**Instructions**

*This consent form can be used for Participating Sites (pSites) overseen by the University of Arizona IRB. This consent form is only for research that does not collect any biospecimens or will access HIPAA protected information. Delete the* ***RED*** *text prior to submitting this form to the IRB. Required language* *is in* *regular text. Additional language, as appropriate, are in comments.*

**Name of pSite**

**Consent and/or Parental Permission to Participate in Research**

|  |
| --- |
| **Study Title:** |
| **[Name of pSite] Principal Investigator:** |
| **Sponsor:**  |

Conflict of Interest Statement (If applicable per COI management plan, delete if no COI management plan exists for researchers at this pSite)

**Summary of the research**

**This is a consent form for participation in a research project.** Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether to participate.

If your consent is more than 4 pages, provide a brief explanation of the project, that is concise and focused, and that will most likely assist a prospective subject to understand the research and choose to participate. This presentation of information is to be short and can summarize information explained later in greater detail. It is NOT necessary to repeat information provided in the summary. This summary should include:

* The purpose and expected duration
* Major requirements of the study
* The most important risks and/or benefits
* Other alternatives to participating, if appropriate
* Time commitment

**Why is this study being done?**

Explain this is a research study. Describe the purpose of the research.

**What will happen if I take part in this study?**

Explain the procedures to be followed. Specifically identify any procedures that are for research only.

If educational records will be accessed:

* Specify the records that may be disclosed;
* State the purpose of the disclosure; and
* Identify the party or class of parties to whom the disclosure may be made.

**How long will I be in the study?**

Explain the expected duration of the subject's participation.

**How many people will take part in this study?**

Identify the approximate number of subjects you plan to enroll in the study, both total (study-wide) and local (if different).

# Can I stop being in the study?

Explain 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 applicable, explain what may happen and what procedures are required for orderly withdrawal or termination if the subject leaves the study early, or is withdrawn from the study by the researcher.

**What risks or benefits can I expect from being in the study?**

Explain any reasonably foreseeable risks or discomforts to the subjects as a result of participation from the research. Explain any expected benefits to subjects. If there are alternatives to participating, describe them here.

If applicable, explain that any significant new findings found during the course of the research that may relate to the subject’s willingness to continue will be provided to them.

# Will I be paid for participating in the study or experience any costs?

Explain if a participant will receive any compensation from their participation in the research. Discuss the amount and timing, including a description of any proration, of any compensation (monetary and/or non-monetary).

If applicable, explain if the participant may have any costs as a result of participating in the study. Any additional costs to the subject from participating may include subject's time or transportation.

If applicable, explain the pSite’s local tax reporting policy when subjects receive compensation or reimbursement when participating in research studies.

# Will my study-related information be kept confidential?

# Describe the way you will maintain the confidentiality of records.

# Specify the entity(ies) which would potentially have access to research files.

If applicable, indicate that data collected at this psite will be shared with The University of Arizona and any other collaborating institutions.

# The information that you provide in the study will be handled confidentially. However, there may be circumstances where this information must be released or shared as required by law. The University of Arizona Institutional Review Board; [insert pSite’s name] Institutional Review Board; other federal, state, or international regulatory agencies; or the sponsor of the study, if any, may review the research records for monitoring purposes.

**Will my study-related information be used for future research?**

Use one of the following statements if collecting identifiable data or biospecimens:

Information that may identify you may be used for future research or shared with another researcher for future research studies without additional consent. [Explain]

{OR}

Information that identifies you will only be used for future research or shared with another researcher after obtaining your consent. [Explain]

{OR} Information collected about you will not be used or shared for future research studies.

If your study is funded by the NIH or another agency that requires a Data Management Plan, relevant information from your Data Management Plan will need to be included in this section. This text should mirror the text found in the main study’s consent.

# Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program Director at 520-626-8630 or online at https://research.arizona.edu/compliance/human-subjects-protection-program.

For studies involving greater than minimal risk include: If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*.*** If applicable, include the local pSite’s subject injury language.

# Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

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|  |  |  |  |  |
| **Printed name of subject** |  | **Signature of subject** |  | **Date** |

**If you are enrolling minors or individuals who have a legally authorized representative (LAR), include this section.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Printed name of person authorized to consent for subject (when applicable)** |  | **Signature of person authorized to consent for subject** **(when applicable)** |  | **Date** |

|  |  |
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|  |  |
| **Relationship to the subject** |  |

**If you are enrolling minors, include this section.**

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| **Name of child**  |  |