

Internal Use ONLY

This Informed Consent document was approved by the Campus Institutional Review Board for use as follows:

1. Title of Project:

2. Date of Approval _____ Expiration Date: _____

3. Signature of Campus IRB Official _____ (Title) _____

Campus Institutional Review Board
SAMPLE INFORMED CONSENT DOCUMENT

Researcher's Name(s): [List all key personnel]

Researcher's Contact Information:

Project Title:

YOU ARE BEING ASKED TO VOLUNTEER TO PARTICIPATE IN A RESEARCH STUDY

[You must inform the prospective subject that they are being asked to participate in a "research" study.

You are being asked to participate in a research study. This research is being conducted to help *[include a brief statement foreshadowing the purpose for the research].* **When you are invited to participate in research, you have the right to be informed about the study procedures so that you can decide whether you want to consent to participation. This form may contain words that you do not know. Please ask the researcher to explain any words or information that you do not understand.**

You have the right to know what you will be asked to do so that you can decide whether or not to be in the study. Your participation is voluntary. You do not have to be in the study if you do not want to. You may refuse to be in the study and nothing will happen. If you do not want to continue to be in the study, you may stop at any time without penalty or loss of benefits to which you are otherwise entitled.

[When appropriate, describe the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject].

(If applicable) This research is funded by *[Name of sponsor].*

(If applicable, disclose conflicts of interest here and how the conflict is managed (financial, professional, personal, and/or institutional))(If the research has a vested financial interest in the research, it must be identified here.)

Financial Conflicts of Interest: The Campus IRB will require disclosure of the financial interest to participants in the consent form if a financial conflict of interest, as defined by this policy or the MU Conflict of Interest Committee, is identified. SEE Conflict of Interest Policy.

The Campus IRB requires the disclosure of the following financial interests of investigators and other persons responsible for the design, conduct, or reporting of research, and their spouses and dependent children in the Informed Consent Processes.

Additional Elements of Disclosure: The consent process should disclose anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent. If any of the circumstances occur that result in termination, the IRB must be notified immediately for directives.

WHY ARE THEY DOING THIS STUDY?

The purpose of this research is to *[Describe the purpose(s) of the research here].*

HOW LONG WILL I BE IN THE STUDY?

This study will take *[Describe the expected TOTAL duration of the subject's participation]* **approximately** *[Length of time] to complete.* *[If this is a phased or longitudinal study, please explain their time commitment and when/how many times the subject will be contacted. **There are 3 phases to this project. Phase I will be an** [example: Interview; survey; etc.] **It will take approximately 30 minutes.** [Explain their time commitment for remaining phases if applicable, along with when/how many times the subject will be contacted.]*

WHAT AM I BEING ASKED TO DO?

You will be asked to *[Describe the procedures to be followed. Describe any procedures which are experimental].*

HOW MANY PEOPLE WILL BE IN THE STUDY?

There will be around *[number]* **people in the study.**

Additional Elements of Disclosure: The approximate number of participants involved in the study (locally and in total) is not important to a decision to take part in the research; OR the consent process will disclose the approximate number of participants (locally or in total) involved in the study. The researcher should disclose this information to the subject.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

Your participation will benefit *[Describe any benefits to the subject or to others which may reasonably be expected from the research].*

WHAT ARE THE RISKS OF BEING IN THE STUDY?

Your participation in this study is not expected to cause you any risks greater than those encountered in everyday life. However, you may experience feelings of ... *[Describe any reasonably foreseeable risks or discomforts to the subject]. [If there are substantial risks to subjects, you must describe them here and the IRB will require a plan for you to protect the subjects.] [If the risk involves private information, you must inform the subject of the risk and how you will mitigate it].*

[If applicable, add a statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable].

[If applicable, add a statement regarding any additional costs to the subject that may result from participation in the research].

[If students will participate, you MUST include a statement that their decision to participate will not negatively impact their grades].

Additional Elements of Disclosure: 1) The consent process should disclose the particular treatment or procedure may involve risks to the participant which are currently unforeseeable OR the risk profile of all research-related interventions is well known and the research involves no investigational drugs or devices. 2) There are no anticipated circumstances under which the participant's participation will be terminated by the investigator without regard to the participant's consent. If any of the circumstances occur, the IRB must be notified immediately for directives.

Additional Elements of Disclosure: There are no adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research; OR 1)The consent process will disclose the consequences of a participant's decision to withdraw from the research 2) The consent process will disclose procedures for orderly termination of participation by the participant. If any of the circumstances occur, the IRB must be notified immediately for directives.

WHAT OTHER OPTIONS ARE THERE?

You may also choose another alternative *[Include a disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject].*

You also have the option of not participating in this study, and will not be penalized for your decision. *[If there is not an alternative option, please add that an alternative is to not be in this research study].*

CONFIDENTIALITY

The investigator is required to address how they will maintain the subject's confidentiality.

Your identity and participation will remain confidential.

