s) e.g. University of Utah Health Sciences Center, Primary Children’s Medical Center, Shriners Hospital >> you will not be identified by name, social security number, address, telephone number, or any other information that would directly identify you, unless required by law.*

*Example: In records and information disclosed outside of the << insert appropriate institution(s) e.g. University of Utah Health Sciences Center, Primary Children’s Medical Center, Shriners Hospital >> your information will be assigned a unique code number. We will keep the key to the code <<state how code is kept e.g. “in a locked file”, “in a password protected computer,” etc.>>. We will destroy the key to the code at the end of the research study.*

**Include the following verbatim:**

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 <<insert name and mailing address of PI>>. 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.

**Include the following paragraph if participants will not have access to their information during the study:**

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.
Include one of the following 2 sentences:
This authorization does not have an expiration date.
This authorization lasts until this study is finished.

CONSENT
Please include a consent and authorization statement written in first person such as the following:

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

________________________
Participant’s Name

________________________
Participant’s Signature        Date

________________________
Name of Person Obtaining Authorization and Consent

________________________
Signature of Person Obtaining Authorization and Consent        Date

A witness signature block may be inserted here if required by the sponsor or it appropriate for the participant population. Sample witness signature statements are included below. Delete this section if you do not plan to use a witness to the consent process/signature.

SAMPLE #1:

WITNESS STATEMENT:
The participant was unable to read or sign this consent form because of the following reason:
☐ The participant is illiterate
☐ The participant is visually impaired
☐ The participant is physically unable to sign the consent form. Please describe:

________________________________________________________________________
________________________________________________________________________
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

**SAMPLE #2:**

**WITNESS STATEMENT: (For Non-English Speaking Participants Only)**

Consent was obtained from the participant using a short form for non-English speakers. The short form is available in the participant’s language and this (long) consent form was read to the participant using an interpreter.

As a witness, I confirm that I was present for the complete consent process for this study. I confirm that the participant named above was read the information in this consent document in a language he/she understands and that the participant has agreed to take part in the research study.

____________________________________
Name of Witness

____________________________________  ____________
Signature of Witness  Date

**IMPORTANT:** This signature block for Legally Authorized Representatives (LAR) is only used for populations unable to provide informed consent. Only use the LAR signature block if it has been explained in the new study application (subject to approval by the IRB). Delete this if you do not plan to enroll participants using an LAR.
If the participant is unable to give consent and authorization, consent and authorization is given by the authorized personal representative of the individual:

LEGALLY AUTHORIZED REPRESENTATIVE CONSENT STATEMENT:
I have had the opportunity to ask questions and those questions have been answered to my satisfaction. I am willing and authorized to serve as a surrogate decision maker for

______________________________________.
Participant’s Name

I have been informed of my role and my obligation to protect the rights and welfare of the participant. I understand that my obligation as a surrogate decision maker is to try to determine what the participant would decide if the participant were able to make such decisions or, if the participant’s wishes cannot be determined, what is in the participant’s best interests. I will be given a signed copy of the consent and authorization form to keep.

______________________________________
Name of Authorized Personal Representative

______________________________________
Signature of Authorized Personal Representative

Indicate the legal representative’s authority to act for the individual:

☐ Spouse
☐ Adult (18 years of age or over) for his or her parent
☐ Individual with power of attorney
☐ Guardian appointed to make medical decisions for individuals who are incapacitated