

## INSTRUCTIONS: Exemption Request Information for Human Subject Studies

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, feel free to use the training energizers available on our web site.**

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 and categories are provided on the next two pages.**

### INSTRUCTIONS:

If according to the information found below, you feel that your study may be exempt from IRB review, see individual INSTRUCTIONS on our web site for information on how to register in IRBNet and how to create a new project. Then you must complete the following:

1. Go to [irbnet.org](http://irbnet.org) to register as a researcher in [irbnet.org](http://irbnet.org) and affiliate yourself with Michigan Tech, an activation email with instructions will be sent to your registered email address (you will do this **one time only for your first submission**)
2. log in to [irbnet.org](http://irbnet.org) where you will have access to your projects and forms/templates
3. click the "create new project" button found on the left side of the page and complete all areas indicated by a red \*
4. select the Michigan Tech IRB library to obtain the "FORM: Exemption Request"
5. complete and save your Exemption Request form on either your hard or flash drive
6. build your project package on the designer page, click on the "add new document" button at the bottom of the page to browse your hard drive for all necessary completed documents related to the project and individually upload your completed documents for review
7. share your project with other researchers listed on the project, including an advisor if appropriate, set the appropriate level of access you are granting for each person listed
8. communicate with other researchers listed by clicking on "send project mail" on the left side of the page  
(use this method to inform **full access team members, including an advisor if one is listed regardless of the advisor level of access**, that their "electronic signature" is required on the package you have shared with them)
9. sign the package yourself
10. click on "submit this package"

**(You are not yet approved to proceed with the study!)**

Your request will be processed and you will be notified via email through [irbnet.org](http://irbnet.org) for approval determination.

**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 Compliance, Integrity, and Safety.**

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.