Michigan Tech
Create the Future

Research > Integrity and Compliance > Review Boards > Human Subjects

RESEARCH | Human Subjects in Research

Institutional Review Board (IRB)
FWA 00005174 (expires 2-13-12). All research involving the participation of human subjects must be submitted for review by the Institutional Review Board for the Protection of Human Subjects (IRB). This is done by submitting an application to the IRB.

At the first stage of the board approval process, applications for research considered by the board to be exempt will be waived from further review. Nonexempt applications will receive either an expedited or full board review. All research must be exempted or approved by the IRB before it can be conducted.

The Institutional Review Board is guided by the ethical principles found in the report of the National Commission for the Protection of the Human Subjects of Biomedical and Behavioral Research (entitled "Ethical Principles and Guidelines for the Protection of Human Subjects in Research") and the Code of Federal Regulations. You should also review the Standards for Privacy of Individually Identifiable Health Information.

When reviewing a proposal, the board considers:
- The risks to the subjects
- The anticipated benefits
- The importance of the knowledge that may result
- The informed consent process to be employed

Investigators are responsible for conducting the research as described in the approved or exempted application and for submitting a revision to the application describing any departures from the original before revisions are implemented. Research may be subject to intramural inspection or audit.

Through its program, the IRB ensures that all research associated with Michigan Tech complies with all relevant government rules and regulations.

NOTES

Important Dates
March 29, 2010: submission deadline for the
April 12, 2010: IRB scheduled meeting

Submit applications by hard copy to Research Integrity & Compliance or electronically to REB@MTU.EDU.
New applications, continuations, or requests for changes should be received in the Research Integrity and Compliance Office no later than the submission deadline date listed above to be considered for IRB review and approval at the next scheduled meeting.

Please call Cheryl Gherna at 407-2902 or email cgherna@mtu.edu if you have any questions.

APPLICATIONS

These applications are in PDF.
Human Subjects in Research
Human Subjects in Michigan Tech Classroom Situations
Continuing Review/Completion Form

RESOURCES

Michigan Tech-IRB Policies and Procedures
Training Requirements
Navigating the IRB Process
Michigan Tech-IRB Tutorial
Federal Regulations

INFORMED CONSENT

Informed Consent Details
Templates and Sample Consent Forms
Tips on Informed Consent
Informed Consent Checklist
Informed Consent for Non-English Speakers
Exemplary Language for Informed Consent Documents

IRB ONLY

Login

Vice President for Research

4/1/2010 12:26 PM
APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH

THE USE OF ANY HUMAN SUBJECTS IN RESEARCH WITHOUT PRIOR APPROVAL OF THE INSTITUTIONAL HUMAN SUBJECTS COMMITTEE IS A VIOLATION OF MICHIGAN TECHNOLOGICAL UNIVERSITY POLICIES AND PROCEDURES. TO ENSURE A PROMPT REVIEW, MAKE CERTAIN THAT BOTH YOUR APPLICATION AND YOUR INFORMED CONSENT STATEMENT ARE COMPLETE. WHEN COMPLETED, PLEASE SEND TO THE RESEARCH INTEGRITY & COMPLIANCE OFFICE, ATTN: CHERYL GHERNA

GENERAL INFORMATION

Principal Investigator* __________________________ Department: __________________________
Co-Investigator(s): __________________________
Department: __________________________
Department: __________________________
Project Title: __________________________
Project Duration: Start Date ___________ End Date ___________
Anticipated Funding Agency: __________________________

*The principal investigator of a project must be a faculty or staff member. If students are involved in a project, he/she should be listed as a co-investigator.

REQUIRED INFORMATION

The following materials must be appended to this application:

A. A brief description of the project

B. Specific procedures to be followed - Please describe the project in enough detail so that the Committee will be able to evaluate the risks involved. Try to anticipate any future changes as far as possible and include them; by doing this, you may avoid the need to re-apply later. This must be a separate statement. A reference to a previous application, to a proposal, or to the brief description above will not satisfy this requirement.

C. Potential risks - You must describe and assess any risks (physical, psychological, social, legal, or other) and the likelihood and seriousness of such risks. If your methods of research, development, or other activity create potential risks, describe any other methods that you considered and why you did not use them.

D. Informed Consent Form - Please attach a copy of the Informed Consent Form you will use. The form must describe in detail any possible risks to the subject, and must state that the subject may withdraw at any time from the project without penalty.

INVESTIGATOR'S ASSURANCE

I acknowledge responsibility for this project. I assure that I will obtain committee approval prior to implementing any significant changes in the protocol. I assure that all faculty, staff, and students involved in the project are presently qualified or will be trained to conduct the project in a humane and scientific manner. I assure that the activities do not unnecessarily duplicate previous experiments.

