Murray State University – Human Subjects Research Consent Document Template

Ver. – 090517

The purpose of this template is to assist Murray State University investigators and research personnel in creating consent documents and, where possible, to facilitate consistency across research protocols.

Sections of this document include instructions to provide the user with a general overview of information required in the section. The instructions and optional text are in blueand required text (or official text if it’s not a required section) is in black. These instructions and the sample language are not intended to be comprehensive. Unless otherwise noted, investigators are encouraged to modify the template language whenever appropriate to increase the potential for subject comprehension and relevance to a specific study. Use of the headings is strongly recommended.

**DELETE THIS PAGE, ALL INSTRUCTIONS (BLUE TEXT), AND ANY NON-APPLICABLE SECTIONS BEFORE SUBMITTING THIS FORM TO THE IRB.**

**Tips for writing consent forms:**

* Informed consent is a process, not just a form. Information must be presented that will enable potential participants to voluntarily decide whether to enroll in the study. Informed consent is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, consent documents must be written in plain language with as few technical terms as possible.
* Shorter documents result in greater comprehension of the content. Therefore, consent documents should be limited to required elements and presented in a way that highlights key information.
* The consent document should be written at a level comprehensible to your target population. If your study targets the general public, the ideal consent form would be written at or below an 8th grade reading level, with a readability score of more than 50 (the higher the score, the easier your document is to read). Use Flesch-Kincaid to test the readability level of your document. See [Microsoft Office Support](https://support.office.com/en-us/article/Test-your-document-s-readability-0adc0e9a-b3fb-4bde-85f4-c9e88926c6aa) for more information.
* Use of illustrations, diagrams, color, and supplemental materials are encouraged when their use may enhance comprehension.
* If enrolling children, make appropriate changes to section headings (e.g., replace “I” with “my child”, etc.).
* Write directly to the reader, as though you are explaining the facts in person. Consent language should be written in the second person (“you”), not in the first person (“I”).
* Minimize passive voice to the extent possible. Example of passive voice: “A summary of results will be sent to all study participants.” Example of active voice: “We will send you a summary of the results.”
* Do not include student investigator information other than their name. Only include one point of contact for the study, either the PI (application submitter if multiple PIs) or the FS if PI is a student.
* If your consent form is multiple pages, please adjust the font size (no less than 10pt), paragraph spacing, or margins to fit it onto as few pages as possible. **If it is still multiple pages, you must have “Page # of #” in the bottom right corner with the participant initials beside the page numbers.**

**Use of MSU departmental letterhead is strongly encouraged. Otherwise, there should be a clear indication that this research is being done by MSU.**

**Research Participation {Consent/Permission} {Form/Letter}**

**Study Title:** Must be the same as IRB Application.

**Primary Investigator:** {PI NAME, DEPT} or {STUDENT and FACULTY NAME, DEPT} – Same as application.

**Co-Investigator(s):** Everyone included in application. Remove if none.

**Funding Agency:** Remove if none.

**Faculty Sponsor Contact:** NAME, PHONE, EMAIL – Same Faculty member as above. Remove if none.

You are being invited to participate in a research study conducted through Murray State University. This form contains information you will need to help you decide whether to be in this research study or not. You must be at least 18 years old to participate (if using participants in an age range [e.g., 18 to 45], change this to indicate that). Please read the form carefully and ask the study team member(s) questions about anything that is not clear. You will be given a copy of this form to keep.

1. **Nature and Purpose of Project:** The purpose of this study is to {briefly describe the purpose of the study; indicate here if research is being done by a student for a thesis/dissertation}.
2. **Participant Selection: Delete if participants self-selected** (i.e. volunteered in response to an advertisement). You are being asked to participate because {reason they have been selected to participate in study}.
3. **Explanation of Procedures:** Make clear that the activity involves research and describe the overall experience that will be encountered. Explain the procedures, including any parts that are experimental.

The study activities include {Include all study activities (e.g. surveys, questionnaires, interviews, randomization, observation, description of study arms, etc.)}. If the study activities are complex, lengthy, or repetitious, it may increase comprehension to provide simple charts or calendars and supplemental documents that include the detailed descriptions.

Study duration: Insert the expected length of time it will take for study visits or scheduled procedures, as well as the total expected length of participation (e.g. the interview will take about one hour; you will be asked to visit the lab three times and each visit will take about two hours). Avoid references to specific dates in case your study does not begin or end on schedule.

1. **Recordings/Photographs: Delete if none.** If you plan to use audio/video recordings or take photos of participants, describe where, how, and why in this section. If being recorded is required for participants, inform them of this and say that they should not enroll in the study if they do not want to be recorded. If recording is optional, use this section to get consent for recording by having them initial one of the two options below:

**\_\_\_\_\_\_** I agree to be {type of recording}.

*Initials*

**\_\_\_\_\_\_** I do **not** agree to be {type of recording}.

*Initials*

1. **Discomforts and Risks:**The possible risks and/or discomforts associated with the being in the study include: All reasonably foreseeable risks, discomforts, inconveniences, and harms that are associated with the research activity should be described. Investigators should be honest about risks and not understate reasonably foreseeable risks.

