

Guidelines for Constructing an Informed Consent Document

For related links and information pages and templates, visit us online at:
<http://www.mtu.edu/research/administration/integrity-compliance/review-boards/>.

Format and language: Use Michigan Tech letterhead. When the consent form is more than one page, you are required to number all pages and indicate a space at the bottom of the page for subjects to initial they have read the page by indicating “_____ initials”. All language must be written in first person such as “you will”, “you are”, etc. (not referred to as “the subject” or “the participant”).

Include all of the information indicated below as appropriate to the study. Use the headings indicated in *BOLD RED*. For most sections the information should be express in a few simple sentences, written at a 6th-8th grade reading level.

1. **TITLE:** Research Study Title
2. **RESEARCHERS:** List names of principal investigator(s) and other key personnel. If investigator(s) are students, the faculty advisor must also be listed by name and department.
3. **PURPOSE:** State the purpose of the research study.
4. **REASON FOR INVITATION:** State the reason for inviting individuals to participate.
5. **HOW PARTICIPANTS WILL BE SELECTED:**
 - Basis of selection into the study, if any.
 - Basis for exclusion from the study, if any. If none, omit mention of exclusions.
6. **PROCEDURES:**
 - Briefly describe all procedures participants will perform, and their locations.
 - State approximate time required for each procedure.
 - Specify all out of pocket costs to participants, if any. If none, omit mention of costs.
7. **RISK:** Describe the known risks to participants from participating in the research itself, if any. Include likelihood of each risk. If no risks are anticipated, state “We do not think there is any risk to you from participating in this research”.
8. **COMPENSATION FOR HARM: NOTE: do not include this section if there are no anticipated harms from participating in the research.** Suggested language if needed: “If you are harmed from participating in this research, emergency first aid will be provided to you and you will be referred to an appropriate medical care center. Any costs for additional medical care that may be required are your responsibility and that of your own medical insurance company”.
9. **POTENTIAL BENEFITS TO YOU:** Describe the potential direct or indirect benefits to participants from participating in the research. If none, state there are none. Compensation for participation is not a benefit and should be addressed as PAYMENT as indicated below.
10. **POTENTIAL BENEFITS TO SOCIETY:** Describe the anticipated direct or indirect benefits to society from completion of the study and dissemination of results. All studies should include at least one potential benefit to society. Do not exaggerate the potential for benefit.

11. **VOLUNTARY PARTICIPATION STATEMENT suggested language:** “Your participation in this research study is completely voluntary. You do not have to participate. You may stop at any time without penalty to you.” If participation is for class credit being given explain in detail to students (i.e., ...the amount of credit earned is [____] for [____ amount of time spent]), in addition explain that an alternate assignment will be given if the participants chooses to discontinue and participation or withdrawal will have no effect on any grades received in any particular class.
12. **PRIVACY and CONFIDENTIALITY STATEMENT suggested language:** “Your name will not be given to anyone other than the research team. All the information collected from you or about you will be kept confidential to the fullest extent allowed by the law. In very rare circumstances, specially authorized university or government officials may be given access to our research records.”
13. **RESEARCH STUDY RESULTS suggested language:** “If you wish to learn about the results of this research study you may request that information by contacting: [insert name, phone, email info].”
14. **PAYMENT if applicable:** Describe any payment and amount for participating in the research study that will be offered to all participants. This may be as compensation for time and effort or an incentive to participate. Incentives must be minor and may not constitute undue influence to participate. If the incentive involves entering a drawing for a prize, describe the drawing, prizes, and approximate chances of winning. **If there is no payment, either state “There will be no payment for participating in the research.” or omit mention of payment.**
15. **QUESTIONS REGARDING THIS STUDY:** Describe who to contact by name, phone, or email, and address as applicable.
16. **HUMAN SUBJECT RIGHTS required language:** “The Michigan Tech Institutional Review Board has reviewed my request to conduct this project. If you have any concerns about your rights in this study, please contact the Office of Compliance, Integrity, and Safety at 906-487-2902 or email IRB@mtu.edu.”
17. **AGREEMENT TO PARTICIPATE suggested language:** By signing this consent form below, you are stating the following:
 - The details of this research study have been explained to me including what I am being asked to do and the anticipated risks and benefits;
 - I have had an opportunity to have my questions answered;
 - I am voluntarily agreeing to participate in the research as described on this form;
 - I have been given a copy of this document for my records;
 - I may ask more questions or stop participating at any time without penalty.

Print name: _____

Signature: _____

Date: _____

Note: If persons under the age of 18 will be enrolled in the research, the parental consent, and a child assent must be prepared and submitted in the IRBNet package. See examples of these forms on the web site listed above.