Principal Investigator’s Signature __________________________ Date __________________________

Rev 4.10.08
CONSENT TO PARTICIPATE IN RESEARCH

An Ethnography of the Quincy Smelter: Past, Present, and Prospects

You are asked to participate in a research study conducted by YOUR NAME HERE and YOUR INSTRUCTOR'S NAME from the Social Sciences Department at Michigan Technological University as part of an undergraduate class project. Your participation in this study is entirely voluntary. Please read the information below and ask questions about anything you do not understand, before deciding whether or not to participate.

- PURPOSE OF THE STUDY
This project examines a range of viewpoints on the abandoned Quincy Smelter site. Specifically, researchers in this class project interview people with different connections to the smelter, including former workers, local residents, representatives from governmental agencies, and interest groups engaged at some level with proposed environmental remediation or historical restoration. Beyond canvassing different perceptions about the smelter, the primary aim of this project is to give students firsthand experience in conducting interviews. The class, SS3211 "Ethnographic Methods," introduces students to the tenets of ethnographic research, the primary methods by which anthropologists go about collecting their data. Interviews conducted as part of this class form one of a set of class exercises intended to develop field skills.

- PROCEDURES
If you volunteer to participate in this study, you will be asked to do the following:

1. Participate in a tape-recorded interview, anticipated to last one-half hour to one hour long, in which the student may invite you to talk about your current perceptions of the smelter, recollect past events, or discuss other related issues of concern to you. Following the interview, students will transcribe the recorded conversation and send you a copy. This turnaround is expected to take two to three weeks.

2. On being sent a copy of the transcribed interview, you are welcome to contact the interviewer to make editorial changes or add comments. This interview transcript will be shared among other class members, although names will be kept confidential. All transcripts and tapes will be destroyed at the end of class to ensure confidentiality.

- POTENTIAL BENEFITS
This study will not bring you specific benefits outside of an opportunity to share your views and opinions. Your participation, however, will be of considerable benefit for educational purposes, for it will give students a critical opportunity to develop professional skills and also to learn about local events and opinions.

- POTENTIAL RISKS
This project is not intended to provoke any physical or emotional discomfort. However, you may choose to share sensitive and confidential information during the interview. All efforts will be made to ensure confidentiality. In the event of physical and/or mental injury resulting from participation in this research project, Michigan Technological University does not provide any medical, hospitalization or other insurance for participants in this research study, nor will Michigan Technological University provide any

IRB Number: M0288
Date of IRB Approval: 13 February 2008
Project Expiration Date: 13 February 2009

Page 1 of 2
medical treatment or compensation for any injury sustained as a result of participation in this research study, except as required by law.

- **CONFIDENTIALITY**
Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by using a pseudonym instead of your name when transcribing the interview. Students will keep their interview tapes and pseudonym keys in a locked box separate from the transcripts for the semester. These materials will be handed to the course instructors at the end of the semester and will then be destroyed.

- **PARTICIPATION AND WITHDRAWAL**
You can choose whether or not to be in this study. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind or loss of benefits to which you are otherwise entitled. You may also refuse to answer any questions you do not want to answer.

- **IDENTIFICATION OF INVESTIGATORS**
If you have any questions or concerns about this research, please contact the class instructor:

**PROVIDE NAME AND CONTACT INFORMATION HERE**

- **RIGHTS OF RESEARCH SUBJECTS**
The MTU Institutional Review Board has reviewed my request to conduct this project. If you have any concerns about your rights in this study, please contact Joanne Polzien of the MTU Office of Research Integrity and Compliance at 906-487-2902 or email jpolzien@mtu.edu.

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

Printed Name of Subject

Signature of Subject

Date

Signature of Witness

Date

IRB Number: M0288
Date of IRB Approval: 13 February 2008
Project Expiration Date: 13 February 2009
Historical Background on Institutional Review Boards
From http://gra.sdsu.edu/irb/tutorial/

**Significant Events**

In the past century, there have been many examples of ethical problems in human subjects research that scholars continue to discuss and debate today. Several controversial studies have contributed to the development of regulations to protect human research participants. These studies have also brought the issues associated with ethical treatment of research subjects to the forefront of public attention. A few examples of controversial research studies follow:

- **Nazi Government Research**: During WWII, prisoners in concentration camps were used as subjects in Nazi experiments designed to advance the war effort. The studies involved battlefield medicine and chemical warfare experiments in which prisoners were tortured, usually to death. These experiments violated all presently recognized ethical principles, as discussed in the *Belmont Report*, including respect for persons, beneficence and justice (see "World Response" section for more information about the *Belmont Report*). Participants were denied the basic right of informed consent and voluntary participation. The risks associated with participation far exceeded any potential benefits to the individual or to society and participants died or suffered tremendously as a direct result of participation in these experiments. The experiments were clearly unjust since the subjects were captive prisoners who were forced or manipulated to participate. As a result of the methods used to conduct the experiments, the physicians involved were put on trial by the International Military Tribunal in Nuremberg, Germany from October 1945 to October 1946. Additional trials conducted by United States judges appointed by President Truman were held from December 1946 to August 1947. Fifteen of the 23 defendants were convicted and seven were executed for murder, torture and other atrocities.