If using focus groups, include the following language: We will ask members of the focus group to maintain the confidentiality of comments made during the discussion. However, there is still a risk that comments you make during the discussion may be shared outside of the group.

If this is research which is done over the computer (online surveys, email responses, etc.) **AND** it involves information that is either (a) sensitive information or (b) information which would put participants at risk if disclosed, then you must include the following language: All responses from online participants will be treated confidentially and stored on {state how stored (e.g., secure server, encrypted hard drive, encrypted file, unencrypted hard drive, etc.)}. However, we are unable to guarantee the security of the computer on which you choose to enter your responses. Information (or data) you enter, and websites you visit online can be tracked, captured, corrupted, lost, or otherwise misused.

**Do not include evaluative statements about the risks, such as, “Risks are minimal.”** If the actual probability of risk is known, this information can be included if it could further enable a participant to assess their personal risk. For example, “In previous studies, about 10% of the participants felt dizzy after the [intervention].”

Depending on the type of study, some risks may be better described as things that could make the participant “uncomfortable” – such as fatigue or embarrassment.

If there are no known risks: There are no anticipated risks and/or discomforts for participants.

1. **Benefits:** Any benefits to subjects or others that may reasonably be expected from the research should be described. Investigators should not overestimate or magnify the possibility of benefit to the subject. If there is no reasonable expectation of benefit, the subject should be told this. Payment to subjects should not be listed or described as a benefit of participating in the research. Benefits should be the direct result of experimental conditions or interventions – e.g., a student involved in a new teaching method may benefit from a better understanding of the subject. Research participation (“experience”) is not a benefit.

Use if direct benefit to participants is anticipated: We do not know if you will benefit from being in this study. However, you may {insert anticipated benefit}.

Use if no direct benefit to participants is anticipated: This study is not designed to benefit you directly. However, your participation may help to increase our understanding of {research subject}.

1. **Participant Compensation: Delete if there is no compensation.** You will be paid for being in this research study. {Clearly describe the monetary compensation (total amount, average total amount, amount per visit, amount per hour, etc.). If compensation is pro-rated when a participant withdraws prior to completing the study, explain how it is pro-rated. If participants must complete the study activities in order to receive compensation, please state. Describe any non-monetary compensation (e.g., extra credit, gift certificate), separately from monetary compensation and include the approximate value when appropriate.
2. **Confidentiality:** The statements below should be used to accurately reflect whether or not a subject will be identifiable.

Option 1) If the identity of the subject will never be known to the researchers (e.g., online survey with no record of IP address), insert this: Your participation in this study is anonymous. Neither the researcher(s) nor anyone else will know if you have participated or how you responded.

Option 2) If the identity of the subject will be known to the researchers, insert this sentence: Your identity will be known to the researchers, but the information you provide will be kept confidential.

If data will be shared with individuals or organizations external to MSU (e.g., collaborators, off-campus research sites, etc.), provide general information about what will be shared, with whom, and whether it will be individually identifiable. For example: “We will share your responses with researchers at other universities, but we will not include your name.” Note that names of individual recipients of shared data or samples are not necessary.

1. **Refusal/Withdrawal:** Your participation is strictly voluntary and you are free to withdraw/stop participating at any time with absolutely no penalty. If the study involves interviews, surveys, or questionnaires, with optional questions, include a statement that the participant is free to skip any questions that he/she would prefer not to answer. If answering all questions is required, clearly state that while study participation is voluntary, all questions must be answered in order for their individual responses to be included in the study results.
2. **Contact Information:** Any questions about the procedures or conduct of this research should be brought to the attention of {PI [or FS if PI is student]} at {phone number} or {email}. {If you would like to know the results of this study, please contact {PI [or FS if PI is student]}.

Use the appropriate voluntary participation statement for the kind of study you are doing:

**{Your signature; Your continued participation; Your response submission; Clicking the link below} indicates that this study has been explained to you, that your questions have been answered, and that you agree to take part in this study.**

The dated approval stamp on this document indicates that this project has been reviewed and approved by the Murray State University Institutional Review Board (IRB) for the Protection of Human Subjects. If you have any questions about your rights as a research participant, you should contact the MSU IRB Coordinator at (270) 809-2916 or msu.irb@murraystate.edu.

Participant's Name (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (Signature of Participant) (Date)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature of Person Obtaining Consent) (Date)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(**When presenting IC orally:** {Witness} or {Translator}) (Date)

Include any other applicable signature lines. Delete signature lines that are not applicable. For Parental Consent, replace participant lines with the following:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Parent/Guardian/ Legally Authorized Representative) (Date)

Delete all signature lines if a waiver of documentation (signature) is requested.