**This is a written consent template for social, behavioral, and educational research studies.**

* It must be edited to include study-specific information.
* Remove the italics when study-specific text has been added. The text not italicized should stay in.
* If this will be used for parental or guardian consent of a child, change “you” to “your child” where appropriate.
* Review the separate template document called “Example Consent Text for Study-Specific Activities” to ensure no other text needs to be included.
* Use plain language, generally at an 8th grade reading level. Avoid jargon and complex terms unless defined. Avoid 1st person.
* You must delete all this red text and reformat before submitting to the IRB

**Written Consent to Participate in a Research Study**

**Project Title:** *(insert title)*

**Principal Investigator Name:** *(insert PI name and advisor if this is a student-led project)*

**Sponsor:** *(insert sponsor name if sponsored or remove)*

**IRB Assigned Project Number:** *(insert the 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 to which you are otherwise entitled. *(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 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).*

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

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

*Only include the following two statements if the study collects biospecimens (i.e. saliva, urine, blood, tissue) – 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. *Refer to the “Example Consent Text for Study-Specific Activities” document for relevant text regarding sharing of incidental/research findings.*

**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. *(this is just sample text; it must be edited to describe whether they may expect direct benefits or if there are no direct benefits. Study-specific information must be included here)*

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

There are minimal risks expected when taking part in this study. There are some that we know about and some may not know about yet. Some possible risks include *(this is just sample text; it must be edited to describe potential risks).*

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

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

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

If you are pregnant or become pregnant while in this study *(add timeframe if expands beyond study)*, there may be risks to you, the embryo or fetus that we do not know yet. *(Include precautions the study is taking to minimize these risks – i.e. pregnancy testing, abstinence)*

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 simply choose not to participate. You can look for other research projects you may be interested in instead of this study. *(list any alternative procedures or courses of treatment, if any, that may be advantageous to the subject).*

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.

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)*

*Only include if SSN is required to collect:*

We will need your Social Security Number in order to pay you. Any payment may need to be reported as income on your tax return. If you are not a resident/citizen (non-resident alien) of the United States, you will need to work with the MU Nonresident Tax Specialist at 573-882-5509.

*Include the following if course/extra credit is offered to students – 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. Your records will be given a code number and will not contain your name or other information that could identify you. The code number that connects your name to your information will be kept in a separate, secure location. *(remove coding language if information will not be coded)*

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. *(this section will need to be edited as needed)*

*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.

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.

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 to compensate human subjects in the event the research results in injury.

The University of Missouri, 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, its faculty and staff. The University of Missouri 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.

In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, 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 questions about this study or experience a research-related injury, you can contact the University of Missouri researcher at (*insert phone number and email address*).

If you have questions about your rights as a research participant, please contact the University of Missouri Institutional Review Board (IRB) at 573-882-3181 or muresearchirb@missouri.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**

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

*Remove additional signature lines if not required for your study:*

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|  |
| **Child’s Name** |

*(Include for Parental/Guardian Consent 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)*

***MO Rev Stat 431.064:******Experimental treatment, tests, and drugs, consent to administer by third party — life-threatening emergencies, consent by whom. —***

*1. When an adult person, because of a medical condition, is treated by a teaching hospital for a medical school accredited by the American Osteopathic Association or the American Medical Association and such person is incapable of giving informed consent for an experimental treatment, test or drug, then such treatment, test or drug may proceed upon obtaining consent of a legal guardian, attorney-in-fact, or a family member in the following order of priority:*

*(1) Spouse unless the patient has no spouse, or is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or the spouse is overseas;*

*(2) Adult child;*

*(3) Parent;*

*(4) Brother or sister;*

*(5) Relative by blood or marriage.*

*2. Nothing in this section shall authorize such legal guardian, attorney-in-fact, or family member to consent to treatment in contravention to such incapacitated person's expressed permission regarding such treatment.*

 (L. 1993 H.B. 564 § 33, A.L. 2003 S.B. 431, A.L. 2006 H.B. 1601 merged with S.B. 765)

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| **Relationship to Subject** |

*(Include for LAR and parental/guardian consent)*

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

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

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

*(Required for FDA regulated, and/or treatment/medical procedures)*