### Sample Adult Consent Template – Expedited/Full Board Studies

* Insert study-specific language where indicated
* **If this will be used for parental or guardian consent of a child, change “you” to “your child” where appropriate.**
* **Use lay language, generally at an 8th grade reading level. Avoid jargon and complex terms unless defined. Avoid 1st person.**
* Delete these instructions and all red text prior to submitting to the IRB

University of Missouri–St. Louis

Informed Consent for Participation in Research Activities

**Project Title:**

**Principal Investigator: This should also include the advisor for student projects**

**Department Name:**

**Faculty Advisor: This should be listed for student projects. If not applicable**

**Sponsor/Funder: Insert sponsor name, if funded or remove**

**IRB Project Number:**

**Key Information About the Study**

You are being asked to participate in a research study. The purpose of the research study is (Provide a brief summary of the purpose of the research. More detail can be included later). You are being asked to (describe what they are mainly being asked to do). Possible benefits include (include a brief summary here). Some possible risks may include (include a list of the most important potential risk(s) in this section).

Please read this form carefully and take your time. Let us know if you have any questions before participating. The research team can explain words or information that you do not understand. Research is voluntary and you can choose not to participate. If you do not want to participate or choose to start then stop later, there will be no penalty or loss of benefits. (If there are consequences of a subject’s decision to withdraw from the research, explain here, and include the procedures for orderly termination of participation by the subject. If it’s possible their participation may be terminated by the investigator without regard to their consent, explain here)

**Purpose of the Research**

You are being asked to participate in this study because (describe why they were chosen to participate). The purpose of the study is to (insert purpose of the study here).

(If there any conflicts of interest to disclose include here otherwise remove).

**What will happen during the study?**

You are being be asked to (describe all research activities required of them – include lists, bullets, or other organized ways to present the information. Different visits should be separated with clear expectations. List any procedures which are experimental).

If the study involves photographs/audiotapes/videotapes include the following language – if not, REMOVE: As part of the research study, the researcher will record your [image and/or voice] in a [videotape/audio recording/photograph]. The [recording/photo] may be used in a presentation or publication about this research study. The use of the [recording/photograph] may include news releases, professional conferences, websites and exhibits related to this research study.

Also, the [recording/photograph] may be kept for future research studies or educational purposes. OR if not retaining the video/audio tape: After the researcher has taken notes from the recording, it will be destroyed to protect your identity.

The [recording/photograph] will include [a picture of your face/sound of your voice], but the researcher will not reveal your name or other identifying information.

\_\_\_\_\_ Yes, I can be audio/video recorded

\_\_\_\_\_ No, I don’t want to be audio/video recorded.

Your participation is expected to last (include expected duration).

There will be (include number of subjects) participating in this study.

If the study collects biospecimens (i.e. saliva, urine, blood, tissue) include the following two statements– if not, REMOVE ALL:

Your biospecimens may be used for commercial profit, but you will not share in this commercial profit. (If they receive profit, this will need to be edited)

The research might include whole genome sequencing (i.e. sequencing of a human germline for somatic specimen with the intent to generate the genome or exome sequence of the specimen). (If this will definitely happen, change “might” to “will”, or remove altogether if it will not happen)

Only include the following statement if applicable – if not, remove:

If we find any clinically relevant research results, including results about you, we will inform you as soon as possible.

**What are the expected benefits of the study?**

You may or may not benefit as a result of your participation in the study. Information learned from the study may help other people in the future by (this is just sample text; it must be edited to describe whether or not they may expect direct benefits. Study-specific information must be included here)

**What are the possible risks of participating in this study?**

There are certain risks and discomforts that may occur if you take part in this research study. They include (describe the risks).

To help lower these possible risks, we will (describe what is being done to minimize risks to subjects).

As this study involves the use of your personal information, there is a chance that a loss of confidentiality will occur. The researchers have procedures in place to lessen the possibility of this happening, as described in the “Will information about me be kept private” section.

We will tell you about any new important information we learn that may affect your decision to continue to participate in this study.

What other choices do I have if I don’t want to be in this study?

You are not required to be in this study. You can choose not to participate.

