If you are performing research involving human subjects, it is your responsibility to address the issue of informed consent for participating in the research. This template is intended to provide guidance for crafting an informed consent document. The Committee for Research Involving Human Subjects (IRB*) strongly* recommends that you model your consent form on this template. However, if you choose a different approach, it must contain at a minimum the same elements as this standard version. Language and terminology used in the consent form must be written at no more than the 8th grade level, so that the potential participant can clearly understand the project, how it is going to be conducted, and all issues that may affect his or her participation*.* In addition, please write the consent form in a manner that addresses your subjects directly instead of writing it in a manner that addresses the University Research Compliance Office directly. *Information on the important issue of informed consent can be found in 45 CFR 46 at* <https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116>.**Federal law mandates that all signed and dated informed consent forms be retained by the P.I. for at least three years following completion of the study.**

WAIVER OF INFORMED CONSENT: *There are limited instances where the requirement for a formal informed consent document may be waived or altered by the IRB.*

*45 CFR 46 states that “An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:*

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|  | *1)* | *That the only record linking the subject and the research would be the consent document and the principal risk* |
|  |  | *would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject* |
|  |  | *wants documentation linking the subject with the research, and the subject's wishes will govern; or* |
|  | *2)* | *That the research presents no more than minimal risk of harm to subjects and involves no procedures for which* |
|  |  | *written consent is normally required outside of the research context.”* |

If a study employs only questionnaires and surveys as the source of their data, it may generally be assumed that to answer and return the questionnaire is an appropriate and sufficient expression of free consent. However, there are circumstances that might call this assumption into question - e.g., teacher-student relationship between the investigator and the subject, etc. However, a statement should be included on the questionnaire or survey form indicating that participation of the subject is strictly voluntary, the length of time reasonably expected to complete the questionnaire or survey form, and that questions that make the participant uncomfortable may be skipped.

Form Content

**PROJECT TITLE:** Full title of project. If possible, the title should be identical to that used in any funding/contract proposal.

**PROJECT APPROVAL DATE/ EXPIRATION DATE:** provided in the approval letter, must be in place before distributing to subjects.

**LENGTH OF STUDY:** Estimate the length of time the subject will be expected to participate.

**PRINCIPAL INVESTIGATOR/CO-INVESTIGATOR(S):** Must be a regular member of the faculty.

**CONTACT DETAILS FOR PROBLEMS/QUESTIONS:** Name, phone number and/or email address of the P.I.

**IRB CHAIR CONTACT INFORMATION*:*** *For the subject should he/she have questions or wish to discuss on any aspect of the research with an official of the university or the IRB. These are:* Rick Scheidt, Chair, Committee on Research Involving Human Subjects, 203 Fairchild Hall, Kansas State University, Manhattan, KS 66506, (785) 532-3224; Cheryl Doerr, Associate Vice President for Research Compliance, 203 Fairchild Hall, Kansas State University, Manhattan, KS 66506, (785) 532-3224.

**PROJECT SPONSOR:** Funding/contract entity.

**PURPOSE OF THE RESEARCH:** Explain in lay terms that this is a research project, and why the research is being done.

**PROCEDURES OR METHODS TO BE USED:** Explain in lay terms and in language understandable at the 8th grade level how the study is going to be conducted and what will be expected of participants. Tell participants if they will be audio or videotaped, if they will be paid, etc.

**ALTERNATIVE PROCEDURES OR TREATMENTS, IF ANY, THAT MIGHT BE ADVANTAGEOUS TO SUBJECT:** Explain any alternative procedures or treatments if applicable.

**RISKS OR DISCOMFORTS ANTICIPATED:** Describe any foreseeable risks or discomforts from the study. If there are no known risks, make a statement to that effect.

**BENEFITS ANTICIPATED:** Describe any *reasonably expected* benefits from the research to the participant or others from the research.