- **Willowbrook Hepatitis Study (Mid 1950s to Early 1970s)**: The Willowbrook study involved infecting mentally retarded children with a Hepatitis virus to study the progression of the disease and to test vaccinations that were being developed at the time. Due to overcrowding, children were denied entrance to the Willowbrook State Mental Hospital unless parents enrolled their children into the less-crowded hepatitis ward. This practice did not allow for voluntary participation since there were scarce resources available to care for severely retarded children which limited the treatment options from which parents could select. The institution’s director was in charge of the study and conducted subject recruitment by sending a misleading informed consent to parents that included an exaggeration of the study benefits. Parents may have felt coerced and unduly influenced since the latter came from the institution’s director who was also the principal investigator. After a teacher in a neighboring school became infected with hepatitis which elicited public outcry, researchers defended their actions by claiming that children would have naturally become infected anyway during their stay at Willowbrook because of facility’s lack of sanitary conditions. Scientists have since argued that improving hygiene at the institution would have substantially reduced the transmission of hepatitis infection.

- **The Tearoom Study (1975)**: A graduate student conducting his dissertation, which would later become a book, observed sex acts in public restrooms. The researcher posed as a police "look-out" and took notes on the characteristics and behavior of the individuals in the restroom. The researcher also took down the license plate numbers to locate names and addresses of subjects for participation in future interviews. Some interviews took place in the presence of the subject’s wives and children. The description of the participants was so detailed in both the dissertation and the accompanying book, that subjects were easily identified. The procedures used in this study illustrate violations of subject privacy (observing sexual behavior) and confidentiality of information (disclosing identifiable information within the research publication). The use of deception raises ethical debate regarding the subject’s right to informed consent versus the
investigator's goal to collect unbiased information.

**Tuskegee Syphilis Study**: In 1932, the Public Health Service enrolled several hundred syphilitic black males to document the effects of the untreated disease over time. Tuskegee was chosen because approximately 40% of the male population of the town was infected with the disease. Treatment was withheld from study subjects when penicillin was accepted as the treatment for syphilis in 1943. This study was stopped in 1973 but not before many subjects became seriously ill, transmitted their disease to others or died. This study exemplifies unfair subject selection practices (syphilis can potentially affect all human beings and is not limited to African American males), denial of informed consent and excessive risk in relation to study benefits.

**Milgram Study (1963)**: The Milgram study involved instructing subjects to administer electric shocks to a study confederate in response to poor performance. The subject believed that he/she was involved in a study about learning and memory with each shock intended to affect the learning process. The confederate pretended to be hurt by the shock - in some cases, to the point of losing consciousness; however, he/she did not really feel any shock. The study objective was to assess obedience to authority. This study resulted in significant psychological stress for some subjects including sweating, trembling, stuttering and serious seizures in three subjects. However, in a post-experimental interview, about half of the subjects expressed that they were glad to have participated in the experiment. The question of whether this study was ethical remains open to debate among scholars today.

**US human radiation experiments (1944-74)**: Thousands of experiments took place during the cold war era in which humans were exposed to dangerous levels of radiation to test the effects of the atomic bomb, to gather safety data on the effects of the atomic bomb and to develop treatments for cancer patients. In many cases, subjects provided informed consent prior to their participation, however this was not the case for subjects who were sick, imprisoned or otherwise vulnerable, including 54 mentally retarded children who were intentionally fed radioactive breakfast cereal. In 1993, an advisory committee to former President Clinton apologized for conducting these experiments.

For additional information on historical examples of controversial research studies, please access the following resources:


**World Response**

In response to these significant events pertaining to the unethical treatment of human subjects, several documents were adopted as accepted international guidelines to protect human subjects including:

**The Nuremberg Code (1947)**: This code outlines basic standards of ethical treatment of human research participants and was created as a benchmark by which Nazi physicians on trial for maltreatment of prisoners of war were judged.
Declaration of Helsinki (1964). This document was drafted by the World Medical Association to outline international recommendations pertaining to research ethics.

Belmont Report (1979). The Belmont Report was written in response to the exposé of both the Syphilis Study and U.S. human radiation experiments. The three basic principles of the Belmont Report are:

Respect - recognition of the personal dignity and autonomy of individuals and special protection for those with diminished autonomy.

Beneficence - obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.

Justice - fairness in the distribution of research benefits and burdens.

