



Human Subject Use Required Elements Guide

For related links and information pages and templates, visit us online at:

<http://www.mtu.edu/research/administration/integrity-compliance/review-boards/>

INSTRUCTIONS:

The following required elements must be attached to your IRBNet package, if you are unsure of what forms to complete see the *“Required Forms Checklist”* found in the IRBNet library. Obtain appropriate signatures in IRBNet. Submit this completed request through IRBNet. Consent and Assent templates are also available on our web site listed above in the human subject research resources boxes on the right side of the page. Incomplete requests will be returned, not reviewed.

Once you have logged in and completed the wizard for the “Application Coversheet”, the next step to completing your submission is to include / append the following documents to the package.

Note: all investigators whom this project is shared with must register their affiliation with Michigan Tech and electronically sign the individual package in IRBNet prior to the final submission for review processing. If you have any questions, feel free to contact the Research Integrity and Compliance Office via email IRB@mtu.edu or phone 906-487-2902.

Please use a word processor and present your responses in lay terminology.

1. **Protocol:** Describe the procedures that relate to the human subject’s participation. What will the participant do and/or what will be done to them? **Attach** copies of all test instruments and/or questionnaires that will be used. Describe how interviewers or data collectors will be trained. *(Note: All attachments must be in final form; drafts are unacceptable.) Include the following information:*

Objectives and Significance: What are the objectives and significance of the proposed research project involving human participants?

Recruitment, Selection of Participants and Voluntariness: Describe (a) the participant population and any special characteristics of participants, (b) methods for selecting participants and (c) explain the need if a specific population will be recruited (d) procedures for assuring that their participation is voluntary.

Attach copies of flyers, posters, and/or letters that will be used to recruit participants, if applicable. *(Note: All attachments must be in final form; drafts are unacceptable.)*

Compensation: If participants will receive payment, extra credit points, or other form of compensation for participation, state the amount, form, and conditions for award. Explain alternate activities and compensation that will be available to persons who elect to not participate in the research, if applicable.

Deception: If participants will be deceived or misled or if information is withheld from participants, identify the information involved, justify the deception, and describe the debriefing plan and attach a debriefing document, if applicable.

Privacy and Confidentiality: Please explain if the participants will be identified and/or if their participation in the study might reasonably place them at risk for criminal or civil liability or be damaging to their financial standing, employability, insurability, or reputation or be stigmatizing. Describe the protections that will be implemented to reduce risks related to invasion of privacy and breach of confidentiality, including data reporting methods and the long-term protection, destruction, and/or disposal of participant’s data or records. (Note: Federal IRB regulations require the retention of records for three years after the completion of the final report. Research sponsors or the institution may impose longer retention periods that must be observed by the researcher.)

Risks: Describe all risks of the proposed study to the participants and the precautions that will be taken to minimize those risks. Otherwise, include a statement indicating there are none known.

Benefits: Describe benefits likely to accrue to the participant, if any. Describe the benefits of the proposed research to science and/or society, if there is no direct or immediate benefit state this.

2. Informed Consent or Parental Consent and Child Assent: **Attach** a copy of the written informed consent and/or parental consent and child assent documents to be signed by the participant(s) or provide written information for any verbal or written explanation which will be given to the participant in lieu of a written and signed informed consent form. (Note: The written or read consent form must be written or read at the eighth grade comprehension level and comply with the required elements as provided in the examples of Informed Consent Form or Parental Permission Forms included in the IRBNet library.) If a waiver of written informed consent is requested, complete and attach the Request for Waiver of Written Informed Consent Form. *(Note: All attachments must be in final form; drafts are unacceptable.)*

3. Conflict of Interest: All Principal Investigators and co-investigators must disclose any conflicts of interest (COI) in accordance with the policy set forth by Michigan Tech. In the event a conflict of interest exists, a COI disclosure needs to be completed and submitted in IRBNet. Do not attach that form to this study, instead it must be submitted to the appropriate Michigan Tech COI committee. This form is located in the COI library in IRBNet.

4. Attach documents to your new project package. REMEMBER; **Our institution also requires the completion of an online IRBNet Document Wizard** – “Michigan Tech New Study Application Coversheet”; see *Instructions for Submitting a NEW Research Protocol*.