**EXTENT OF CONFIDENTIALITY:** Explain how you plan to protect confidentiality.

**IS COMPENSATION OR MEDICAL TREATMENT AVAILABLE IF INJURY OCCURS:** *In cases where more than minimal risk is involved.*

**PARENTAL APPROVAL FOR MINORS:** If minors or those who require the approval of a parent or guardian are participants, you should include a space for their consenting signature.

**PARTICIPANT NAME/SIGNAUTRE:** Name of research participant and signature.

**WITNESS TO SIGNATURE (PROJECT STAFF):** Staff signature.

**If any of the following content sections do not apply to your research, feel free to delete from the consent form.**

|  |
| --- |
| **PROJECT TITLE:** |
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| **PROJECT APPROVAL DATE:** |  | **PROJECT EXPIRATION DATE:** |  | **LENGTH OF STUDY:** |  |

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| **PRINCIPAL INVESTIGATOR:** |  |

|  |  |
| --- | --- |
| **CO-INVESTIGATOR(S):** |  |

|  |  |
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| **CONTACT DETAILS FOR PROBLEMS/QUESTIONS:** |  |

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| **IRB CHAIR CONTACT INFORMATION:** |  |

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| **PROJECT SPONSOR:** |  |

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| **PURPOSE OF THE RESEARCH:** |
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| **PROCEDURES OR METHODS TO BE USED:** |
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| **TYPES OF DATA COLLECTED (Including special categories):** |
| [ ]  **Racial or ethnic origin** | [ ]  **Political opinions** |
| [ ]  **Religious or philosophical beliefs** | [ ]  **Trade union membership** |
| [ ]  **Processing of genetic data** | [ ]  **Biometric data for the purposes of unique identification**  |
| [ ]  **Other (please specify):**  |

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| **BIOLOGICAL SAMPLES COLLECTED (Describe procedure, storage, etc.):** |
|  |
| **[Select a statement from the drop down menu]** |
| **[Select a statement from the drop down menu]** |

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| **ALTERNATIVE PROCEDURES OR TREATMENTS, IF ANY, THAT MIGHT BE ADVANTAGEOUS TO SUBJECT:** |
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| **RISKS OR DISCOMFORTS ANTICIPATED:** |
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| **BENEFITS ANTICIPATED:** |
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| **EXTENT OF CONFIDENTIALITY:** |
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| **[Select a statement from the drop down menu]** |

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| **WHO WILL HAVE ACCESS TO DATA:** |
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| **DATA SECURITY (Including storage and transfer of data):** |
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| **LENGTH OF TIME DATA WILL BE RETAINED:** |
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**IS COMPENSATION OR MEDICAL TREATMENT AVAILABLE IF INJURY OCCURS?** [ ] Yes [ ] No

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| **PARENTAL APPROVAL FOR MINORS:** |  |  |  |
| **PARENT/GUARDIAN APPROVAL SIGNATURE:** |  | **DATE:** |  |

Terms of participation: I understand this project is research, and that my participation is voluntary. I also understand that if I decide to participate in this study, I may withdraw my consent at any time, and stop participating at any time without explanation, penalty, or loss of benefits, or academic standing to which I may otherwise be entitled. If I reside in the European Union, I acknowledge that I have received a copy of the European Union General Data Protection Regulation Privacy Notice and, if applicable, executed the Consent Form for the Processing of Sensitive Information.

I verify that my signature below indicates that I have read and understand this consent form, and willingly agree to participate in this study under the terms described, and that my signature acknowledges that I have received a signed and dated copy of this consent form.

(Remember that it is a requirement for the P.I. to maintain a signed and dated copy of the same consent form signed and kept by the participant).

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| **PARTICIPANT NAME:** |  |  |  |
| **PARTICIPANT SIGNATURE:** |  | **DATE:** |  |
| **WITNESS TO SIGNATURE: (PROJECT STAFF)** |  | **DATE:** |  |