

CONSENT FORM TEMPLATE FOR HUMAN SUBJECTS PARTICIPATING IN RESEARCH DETERMINED EXEMPT

Human Research Protection Program Michigan State University

Instructions to the Researcher

Informed consent is one of the most basic and important principles in the protection of human subjects in research. The approach of researchers toward the informed consent process is very important in ensuring its effectiveness. The consent process should be informative and empowering. It should give potential participants the information they need to decide whether to participate or not (being completely voluntary is another basic principle of human subject protection). No exculpatory language can be included in the consent form. For examples of exculpatory language, please visit <http://hhs.gov/ohrp/humansubjects/guidance/exculp.htm> .

Please remember that the consent form is only a part of the consent process. How you inform the participants, present and review the consent form with them, and answer their questions, are also parts of the process and should be built into your project design. If participants are non-English speaking, then the consent process and form should be provided in the appropriate language.

You may use this form as a template for developing a consent form for your research if it has been determined to qualify as EXEMPT.

The entire content should be in lay terms – define any technical terms. It is often suggested to aim for an 8th grade reading level for studies of the general population, but the reading level should correspond with the targeted population. Write in second person (“You are being asked...”).

Documentation of Consent

The standard practice of consent is to obtain the signature of the participant in order to document that the consent form was provided, read, and voluntarily signed. This is important for the protection of both the participant and the researchers. **HOWEVER, in some instances, ESPECIALLY FOR RESEARCH THAT QUALIFIES AS EXEMPT, a signature of informed consent is not necessary. In these circumstances, statements such as the following may be used: “You indicate your voluntary agreement to participate by completing and returning this survey” –OR- “You indicate your voluntary agreement to participate by beginning this phone interview” –OR- for online surveys: “By clicking on the button below, you voluntarily agree to participate in this online survey.”**

Note to researcher when using this template

- Standard text is language that can be directly used or directly inserted. *Italicized text* is instructional language.
- Use only those statements that are appropriate – this template gives many different possibilities for many types of research, thus not all the statements are relevant for all projects.

Research Participant Information and Consent Form

1. EXPLANATION OF THE RESEARCH and WHAT YOU WILL DO: *(Must state “research”)*

Points to include:

- You are being asked to participate in a research study of...
- *Discuss what, if anything, the participants have to do, not do in the study. Describe the procedures chronologically.*
- You must be at least 18 years old to participate in this research.

2. YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW:

Points to include:

- Participation in this research project is completely voluntary. You have the right to say no. You may change your mind at any time and withdraw. You may choose not to answer specific questions or to stop participating at any time. Whether you choose to participate or not will have no affect on your grade or evaluation.

3. COSTS AND COMPENSATION FOR BEING IN THE STUDY: *(If applicable)*

Points to include:

- *Discuss any costs to the participant.*
- *Discuss any compensation (amount, timing) to the participant.*
 - You will be compensated....
 - You will receive...
- *For research on students, tell the participant if they will receive credit or extra credit – include amount.*
- *Inform students of the equivalent, non-research assignment which may be done in place of research participation.*

4. CONTACT INFORMATION FOR QUESTIONS AND CONCERNS: *(Investigator contact information is necessary; HRPP contact info is NOT required for EXEMPT research)*

If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher (name and complete contact information: mailing address, e-mail address, phone number).

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University’s Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 207 Olds Hall, MSU, East Lansing, MI 48824.

5. DOCUMENTATION OF INFORMED CONSENT.

A signature is not a required element of consent for EXEMPT protocols:

You indicate your voluntary agreement to participate by completing and returning this survey. *-Or-* You indicate your voluntary agreement to participate by beginning this phone interview. *-Or-* By clicking on the button below, you indicate your voluntary agreement to participate in this online survey.

-OR-

If you would like to ask participants to sign, please use the statement below:

Your signature below means that you voluntarily agree to participate in this research study.

Signature

Date