Consent and Authorization Document

**NOTE TO LEAD SITE:** The information in this part of the document should be the same for all sites. Please recommend to your sites that they do not revise this language. If they need to make revisions to this language to accommodate a local law or policy, they should contact the UU IRB for assistance.

**SUMMARY OF KEY INFORMATION**

Begin with a concise and focused presentation of key information.

1. The fact that consent is being sought for research, and participation is voluntary.
2. Purpose of the research, expected duration, and procedures.
3. Reasonably foreseeable risks.
4. Benefits that may be reasonably expected.
5. Appropriate alternative procedures or courses of treatment, if any.

**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.
* How long will the participant be in the study? Include the total length of time that the participants will be involved both in the active study and for follow-up.
* State the approximate number of participants to be enrolled. Indicate whether this study is part of a national study.
* Is there a description of the procedures to be followed including the identification of any procedures that are experimental?
* Briefly explain who is conducting the study and who is sponsoring the study.
* 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.

**STUDY PROCEDURES**

* Describe of the procedures to be followed including the identification of any procedures that are experimental.
* Describe all procedures in lay language using simple terms and short sentences.
* Describe any alternative procedures or courses of treatment that might be advantageous to the participant.

**RISKS**

* Describe 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.
* For studies involving possible reproductive risks, address the requirements outlined in the IRB’s guidance on the topic.
* State that participation in the study may involve risks that are currently unforeseeable.
* Risks to privacy and confidentiality should always be listed.

**BENEFITS**

* This section should describe any potential benefits to the participant or to others which may reasonably be expected from the research.

**VOLUNTARY PARTICIPATION**

* State that participation is voluntary.
* State that individuals may refuse to participate or discontinue participation without penalty or loss of benefits?
* If withdrawal of a participant by the investigator can occur, possible reasons should be listed.
* State that new findings developed during the course of the research that may affect to the participant’s willingness to continue participation will be provided to the subject.

**CONFIDENTIALITY**

* Describe what will happen to any data, identifiable private information, or identifiable biospecimens collected for this research.
* There are additional requirements for studies that collect, use, or plan to save biospecimens for research or future research, or conduct genetic testing. Please contact the IRB for more information.

**NOTE TO LEAD SITE:** The information in this part of the document should customized for each site. Instruct your site to work with their local IRB/HRPP to ensure their applicable local language is included for the following sections. If the site does not have specific language or preferred language for any of these sections, you may include the UU’s preferred language or omit the section as appropriate. If the site investigators or their IRB/HRPP has any questions about what information should be included here, they can contact the UU IRB for assistance.

**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.
* Add the UU IRB’s contact statement (all sites should include this verbatim):
 **Institutional Review Board:** The University of Utah Institutional Review Board (IRB) has approved this study.Contact the University of Utah 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. You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.
* If the site’s IRB would like their information included, please add it to this section.
* ***EXAMPLE LANGUAGE FOR THIS SECTION****:

If you have questions, complaints or concerns about this study, you can contact <<insert study coordinator name>> at <<insert phone number>>. If you think you may have been injured from being in this study, please call <<insert principal investigator’s 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>>.***Institutional Review Board:** The University of Utah Institutional Review Board (IRB) has approved this study.Contact the University of Utah 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. 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 information about what coverage is available at the site in the case of a research-related injury. Do not include language that could be considered exculpatory.

**COSTS AND COMPENSATION TO PARTICIPANTS**

* State whether there will be any costs to participants, and whether they will be compensated or reimbursed for their participation.
* If participants will be compensated, specify the overall amount and the schedule of payment(s), and any plan for prorating payments if a participant does not complete the study.
* Costs related to standard of care and costs related to research procedures should be separated and explained. 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.

**AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION**

* Include HIPAA Authorization language.
* Recommended language is available at: <https://irb.utah.edu/informed-consent/authorization-language.php>. Sites may use their own preferred language, or use the University of Utah’s language instead.

**CONSENT**

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

**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