

Human Subject Use Request for Exemption Form ver.1

Federal regulations (45 CFR 46) permit the exemption of some types of research from IRB review.

Exemption does not mean that you do not need to submit a study for review; our office requests information about your study and will determine the level of review required for approval.

If you have any questions, feel free to contact our office.

Eligible for Exemption: There are several classifications of research which may involve human subjects but their classification falls outside of the IRB's policies and jurisdiction.

Determination that research is exempt from the Institutional Review Board (IRB) is made through the Office of Compliance, Integrity, and Safety. Exemption from review is only available to certain categories of research as defined by federal regulation. If you have questions about whether your project might qualify for exemption, please contact our office. Examples are provided on attached pages.

INSTRUCTIONS: Incomplete requests will be returned, not reviewed.

1. After reviewing the attached explanation of categories on the last pages of this form, you may submit a request for exemption by **completing this form, saving it to you hard or flash drive, then creating your project** through irbnet.org for determination. You must first be a registered IRBNet user.
 - . Log in and create a new study package.
 - . You are only required to complete this form and attach it to your study package in IRBNet.
2. **When the PI has a student status, an advisor must be listed and access to the study must be shared with the advisor.** If an advisor is listed below, the project must indicate shared access with your advisor in IRBNet, and they must sign the package. The “signature” of the advisor in IRBNet represents acknowledgment of the submission, that it is compliant with Federal regulations along with Michigan Tech policies, and that procedures will be monitored with the student PI regarding this study. **The advisor must be a registered user and log in to “sign” the package which acknowledges this study or processing will be delayed.**

Project Title:

Project Dates - Start:

End:

Principal Investigator:

Department:

E-mail:

Phone:

PI status check one: Faculty / full time staff undergrad graduate student

Coordinator / advisor name:

Department:

E-mail:

Phone:

Title:

Principal Investigator:

1. **To apply for exemption: Provide a brief description of your proposed research in language that can be understood by a non-scientist. Continue answering the questions below until you are instructed to stop.** The description should summarize the objectives of this project and the procedures, population, the nature of the data to be obtained, including compensation you will employ to recruit human participants or access data about the participants along with how participant privacy will be protected or confidentiality of the data will be maintained. If applicable, attach final copies of all test instruments/questionnaires that will be used.

Provide a brief description here:

Title:

Principal Investigator:

2. **Yes No** Does the Michigan Tech Institutional Review Board define the project as **research**? The IRB defines “research” as a systematic investigation designed to develop or contribute to *generalizable knowledge*”.

3. **Yes No** Are the human subjects in your study *living* individuals?

If you answered NO to Questions 2 or 3, complete questions 7- 10 and submit this form for informational purposes only. If you answered YES to both questions, continue.

4. **Yes No** Will you obtain data through *intervention* or *interaction* with these individuals? Intervention” includes both physical procedures by which data are gathered (e.g., measurement of heart rate or venipuncture) and manipulations of the participant’s environment that are performed for research purposes. “Interaction” includes communication or interpersonal contact between the investigator and participant (e.g., surveying or interviewing).

5. **Yes No** Will you obtain *identifiable private* information about these individuals? “Private information” includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information provided for specific purposes which the individual can reasonably expect will not be made public (e.g., student record). “Identifiable” means that the identity of the participant may be ascertained by the investigator or associated with the information (e.g., by name, code number, pattern of answers, etc.)

If you answered NO to Questions 4 and 5, complete questions 7 - 10. No review is required; you only need to submit this form for informational purposes. If you answered YES to either question, continue.

6. **Yes No** Does the study present *more than minimal risk* to the participants? “Minimal risk” means that the risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. Note that the concept of risk goes beyond physical risk and includes psychological, emotional, or behavioral risk as well as risks to employability, economic well being, social standing, and risks of civil and criminal liability.

If NO, continue. If YES, STOP HERE. Your protocol is not exempt from review. You must register with IRBnet and submit all required documents for your human research project through IRBNet. - see Instructions for Registering and Submitting a NEW Research Protocol on our web site.

Federal regulations (45 CFR 46) permit the exemption of some types of research from IRB review. See attached pages 4 and 5 for explanation of categories.

If your research can be described by one or more of the categories listed below, check all appropriate categories. If your research cannot be described by any of these categories, your research is not exempt, and you must complete an application for the use of human subjects in a research study.

Note: Exemption categories cannot be applied to research involving fetuses, pregnant women, human in-vitro fertilization or prisoners.

7. Category, check all that apply, see attached explanation:

1 2 3 4 5 6

8. **Yes No** Is this a graduate level research project?

9. **Yes No** Will data be collected and stored in a manner such that participants may be individually identified directly or indirectly?

10. **Yes No** Is this research supported by grants or external funds?

All research studies involving human participants conducted by Michigan Tech faculty, staff, or students are subject to IRB review and must be submitted through the Office of Research Integrity and Compliance.

Some studies that involve human subjects that ARE NOT considered research and **ARE NOT** subject to IRB review includes:

- Michigan Tech president, dean/chair, teacher, and student evaluations;
- Program evaluation research to benefit Michigan Tech and/or programs carried out by Michigan Tech administrative officials;
- Projects designed to enhance or improve curricula offerings;
- Projects designed to enhance or improve customer satisfaction;
- Benefits or Human Resource surveys and evaluations;
- Michigan Tech employee performance evaluations;
- State of Michigan mandated program evaluations;
- Marketing research that is designed to market the institution as a product;
- Classroom projects (which do not extend beyond the classroom).
 - Are a general requirement of a course,
 - Have the sole purpose of developing the student’s research skills, and
 - Will be overseen by a faculty member

Some other studies that **ARE** considered research and **ARE** subject to IRB review, include studies that are:

- Intended to satisfy the academic requirements for independent study, dissertation, or master’s thesis;
- Intended or expected to result in publication, presentation outside the classroom, or public dissemination in some other form;
- Part of a larger research project that has current Michigan Tech IRB approval; or
- Conducted outside the classroom and/or department research participant pool if they involve
 - Minors (i.e., persons under the age of 18),
 - A targeted population of adults whose ability to freely give informed consent may be compromised (i.e., person who are socio-economically, educationally, or linguistically disadvantaged, cognitively impaired, elderly, terminally ill, or incarcerated),
 - Pregnant women and/or fetuses,
 - A topic of sensitive or personal nature, the examination or reporting of which may place the research participant at more than minimal risk, or
 - Any type of activity that places research subjects at more than minimal risk.
- Part of a larger research project that has current approval of a registered IRB at another institution, provided that, if research participants are to be recruited at Michigan Tech, and the Michigan Tech IRB has given permission for such on-campus recruitment.

Federal regulations (45 CFR 46) permit the exemption of some types of research from IRB review.

Category 1 – Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special educational strategies; or (b) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

Category 2 – Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (a) information obtained is recorded in such a manner that the human participants can be identified, directly or through identifiers linked to the participants; and (b) any disclosure of the human participants’

responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

Note: Exemption for survey and interview procedures does not apply to research involving minor age children. Exemption for observation of public behavior does not apply to research involving children except when the investigator does not participate in the activities being observed.

Category 3 – Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2 above if: (a) the human participants are elected or appointed public officials or candidates for public office; or (b) federal statute requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Category 4 – Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Category 5 – Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to these programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

Category 6 – Taste and food quality evaluation and consumer acceptance studies: (a) if wholesome foods without additives are consumed; or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.