Federal Regulations

In 1974, Congress passed the National Research Act, which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The National Commission wrote the Belmont Report, which provided the foundation for current federal regulations to protect human research subjects. The National Research Act required the government to publish regulations for the ethical treatment of human subjects, including obtaining informed consent and called for oversight of research by Institutional Review Boards (IRB). The federal regulations pertaining to the human subjects protections may be found in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46).

Institutional Review Board (IRB)

The Institutional Review Board (IRB) implements a review process established within the regulations to ensure that research complies with federal regulations. According to federal regulations, research is defined as "a systematic investigation designed to develop or contribute to generalizable knowledge." A human subject is defined as "a living individual about whom an investigator (whether a professional or a student) conducting research obtains data through intervention or interaction with the individual or identifiable private information."

An IRB is composed of individuals with the expertise and background needed to conduct a complete and adequate review of the research planned by the institution. Federal regulations require an IRB to have at least 5 members with varying backgrounds and expertise, including at least one non-affiliated community member. Nearly 4,000 IRBs are authorized by the U.S. Department of Health & Human Services to perform this task.

Each IRB maintains an agreement with the Office for Human Research Protections (OHRP) stating its requirements and procedures for human subjects protections and assuring that all research conducted within its jurisdiction complies with the Code of Federal Regulations pertaining to human subjects (45 CFR 46)
RESEARCH | Human Subjects (CITI) Training

The protection of human subjects participating in research projects is essential to the ethical conduct of University activities. It is imperative that these projects be designed and conducted in a manner that:

1. Protects the integrity of the human subject, and
2. Is in accordance with applicable Federal Regulations and University Policy.

CITI Course Training for the Protection of Human Subjects in Research

Register and select the appropriate training program.

1. Login to CITI Login and Registration—for first-time user;
   a. Click on the link “New Users Register Here”
   b. Under “Participating Institutions,” select MICHIGAN TECHNOLOGICAL UNIVERSITY, in the drop down box (then submit).
   c. Create your own username and password (then submit).
   d. Enter your first name, last name, and preferred email address (then submit).
   e. Please provide the requested information (then submit).
   f. Now you can choose your CITI Curriculum.

2. Next, choose the following CITI Curriculum (see sample PDF) by scrolling down to Question 1 and selecting:
   a. Students conducting no more than minimal risk research.
   b. All Investigators, faculty, staff, or students on the project are required to complete, at a minimum, this course.

3. Scroll to the bottom of the page and click on the Submit button.

This module should take approximately 20–30 minutes to complete. If needed, you may complete the training course in several sessions. Returning to the site requires signing in with your Username and Password.

Certification of successful completion can be obtained by downloading the Completion Report after finishing all of the prescribed modules. Do not print and submit your grade book as evidence of completion. Your grade will be electronically sent to our office.

NOTE: Michigan Technological University is requiring researchers to take the CITI refresher courses every two years. If you have the NIH training, this will be valid up to two years from the time you completed the training.
How to Register for and Take the CITI Tutorial

Go to the CITI page at:
https://www.citiprogram.org/default.asp?language=english

1. Click on the Link "New Users Register Here" and register
2. Under "Participating Institutions", select MICHIGAN TECHNOLOGICAL UNIVERSITY, in the drop down box (then submit).
3. Create your own username and password (then submit).
4. Enter your first name, last name, and preferred email address (then submit).
5. Please provide the requested information and choose your CITI Curriculum – Follow the directions below very carefully:

On the "Select Curriculum - Michigan Technological University" page of the website, students should respond in the following manner:

1. If this is your first time taking a CITI course at Michigan Technological University, choose one learner group below based on your role and the type of human subjects activities you will conduct. You will be enrolled in the Basic Course for that group.

   Students should select "Students conducting no more than minimal risk research"

2. Select the statement that is most appropriate for your current needs. You will be enrolled in the Refresher Course for that group.

   Students should select "I have not completed the basic course for my learner group..."

**THIS IS VERY IMPORTANT:** Students should not select any response from questions 3 and 4 on this page.

On the "Course Registration" page of the website, select the following choices from the drop down menus:

Which course do you plan to take? Basic Human Subjects - Social & Behavioral Focus
Role in Human Subjects Research? Student Researcher - Undergraduate

This will bring you to one training module with 4 sections. The "lesson" part of the module is probably the equivalent of reading 10 pages in a text book. Following the reading, you take a 10 question quiz. (If you have more than one training module listed when you are done following the steps above, you probably checked a box that you should not have on the "Select Curriculum" page.)

Print out a copy of the page that verifies you have successfully completed the course.

Go back to the main menu screen in the CITI website. The course you took will be listed there in a table. There is a link beside it under "Completion Reports" that says "Print." Click on that, and then on the next screen there is a link called "Print completion report." You should be able to print a one page report when you click on it.