**Consent for Participation in a Research Study**

Text in green contains instructions for each part of this consent form template. Make sure to delete all green text, and where applicable, replace it with the relevant information. Make sure that the consent form is written at about an eight-grade reading level and is as clear and concise as possible.

**Study Title:** Provide a title for your study. This should match on all study documents.

**Principal Investigator:** Give the name, degree (if any), and affiliation of the primary investigator.

**Faculty Sponsor:** Give the name, degree, and affiliation of the faculty sponsor. **If not applicable, delete this line.**

|  |
| --- |
| **KEY INFORMATION: This box should contain key information about the study presented in a concise and organized way. More detailed information is provided later on.*** The fact that consent is being sought for research and that participation is voluntary;
* The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;
* The reasonably foreseeable risks or discomforts to the prospective subject;
* The benefits to the prospective subject or to others that may reasonably be expected from the research; and
* Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.
 |

**STUDY INFORMATION:**

**What is the purpose of this study?** Briefly and concisely explain why the study is being conducted (i.e., the scientific justification). Avoid using jargon or overly technical language

**Who is participating?** Briefly describe how participants are being selected (e.g., approximate number of people, inclusion/exclusion criteria, etc.).

**What will happen or what are you expected to do in this study?** Describe in clear and simple terms, what will happen to subjects during the study (usually chronologically). List all procedures and treatments in this section and clearly distinguish experimental procedures from routine care. **Include a statement about the expected duration of the study/when participation will be over.**

• Eligibility Testing.

• Experimental intervention/interaction

• Randomization or blinding procedures

• Data collection methods/measures

• Use of medical records information

• Photography or video/audio recording (may need additional consent for release)

•Other research procedures or activities

**What are the risks if you participate?** List any foreseeable risks or discomfort that the participants may experience as a result of participation. Also explain how you will work to minimize risks and discomfort. Or state that you do not foresee any risks as a result of participation.

**How might you benefit if you participate?** Describe any benefits that the participant or others can reasonably expect from participation in the research.

**How will we compensate you for being part of the study?** Describe the nature, amount, and timetable for compensation**. Delete this section if not applicable to the study.**

**How will we protect your information?** Explain how the information will be used, how information will be protected, and who may see or have access to the information. Also describe any limits to confidentiality.

**What will happen to your information after the study is over?** Participants must be told what will happen to their information according to one of the two following scenarios:

1. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
2. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

**What alternatives do you have if you do not want to take part in this study?** Describe alternatives to participation in the research study, for example, interventions or treatments available outside the research context. **Delete this section if not applicable to the study.**

**Your participation is voluntary:** Include statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

**If you have questions or experience an injury as a result of participation in this study:** Provide a statement as to what to do when there are questions or injuries, andprovide contact information for the study’s investigator and/or faculty sponsor, as well as for the chair of the IRB.

**Use only one of the following.**

**PARTICIPANT CONSENT:**

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree to take part in this study.*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Subject Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

**OR when there is a waiver of documentation, use the following statement and remove signature lines:**

Before agreeing to be part of the research, please be sure that you understand what the study is about. We will give you a copy of this document for your records [or you can print a copy of the document for your records for electronic forms]. If you have any questions about the study later, you can contact the study team using the information provided above.

**OR for research with minors:**

**Parent or Legally Authorized Representative Permission:**

By signing this document, you are agreeing to [your child’s **OR** the person’s named below] participation in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree for [my child* ***OR*** *the person named below] to take part in this study.*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Subject Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Parent/Legally Authorized Representative Name and Relationship to Subject

**Additional information that should be provided and should be added in as appropriate.**

* If the study is more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
* A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.
* Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent.
* Any additional costs to the subject that may result from participation in the research;
* The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
* A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.
* A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
* A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
* For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).