Will I receive compensation for taking part in this study?

Include one of the following statements – remove the other:

You will not be compensated for taking part in this study. OR You will be compensated for taking part in this study. For your time and effort, you will receive (Include amount, timing, and method of payment/credits. If prorating is necessary, include your proration plan)

If course/extra credit is offered to students include the following – remove if not:

You will receive (include number of credits) credits for participating in the study. (include prorated plan if required) If you choose not to participate in this study, you can still receive the credits by (insert alternative assignment).

Are there any costs for participating in this study?

You should not expect any additional costs by participating in this study. (If there are any additional costs to the subject that may result from participation, include here)

Other costs to you from being in this study may include transportation, parking, childcare, and/or time off work.

You should discuss any questions about costs with the researchers before agreeing to participate.

Will information about me be kept private?

The research team is committed to respecting your privacy and keeping your personal information confidential. We will make every effort to protect your information to the extent allowed by law.

When the results of this research are shared, we will remove all identifying information so it will not be known who provided the information. Your information will be kept as secure as possible to prevent your identity from being disclosed. In order to protect your information, the researcher (or insert name of PI) will (include information on how you will protect the data).

If the project collects identifiable information or biospecimens, you must include one (not both) of the following statements – if no identifiers are collected, then remove all this language:

What we collected from you as part of this research will not be used or shared for future research studies. It will only be used for purposes of this study.

OR

We may share what we collected from you as part of this research, after removing your identifiers, for future research without additional informed consent from you.

If the study involves mandatory reporting, use the following language:

Under State law, we cannot keep information about known or reasonably suspected abuse or neglect of a child confidential, including but not limited to physical, sexual, emotional abuse or neglect. If any member of the study team has or is given such information, he or she is required to report it to the appropriate authorities

If your study has NIH funding or plans to apply for a Certificate of Confidentiality, you must include language about the protections and limitations of the Certificate of Confidentiality here – see the Supplemental Consent Language Document for the language to use about the Certificate of Confidentiality.

If your study is a NIH sponsored Clinical Trial, use the following language:

A description of this study and study results will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. You can search this website at any time.

What if I am injured during the study? (Remove this entire section if the study is minimal risk. If industry sponsored, you must use the sponsor’s injury language instead of the language below)

It is not the policy of the University of Missouri–St. Louis to compensate human subjects in the event the research results in injury.

The University of Missouri–St. Louis, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri–St. Louis, its faculty and staff. The University of Missouri–St. Louis also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri–St. Louis.

In the event you have suffered injury as the result of participation in this research program, you are to contact the UM System Risk Management Office, telephone number (573) 882-8100, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

Who do I contact if I have questions or concerns?

If you have any questions or concerns about this research study, or if you have any problems that occur from taking part in this research study, you may call the researcher (insert name) at (insert PI’s phone number and email address).

If you have questions about your rights as a research participant, please contact the University of Missouri–St. Louis Institutional Review Board (IRB) at 314-516-5972 or irb@umsl.edu. The IRB is a group of people who review research studies to make sure the rights and welfare of participants are protected.

**Do I get a copy of this consent?**

You will receive a copy of this consent for your records.

We appreciate your consideration to participate in this study.

**Consent Signatures**

|  |  |
| --- | --- |
|  |  |
| **Subject’s Signature** | **Date**  |

The following are additional signature lines that may be applicable to your study. If not applicable, remove.

|  |
| --- |
|  |
| **Child’s Name** |

(If this is a parental/guardian consent, include this line to help link with child)

(If study requires two parent consent, must include an extra subject signature line and date)

|  |  |
| --- | --- |
|  |  |
| **Legally Authorized Representative (LAR)** | **Date**  |

(Include when adult subject is incapable of providing legal consent)

|  |
| --- |
|  |
| **Relationship to Subject** |

(Include for LAR and parental/guardian consent)

|  |  |
| --- | --- |
|  |  |
| **Independent Witness** | **Date**  |

(Required when Subject or LAR cannot read or sign name, and as required by the IRB)

|  |  |
| --- | --- |
|  |  |
| **Investigator Authorized to Obtain Consent** | **Date**  |

(This signature line should always be included)