[Add a statement to address questions such as "Will my name or information be given to anyone outside of the research team?"]

[Add a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained].

[Add a statement regarding what information or data will be shared and/or published and with whom].

[Add a statement regarding who has access to the data].

[Add a statement regarding how long the data will be stored before it is destroyed].

PRIVACY

[Add a statement regarding HIPAA issues, if applicable]. **The information you will provide us is considered Private Health Information and subject to HIPAA regulations.**

[Add a statement regarding REPORTING REQUIREMENTS, if applicable]

[Add a statement regarding securing a Certificate of Confidentiality, if applicable][If a Certificate of Confidentiality will be used, you must provide a statement regarding how the identity of the subject will be protected in the event there is a request or subpoena, and how you will protect the data].

WHAT WILL I RECEIVE FOR BEING IN THE STUDY?

You will receive *[If you offer an incentive for participation, please describe it here: 1) Explain when and how subjects will receive the incentive; 2) Explain if incentives are offered in increments; 3) Include a statement that they do not have to complete the study before incentives are paid.] for participation in this study.*

[If your subjects are students, and they will be offered extra credit, please include the number of extra credit points. In the case where extra credit is offered, the researcher MUST offer a comparable alternate method to obtain the credit points for those who decline to participate in the research study. Describe the alternative here].

Additional Elements of Disclosure: The consent document should provide that there are no costs to the participant that may result from participation in the research; OR the consent process will disclose additional costs to the participant that may result from participation in the research. If any of the circumstances occur, the IRB must be notified immediately for directives.

WHAT IF I AM INJURED?

[Recommended Statement: The General Counsel's Office recommends the following statement when obtaining informed consent from potential subjects]:

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 provides, 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.

If you do not understand what is written above, please contact the investigator listed below.

WILL THE RESEARCHER TELL ME IF SOMETHING CHANGES IN THE STUDY?

Informed Consent is an ongoing process that requires communication between the researcher and participants. The participant should comprehend what they are being asked to do so that they can make an informed decision about whether they will participate in the research study. You will be informed of any new information discovered during the course of this study that might influence your health, welfare, or willingness to be in this study.

[When appropriate, add a statement regarding the anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent].

The consent process will disclose anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent

Additional Elements of Disclosure: Significant new findings during the course of the research which may relate to the participant's willingness to continue participation are unlikely OR the consent process will disclose that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant. If any of the circumstances occur, the IRB must be notified immediately for directives.

WHERE CAN I LEARN MORE ABOUT PARTICIPATING IN RESEARCH?

The Campus Institutional Review Board offers educational opportunities to research participants, prospective participants, or their communities to enhance their understanding of research involving human participants, the IRB process, the responsibilities of the investigator and the IRB. You may access the Campus IRB website to learn more about the human subject research process at <http://www.research.missouri.edu/cirb/index.htm>

WHO DO I CONTACT IF I HAVE QUESTIONS, CONCERNS, OR COMPLAINTS?

Please contact [] if you have questions about the research. Additionally, you may ask questions, voice concerns or complaints to the research team.

Investigator Contact Information

- ✓ List the Researcher(s) Name
- ✓ Address
- ✓ Phone number
- ✓ E-mail address

NOTE: If the subjects involve prisoners, you must provide a reasonable method for them to contact you if they have questions. Prisoners do not have free access to telephones, so the researcher must propose a reasonable alternative to the IRB that will provide a venue of communication. (Example: Self-addressed stamped envelope).

WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT MY RIGHTS, CONCERNS, COMPLAINTS OR COMMENTS ABOUT THE RESEARCH?

The Campus Institutional Review Board approved this research study. You may contact the Campus Institutional Review Board if you have questions about your rights, concerns, complaints or comments as a research participant.

You can contact the Campus Institutional Review Board directly by telephone or email to voice or solicit any concerns, questions, input or complaints about the research study.

Campus Institutional Review Board

483 McReynolds Hall
Columbia, MO 65211
573-882-9585

E-Mail: umcresearchcirb@missouri.edu

Website: <http://www.research.missouri.edu/cirb/index.htm>

NOTE: If English is a second language, the researcher is required to assure the subjects can comprehend the Informed Consent Process. *[If applicable, include information with your IRB application describing the use of a translator. The investigator should submit (2) versions of the consent form → the English version, along with the native language of the subjects. The investigator should provide the Campus IRB with assurance that both versions of the consent form read the same. This can be done by a translator that certifies the authenticity of the document, or any other reasonable method acceptable by the IRB].*

WILL I GET A COPY OF THIS FORM TO TAKE WITH ME?

A copy of this Informed Consent form will be given to you before you participate in the research.

SIGNATURES

I have read this consent form and my questions have been answered. My signature below means that I do want to be in the study. I know that I can remove myself from the study at any time without any problems.

Your Signature Date _____

Legal Guardian/Advocate/Witness Signature (if required) Date _____

Additional Signature (if required) (identify relationship to subject) Date _____