Pregnancy Follow-Up Consent and

Release of Information Authorization

***Note to the Investigator:***  *If data is being requested for research purposes from the pregnant partner of a research participant, informed consent is required from the pregnant partner in addition to the research participant. No data may be collected unless signed consent and authorization has been obtained using an IRB approved consent document.*

***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.*
* *Sample text has been provided only to assist the researcher in creating a simple consent form for a pregnant partner. Investigators are not required to use the exact language unless otherwise noted.*
* *Phrases such as “I understand…” or “You understand…” are not appropriate and should not be included in the document.*

**INTRODUCTION**

State that the purpose of the consent and authorization is to allow the investigator and/or sponsor to follow and gather data regarding the pregnancy and the birth of the child in order to better understand the risks associated with the drug/treatment. Please explain who is conducting the research study.

***Example****: You are being asked to participate in this follow-up only research study because the biological father of your child was participating in a study when you became pregnant. The name of the study is <<insert name of study>>. We know that <<insert study drug or treatment>> has been known to <<insert any known risks>>. It is possible that your child may be affected. There may be other risks that are unforeseeable. For this reason, we would like to collect medical information about your pregnancy and the birth and health of your child. We want to follow your pregnancy to try and find out if the <<insert name of drug or treatment>> has any effect on your pregnancy and the health of your child.*

*Please read this consent carefully and take your time to decide if you want to participate in this follow-up study.*

**STUDY PROCEDURE**

This section should inform the pregnant partner about what they will have to do and what they will experience in the study. Include the length of time that the pregnant partner will be followed. Use simple terms and short sentences. Describe any procedures in detail.

***Example****: We will review your and your child’s medical records relating to pregnancy, the delivery of your child and the health of your child up to <<insert length of time as stated in the research protocol>>.*

**RISKS**

Describe any reasonably foreseeable risks.

***Example****: There is a risk of the loss of confidentiality of your or your child’s medical record information.*

**BENEFITS**

Describe any benefits to the participant or to others that may reasonably be expected from the research. DO NOT include any compensation to be offered to participants in this section. 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.

***Example****: There are no direct benefits to you or your child for taking part in this study. However, we hope that the information we gather about your pregnancy will help future patients and their partners by helping us understand the potential risks of <<insert name of drug/treatment>>.*

**CONFIDENTIALITY**

Describe the extent, if any, to which confidentiality of records identifying the participant will be maintained. This should include information about storage of the records and data pertaining to the participant and how privacy will be protected. Please note who may have access to the data. Inform participants if you collect social security numbers. Tell participants whether they can withhold their social security number and still participate. If your research is subject to FDA regulations, please include a statement that the FDA may inspect research records at any time.

***Example****: We will keep all research records that identify you or your child private to the extent allowed by law. Records about you and your child 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.*

**Person to Contact**

Please include contact information for answers to any questions, complaints or concerns the participant may have about the research or related matters. Include the name of the Principal Investigator with a telephone number where a message can be left. Co-investigator contact information may be included. Include specific information as to whom 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 you believe that there is no chance for a research related injury, you may provide contact information in the event the participant feels they have been harmed by the research (see example).

***Example****: If you have questions, complaints or concerns about this study, you can contact <<insert name>> at <<insert phone number>>. If you feel you have been harmed as a result of participation, please call <<insert name>> at <<insert phone number>> who may be reached 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.

**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.

***Example****: It is up to you to decide whether to take part in this study. Refusal to participate or the decision to withdraw from this research will involve no penalty or loss of benefits to which you are otherwise entitled. This will not affect your relationship with the investigator.*

**COSTS AND COMPENSATION TO PARTICIPANTS**

Costs related to research procedures should be separated and explained from other regular costs participants might incur. Any additional costs to the participant that may result from the research should also be clearly indicated. If there are no costs and/or compensation, please state that.

***Example****: Being in this research study will not cost you any money.*

*This study will not cover any costs related to your pregnancy, delivery or care of your child. You and/or your medical/hospital insurance carrier will still be billed for your regular medical care expenses.*

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

**AUTHORIZATION FOR USE OF YOU and YOUR CHILD’SPROTECTED HEALTH INFORMATION**

If your study involves protected health information (from the University of Utah Health covered entity), include the Authorization section as described:

Signing this document means you allow us, the researchers in this study, and others working with us to use information about your health and the health of your child for this research study. You can choose whether or not you and your child 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>>*
* *<<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>>*
* *<<Outcome of the pregnancy and any adverse events related to the birth of the child>>*
* *<<Child’s vital measurements (e.g. height, weight, Apgar scores, etc.)>>*

Others who will have access to your information and 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 *<< insert appropriate institution(s) e.g. University of Utah Health, Primary Children’s Hospital, 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 Hospital and/or Shriners use the following language:

In conducting this study, we may share your information and your child’s information with groups outside the *<< insert appropriate institution(s) e.g., University of Utah Health, Primary Children’s Hospital, Shriners Hospital >>*. The information we share may include information that directly identifies you and your child. 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 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, Primary Children’s Hospital, Shriners Hospital >>* **oHo**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, Primary Children’s Hospital 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 and your child’s information with anyone outside the <<insert appropriate institution(s) e.g., University of Utah Health, Primary Children’s Hospital, Shriners Hospital>> you and your child will not be identified by name, social security number, address, telephone number, or any other information that would directly identify you or your child, unless required by law.*

***Example****: In records and information disclosed outside of the <<insert appropriate institution(s) e.g., University of Utah Health, Primary Children’s Hospital, Shriners Hospital >> your information and your child’s 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 can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, 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 and the health care of your child. However, your information and your child’s 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 participate in this research study and give permission for my child to be in this study. I authorize you to use and disclose health information about me and my child 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