## Instructions

*This consent form can be used for Participating Sites (pSites) overseen by the University of Arizona IRB. This consent form is for medical research, including collection of biospecimens or research that 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 and/or Funder** (delete if not sponsored):

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 study.** 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.

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 may be a page or more, depending on the study. 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

## [If applicable]: The University receives compensation from the sponsor of this study for the conduct of this study. If you have any questions, please discuss this with your study doctor.

**Why is this study being done?**

Explain the purpose of the study and a statement that the study involves research.

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

Explain the procedures to be done. Specifically identify any procedures that are for research only. Include:

* The probability for random assignment to each treatment
* The subject’s responsibilities

**How long will I be in this 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 at the pSite (if different).

**What benefits can I expect from being in this study?**

Explain any reasonably expected benefits to subject or others.

* When there is no intended clinical benefit to the subject, a statement to this effect
* Do not include statements of unproven claims of effectiveness or certainty of benefit, either implicit or explicit

**What risks, side effects or discomforts can I expect from being in the study?**

Explain any reasonably foreseeable risks or discomforts to the subjects because of participation or procedures from the research. Explain, if applicable, that a particular treatment or procedure may involve risks that are currently unknown or foreseeable.

Explain that if there are significant new findings that may impact a subject’s participation they will be informed.

**What other choices do I have if I do not take part in this 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.

Describe any appropriate alternative procedures or courses of treatment. For some studies, the only alternative would be to not participate.

**When may participation in the study be stopped?**

Under what circumstances the subject's participation may be stopped by the investigator, the consequences of a subject's decision to withdraw from the research, and the procedures for orderly withdrawal of participation by the subject.

What happens if I am injured because I took part in this study?

If applicable, include the local pSite’s subject injury language.

For research involving more than minimal risk, include the following elements:

* An explanation as to whether any compensation is available if injury occurs
* An explanation as to whether any medical treatments are available if injury occurs
* If compensation and/or treatment is available: what comprises that compensation and/or treatment, or where further information may be obtained

The University of Arizona has no funds set aside for the payment of treatment expenses for this study.

**What are the costs of taking part in this study?**

If applicable, include the local pSite’s cost language.

Explain who will pay for the study procedures and/or medications required for participation. If third party payers are expected to pay for standard care treatment, identify what the subject will be responsible for.

Interventional studies:

The (insert investigational items supplied) and services performed for research only will be provided at no charge to you or your insurance company. Routine medical care performed while participating in study will be billed to you and / or your insurance company. This will include (but is not limited to) (insert general care references such as physical exam and lab work if applicable), administration of medications, and the treatment of side effects.

Not all insurance companies are willing to pay for services performed in a clinical trial. You will be responsible for any charges that your insurance does not cover including regular co-payments and deductibles. Please speak with your insurance company to find out what you may be financially liable for.

*Non-Interventional:*

There are no anticipated additional costs for you to be in this study, except for your time.

Regular medical care performed while participating in study will be billed to you and / or your insurance company as usual. Not all insurance companies are willing to pay for services performed in a clinical trial. Please speak with your insurance company to find out what you may be financially liable for.

**Will I be paid for taking part in this study?**

Discuss the amount and timing, including a description of any proration, of any compensation (monetary and/or non-monetary).

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

**Will my data or specimens be stored for future research?**

The consent must include either:

* A statement that identifiers will or will not **[choose one]** be removed from the private information or biospecimens, and that after such removal, the information or biospecimens may be used for future research studies without additional informed consent [Include a description of what information/specimens will be stored and whom they will be shared with (both internal and outside the institution). Explain what research may be conducted with these data/specimens - including unspecified future research, genetics, disease specific, etc.]; or
* A statement that the identifiable information or biospecimen, even if identifiers are removed, will not be used, or distributed for future research.

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.

**Will my specimens be sold for commercial profits?**

Describe whether subjects will or will not share in any commercial profit from the use of their biospecimens, even if identifiers are removed.

**Will I hear back on any results that directly impact me?**

Describe whether any clinically relevant results will be disclosed to subjects, and if so, under what conditions.

**Will Whole Genome Sequencing be done with my specimen?**

Describe, if known, whether whole genome sequencing will be done.

# Will my study-related information be shared, disclosed, and kept confidential?

# Specify the extent, if any, to which confidentiality of identifiable records will be maintained. Specify the entity(ies) which would potentially share or have access to research files and remove those that are not applicable. If applicable, insert the pSite’s local HIPAA Authorization language. A separate standalone HIPAA Authorization from the pSite is acceptable.

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

# Who can answer my questions about this study?

If at any time you feel you have had a research-related injury, or 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.

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, insert who participants can contact at the pSite to cancel their HIPAA Authorization or get a copy of the pSite’s Privacy Notice.

If applicable: A description of this clinical trial will be available on 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.

# 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,and I authorize the use and/or disclosure of my PHI. I am not giving up any legal rights by signing this form. I will be given a signed 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.**

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

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

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| **Name of child**  |  |

**Some studies may require signature of PI or research staff. This is an optional section.**

**Investigator/Research Staff**

I have explained the research to the participant or the participant’s representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form has been given to the participant or to the participant’s representative.

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| **Printed name of person obtaining consent** |  | **Signature of person obtaining consent** |  | **Date** |